MAQUET
GETINGE GROUP

CARDIOSAVE® RESCUE
OPERATING INSTRUCTIONS



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WARNING

Do not operate this system before thoroughly reading this manual and the associated warnings and cautions. Only use the Quick Reference - Initial Setup if you are already familiar with this product. If not, please continue with the remainder of this manual.

QUICK REFERENCE - INITIAL SET-UP

1. Press the IABP Power Button to turn the IABP on.
2. Verify helium pressure.
3. Establish ECG and pressure connections.
4. If using a Fiber-Optic IAB, ensure that the Fiber-Optic Sensor Connector is attached. Otherwise, zero the transducer:

   Vent the transducer to atmosphere.

   Press the **Zero Pressure** key for 2 seconds.

   Close the transducer.
5. Confirm that the OPERATION MODE is **Auto**.
6. Attach the IAB catheter and extender tubing to the Pneumatic Module.
7. To initiate pumping, press the **Start** key. In response, the IABP will autofill and then begin pumping. If desired, IAB **Deflation** timing can be fine-tuned using the IAB **Deflation** controls.
8. Verify the setting of the **Aug Alarm**:

   Approximately 3 minutes after initiation of assist, verify that the **Aug Alarm** setting is approximately 10 mmHg less than the patient's augmented diastolic pressure.

   If needed, adjust the **Aug Alarm** setting by pressing the **Aug Alarm** key and using the arrow keys to change the value.
9. Initial setup is now complete.

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FOREWORD

This manual is intended to provide information required to properly operate the **CARDIOSAVE Rescue** Intra-Aortic Balloon Pump (IABP). For additional information and assistance, please contact the Representative in your area.

Information for servicing and repair of **CARDIOSAVE Rescue** is provided in the **CARDIOSAVE Service Manual** which is made available once the technical representative has been MAQUET Factory Trained and Certified.

General knowledge of balloon pumping and an understanding of the features and functions of the IABP are prerequisites for the proper use of this equipment. Therefore, **DO NOT OPERATE THE EQUIPMENT BEFORE READING THESE INSTRUCTIONS AND THE WARNINGS, CAUTIONS AND NOTES WHICH FOLLOW.**

Datascope Corp. maintains a policy of continual product improvement and reserves the right to change materials and specifications without notice.

CAUTION:

U.S. Federal Law restricts this device to sale by or on the order of a physician or properly licensed practitioner.

WARNINGS, CAUTIONS AND NOTES

Please read and adhere to the following list of warnings, cautions and notes; some of which are repeated in the appropriate areas throughout this manual.

A **WARNING** is provided if there is reasonable evidence of an association of a serious hazard with the misuse of this device or when special attention is required for the safety of the patient.

A **CAUTION** is provided when any special care is to be exercised by the practitioner to avoid causing damage to this device or other property. They may also include actions to be taken to avoid effects on patients or users that may not be potentially life threatening or result in serious injury, but about which the user should be aware.

A **NOTE** is provided in the appropriate areas throughout the manual when additional general information is applicable.

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WARNINGS

WARNING:

Do not operate this system before thoroughly reading this manual and the associated warnings and cautions. Only use the Quick Reference - Initial Setup Guide if you are already familiar with this product. If not, please continue with the remainder of this manual.

WARNING:

Compressed gasses (helium tanks) and Lithium ion batteries are considered Dangerous Goods/ Hazardous Materials per I.A.T.A. and D.O.T. regulations.

It is a violation of U.S. federal and international law to offer any package or over pack of dangerous goods for transportation without the package being appropriately identified, packed, marked, classified, labeled and documented according to D.O.T. and I.A.T.A. regulations. Please refer to the applicable I.A.T.A. Dangerous Goods Regulations and/or the Code of Federal Regulations 49 (Transportation, Parts 171-180) for further information.

WARNING:

Internal Shock Hazard - This instrument does not contain any user-serviceable parts. DO NOT remove the instrument covers. Refer servicing to MAQUET Factory Trained and Certified Service Personnel.

WARNING:

Operation of the IABP below the minimum amplitude or value of PATIENT physiological signal may cause inaccurate results.

WARNING:

Disconnect the IAB from the IABP in the event of a sudden shutdown to assure IAB deflation.

WARNING:

Use of ACCESSORIES, transducers and cables other than those specified in the manual may result in increased Electromagnetic Emissions or decreased Electromagnetic Immunity of the IABP. It can also cause delayed recovery after the discharge of a cardiac defibrillator.

WARNING:

The IABP should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the IABP should be observed to verify normal operation in the configuration in which it will be used.

WARNING:

Do not use the IABP near an MRI (Magnetic Resonance Imaging) scanner or during an MRI scan.

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WARNING:

Pneumatic Module Leak Test MUST NOT be performed with the pump connected to a patient's IAB.

WARNING:

The System Trainer MUST NOT be connected to a IABP while it is being used for patient therapy.

WARNING:

Re-evaluate and, if necessary, readjust inflation and deflation timing after each manual pressure trigger threshold change.

WARNING:

The Augmentation Alarm, which is automatically set at power-up, provides back-up to IAB alarms (gas loss and IAB catheter alarms) at higher heart rates. Therefore, this alarm should not be manually disabled.

WARNING:

Preventive Maintenance should never be performed when the IABP is attached to a patient.

WARNING:

System Configuration mode is not for clinical use.

WARNING:

To ensure proper system performance and guarantee defibrillator protection, only Datascope Corp. approved cables, accessories, including lead wires, Intra-Aortic Balloons (IABs), System software, and Pneumatic Module assemblies should be used with the IABP.

WARNING:

Do not inflate the IAB using a syringe or any other means if a balloon leak is suspected.

WARNING:

Perforation of a balloon may indicate that the patient’s vascular condition may induce abrasion or perforation in subsequent balloons.

WARNING:

The patient balloon should not remain inactive in the patient (i.e., not inflating and deflating) for more than 30 minutes, due to the potential for thrombus formation.

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WARNING:

Do not leave the patient unattended during IABP therapy.

WARNING:

External bedside monitors used to supply the ECG signal to the IABP in the operating room must be equipped with electro-surgical interference suppression.

WARNING:

Use surgical gloves while replacing Pneumatic Module to avoid contact with residual condensate or other body fluids. Disposal of the used safety disk within the Pneumatic Module should be in accordance with prevailing hospital practices for medical refuse.

WARNING:

Under no circumstances should an IAB patient or the IABP ever be placed in a hyperbaric chamber.

WARNING:

Stabilize the patient's heart rate below 210 bpm to avoid the system triggering on alternate ECG complexes. Inflation may extend into the next cardiac cycle if such trigger conditions exist.

WARNING:

Route cables neatly. Ensure cables, hoses and wires are away from patient's neck to avoid strangulation. Keep floors and walkways free of cables to reduce tripping hazard for hospital personnel, patients and visitors.

WARNING:

Under certain heart rate and timing conditions catheter alarms may be suspended. Refer to this manual for further details.

WARNING:

External monitor output signals must meet certain requirements. See External Monitor Interfacing in section 5.1.

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WARNING:

This unit uses a common isolation path for the ECG leads and the Invasive Pressure Channels. Ensure that conductive parts of the ECG electrodes do not contact other conductive parts including earth ground. Do not connect any non-isolated accessories to the IABP or to the ECG or invasive pressure channel inputs when connected to a patient. Insure that the total chassis leakage currents of all connected units does not exceed 300µA. Use an IEC 60601-1 approved isolation/separation transformer if required. Do not simultaneously touch the patient and any piece of electrical equipment if any cover has been removed from the equipment.

WARNING:

The AC power cord and interface cables (i.e., non-patient cables) may utilize the same ground. Therefore, removal of the AC power cord does not necessarily isolate the IABP, if non-patient interface cables are attached.

WARNING:

Observe extreme caution when a defibrillator is used on a patient. Do not touch any part of patient, table or IABP when a defibrillator is in use.

WARNING:

Do not put MPSO (Multiple Portable Socket Outlets i.e., Multiple outlet extension cords) used with the IABP or its accessories on the floor. Connect only IABP accessories to the same MPSO as the IABP. Do not overload the MPSO. Do not connect other equipment to the same MPSO with the IABP, as it may increase system leakage current.

WARNING:

Reliably attach Potential Equalization connector to the safety ground when interconnecting IABP with other medical or non-medical electrical equipment to minimize the risk of excessive leakage current and/or shock hazard.

WARNING:

Do not reuse disposable devices.

WARNING:

Pacemaker Patients: Rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Keep pacemaker patients under close surveillance. See the Selection of Trigger Source section of the System Operation chapter for disclosure of the pacemaker pulse rejection capability of this instrument.

WARNING:

Use only MAQUET/Datascope Corp. ECG lead wires with the ECG Patient Cable. The use of any other lead wires may cause the system to function improperly.

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WARNING:

Pressure triggering is NOT recommended for use when sustained irregular cardiac rhythms or tachyarrhythmia's are present. Remember to adjust deflation early enough so that deflation is completed prior to systole and to provide continuous observation while triggering from a pressure source. If an "Irregular Pressure Trigger Detected" informational message appears, DO NOT attempt to adjust the deflation control as the system will automatically compensate by deflating earlier to avoid interfering with systolic ejection.

WARNING:

Only personnel familiar with the handling of high pressure gas tanks should install or replace the helium tank.

WARNING:

When pressure is being used as the trigger source, balloon deflation should always be adjusted to be complete at the upstroke of systole. Late deflation timing causes a reduction in, and delay in detection of, systolic pulse pressure. The system relies on a prominent and timely systolic upstroke for consistent, reliable pressure triggering. Any overlap of balloon deflation and systolic ejection, while pressure is the trigger source, could cause triggers to be late or missed, potentially resulting in loss of synchronization.

WARNING:

The user should continually rely on visual alarm messages during high noise transport situations.

WARNING:

Continued assist of an IAB which has a leak may result in formation of a large blood clot within the balloon. This may cause balloon entrapment which may require surgical removal of the IAB.

WARNING:

Do not remain in the internal trigger mode when the patient is generating a cardiac output.

WARNING:

When weaning by reduced IAB augmentation, do not reduce augmentation to a point at which the IAB status indicator moves less than 50%.

WARNING:

If possible, use ECG or Arterial Pressure trigger during CPR. This facilitates synchronization of the assist to the rate and rhythm of chest compressions. In Auto OPERATION MODE, the ECG (R-Wave) or Arterial Pressure signal will automatically be selected as the trigger source. Choice is dependent upon relative signal quality. If neither the ECG nor the Arterial Pressure signals produce adequate trigger reliability to allow for Auto Operation, the IABP may be triggered by its own internal clock. Select Semi Auto OPERATION MODE and set the Trigger Source to Internal.

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WARNING:

If the Manual pressure trigger threshold option is used, the threshold must be adjusted whenever persistent changes in systolic pulse height occur. Height changes may be due to changing patient conditions or may occur following the pump's initial calibration of a Fiber-Optic IAB. Always reevaluate inflation and deflation timing after making adjustments to the trigger threshold for any reason.

WARNING:

If more than one pump is being used in close proximity, ensure that the source of the alarm sound is correctly identified by confirming the corresponding visual indication.

WARNING:

Removing both batteries or removing the energized battery, when AC power is not connected, will stop the therapy, (i.e., power down the pump).

WARNING:

Sufficient additional charged batteries should be on hand during transport to prevent IABP shutdown due to inadequate battery capacity.

WARNING:

A patient must not be connected to the IABP during operation in System Diagnostic mode to avoid potential for injury.

WARNING:

Batteries have the risk of fire, explosion or severe burn hazards. Do not disassemble, crush, heat above 60° C (140° F), or incinerate. Replace only with Datascope Corp. REF 0146-00-0097.

WARNING:

Route hose and position Helium Refilling Station safely. Keep walkways clear to reduce risk of injury

WARNING:

Route Battery Charging Station AC power cord safely. Keep walkways clear to reduce risk of injury

WARNING:

Do not stack the Battery Charging Station with or on other equipment.

WARNING:

Use only Datascope Crop. batteries REF 0146-00-0097.

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CAUTIONS

CAUTION:

U.S. Federal Law restricts this device to sale by or on the order of a physician or properly licensed practitioner.

CAUTION:

Blood pressure transducers used with the IABP shall meet the standard for interchangeability and performance as defined by ANSI/AAMI BP22:1994/(R) 2006, Blood Pressure Transducers.

CAUTION:

The operator is urged to routinely check the IAB catheter extender for the formation of condensate. If excessive condensation is allowed to accumulate it will affect system performance. Excessive condensate may indicate the need to service the Pneumatic Module.

CAUTION:

System batteries must be properly maintained and periodically tested. See the Battery Section of the User Maintenance Chapter.

CAUTION:

After being stored at low temperature, allow **CARDIOSAVE Rescue** to be exposed to room temperature for at least 30 minutes before operating on battery power.

CAUTION:

Use medical grade helium only.

CAUTION:

When power cycling the unit, power off for a minimum of 10 seconds before powering on again.

CAUTION:

Prior to emergency use, when the System is to be powered from an AC inverter, the inverter should be checked for proper operation with the System by qualified maintenance personnel. The message “Battery in Use” will not be displayed during proper AC inverter operation.

CAUTION:

Conductive parts of electrodes and associated connectors for applied parts, including the neutral electrode, should not contact other conductive parts including earth.

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CAUTION:

Never place fluids on top of this unit. Make sure that the saline container and tubing do not hang directly over the IABP. In case of accidental spillage, wipe clean immediately and have the unit serviced to ensure no hazard exists.

CAUTION:

Do not use a damaged or broken unit or accessory.

CAUTION:

Do not operate the unit with the ventilation or speaker vents obstructed.

CAUTION:

To prevent condensation, allow the IABP to warm up and dry if it is moved from a cold area to a warm one.

CAUTION:

The highlighted inflation interval marker should not be used to set timing. Timing should be set by examination of the Arterial Pressure Waveform.

CAUTION:

The displayed ECG signal is automatically scaled (amplified) for optimal screen presentation. Due to the automatic scaling, low ECG amplitudes may appear to be of normal amplitude when displayed. Judgments concerning ECG amplitude should be made with reference to the annotated scale.

CAUTION:

The displayed AP signal is automatically scaled (amplified) and offset for optimal screen presentation. Because of automatic scaling, low AP amplitudes may appear to be of normal amplitude when displayed. Judgments should be made with reference to the annotated scale, patient arterial pressure parameter display.

CAUTION:

To ensure reliable operation of the Autofill system and proper IAB inflation pressures, it is important that the combined total volume of the IAB's membrane and extracorporeal tubing, plus the catheter extender tubing, is not altered. Using tubing of a different length or internal diameter from that supplied with MAQUET/Datascope Corp. IAB products will change IAB inflation pressure levels and may result in Autofill failures. Consequently, such practices must be avoided.

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CAUTION:

During or after any surgery that results in a 6°C or more change in patient core temperature in less than 2 hours, the Fiber-Optic IAB should be recalibrated by pressing and holding the Calibrate Pressure key for 2 seconds while assisting.

CAUTION:

The pull up handle must not be used to lift the Transport System. Use only designated lift points and handles.

CAUTION:

Secure the system during transport to prevent impact injuries.

CAUTION:

When AC power operation is intended, insure that the system is plugged into a live AC receptacle and that the “Battery in Use” informational message is NOT displayed.

CAUTION:

This product requires scheduled preventative maintenance in order to maintain its specified performance. Note that maintenance includes periodic cleaning to assure that proper cooling airflow of the system’s electronics is maintained.

CAUTION:

Do not set the alarm volume to such a low level that it cannot be readily heard over the ambient noise level of the venue in which the IABP is used.

CAUTION:

Do not touch the exposed end of the Fiber-Optic IAB cable, or permit it to contact other surfaces. This could damage or contaminate the sensor connection.

CAUTION:

The Touchscreen is a pressure sensitive surface that should not be in contact with sharp objects or harsh chemicals.

CAUTION

The internal helium tank contains 200 PSI of helium. This tank **MUST** be emptied prior to shipping the system via commercial shipping.

CAUTION

Prior to shipping **CARDIOSAVE Rescue** via commercial shipping the batteries **MUST** be removed.

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CAUTION

CARDIOSAVE Rescue batteries **MUST** be shipped through a shipper that has expertise in the shipping of dangerous goods. Packaging for battery shipments **MUST** be packed and labeled appropriately. Contact MAQUET for further instructions on returning batteries.

CAUTION:

The Helium Refilling Station is not intended for use in transport. The Helium Refilling Station is intended to be used in office buildings, aircraft hangars, or similar environments, and should not be within the vicinity of a patient.

CAUTION:

Follow hospital protocol regarding biohazards to prevent contact with pathogens when refilling IABP with helium.

CAUTION:

Close helium tank valve when not in use.

CAUTION:

The Battery Charging Station is not intended for use in transport. The Battery Charging Station is intended to be used in office buildings, aircraft hangars, or similar environments, and should not be within the vicinity of a patient.

CAUTION:

Beware of pinch points. Keep hands clear when rolling **CARDIOSAVE** into position on the Transport Mounting Plate.

CAUTION:

Position IABP such that there is access to the AC Plug. In the case were there is an AC Mains fault of the IABP, unplug the IABP from the wall receptacle to isolate the IABP from the AC Mains Input.

CAUTION:

Blood pressure transducers used with the IABP shall meet the standard for interchangeability and performance as defined by ANSI/AAMI BP22:1994/(R) 2006, Blood Pressure Transducers.

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INDICATIONS FOR USE

The balloon pump is an electromechanical system used to inflate and deflate intra-aortic balloons. It provides temporary support to the left ventricle via the principle of counterpulsation. The intra-aortic balloon is placed in the descending aorta, just distal to the left subclavian artery. Once the balloon is positioned, the pump is adjusted to trigger in synchrony with the ECG or arterial pressure waveform to ensure that inflation and deflation occur at the appropriate points during the cardiac cycle.

The target population is adult. The balloon pump is intended for use in the health care facility setting.

CONTRAINDICATIONS

- Severe aortic insufficiency
- Abdominal or aortic aneurysm
- Severe calcific aorta-iliac disease or peripheral vascular disease
- Introduction of the IAB catheter without the use of an introducer sheath is not recommended for patients with severe obesity, scarring of the groin or other contraindications to percutaneous insertion

Note:
CARDIOSAVE Rescue is not intended to perform patient monitoring functions.

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BRIEF DESCRIPTION OF INTRA-AORTIC BALLOON THERAPY

The Intra-Aortic Balloon Pump (IABP) is a cardiac assist device. It supports the heart's left ventricle by increasing coronary perfusion and reducing left ventricular work.

Coronary perfusion is increased by augmenting blood pressure during the diastolic phase of the cardiac cycle. This increase in aortic pressure promotes more blood flow through the coronary arteries.

Left ventricular work is reduced by decreasing aortic end-diastolic pressure and reducing resistance to ventricular ejection, resulting in a decrease in blood pressure during the systolic phase of the cardiac cycle.

These beneficial effects are caused by the inflation and deflation of an intra-aortic balloon (IAB) in the patient's descending aorta. The balloon's inflation and deflation must be properly synchronized with the cardiac cycle. IAB inflation is initiated at the onset of diastole at the dicrotic notch and remains inflated through diastole. The IAB is then deflated at, or just prior to, the onset of systole and the balloon remains deflated throughout systole. (Hence, the therapy is also referred to as counterpulsation).

See the Intra-Aortic Balloon (IAB) Catheter Instructions For Use (IFU) for detailed information regarding the instructions for use, indications, contraindications, warnings, and precautions.



UNPACKING INFORMATION

The IABP is shipped as a complete unit in a single shipping container, to be unpacked only by an authorized MAQUET Factory Trained and Certified Technical Representative.

Accessories, helium tanks, and batteries are shipped separately. Please contact an authorized MAQUET Factory Trained and Certified Technical Representative prior to placing the IABP into service.

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OPERATOR PROFILE

The primary intended users of the intra-aortic balloon pump are Critical Care Nurses, Catheterization Lab Technicians and Perfusionists who have been trained in the theoretical, technical and clinical aspects of counterpulsation therapy. Other potential users include Paramedics involved in transporting patients (e.g. flying patients from a rescue site to a hospital). Note that these other potential users are less likely to receive thorough training in the device use, are likely to use the device only for a portion of the therapy and are likely to be dependent on the Primary users at various points to assure proper therapy.

The user of the system needs to understand the concepts of cardiovascular anatomy and physiology in order to integrate the effects of counterpulsation with the other therapies being used to provide cardiac support. The user should not operate the IABP before reading the operating instructions, including the warnings and cautions. The user needs to be able to read and understand English or the other translated languages used to label the controls and features of the system. The user needs to have the visual acuity to clearly view the waveforms on the monitor screen. The color-coded waveforms are also labeled to indicate the source of the waveform so a user with color vision deficiency will be able to identify the source of the waveform source based on the labeling. The primary user must possess the manual dexterity to make the necessary patient connections to the console and to be able to use the touch controls of the user interface. Since the device may also be used for inter-hospital transport, in addition to the above requirements, the user needs to be able to lift/load the device into the transport vehicle with the assistance of other transport personnel using appropriate body mechanics.

MAQUET/Datascope Corp. recommends that medical professionals be properly trained prior to operation of **CARDIOSAVE Rescue**. Training can be provided on-site by contacting the local Sales and/or Clinical representative. Additional information, education and training can be provided by accessing the MAQUET website at: http://ca.maquet.com. In addition, MAQUET/Datascope Corp. provides 24/7 emergency clinical support by calling 1-800-777-4222.

OPERATOR POSITION

The user may operate **CARDIOSAVE Rescue** in either a seated or standing position. The System's monitor can be rotated to accommodate a variety of operator positions. The monitor should be adjusted so that it is easily visible to the operator.

DEVICE POSITION

CAUTION:

Position IABP such that there is access to the AC Plug. In the case were there is an AC Mains fault of the IABP, unplug the IABP from the wall receptacle to isolate the IABP from the AC Mains Input.

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PHONE NUMBERS AND HOW TO GET ASSISTANCE

MAQUET maintains a network of direct service representatives and factory trained/authorized distributors. Prior to requesting service, perform a complete operational check of the instrument to verify proper control settings. If operational problems continue to exist, contact the local Representative or the MAQUET HQ Service Department at 1-800-777-4222 or 1-201-995-8700 for assistance.

Please include the instrument model number, the serial number, and a description of the problem with all requests for service.

Any questions regarding the warranty should be directed to your local representative.

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SYMBOLS AND DESCRIPTIONS



Attention, Consult Accompanying Documents / Refer to Manual



On / Off
(Toggles Pump Console On and Off)



Start (Assist)



Standby



Technical Alarm



High Priority Alarm



Medium Priority Alarm



Low Priority Alarm



Audio Alarm Off



Audio Paused



Alarm Inhibited (Off)



Alarm Inhibited (Paused)



Indicates Approximate Battery Charge Level



Indicates a Transport Power Supply is Installed



Empty Battery Bay



Indicates Approximate Level of Helium Remaining



Indicates a Detected Physiological Trigger Event



Indicates an Internally Generated Trigger Event

IAB Status



Screen Lock



ECG



Blood Pressure



Patient



Patient Monitor



Zero Vent



Trainer



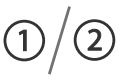
Fiber-Optic Cable



Fiber-Optic Connector Orientation



AC Plug
(Indicated the IABP is currently running on AC Power)



Battery Bay Indicators



Defibrillator Proof Type CF Applied Part



Ethernet Port

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WEEE Compliance (IABP)



WEEE Compliance (Battery)



Equipotentiality



Non-ionizing Electromagnetic Radiation



Direct Current (DC)



Dangerous Voltage



Protective Earth Ground



Consult Instructions for Use



Humidity Limitation



Atmospheric Pressure Limitation



Temperature Limitation



Mass

Rx only

Caution: RX Only U.S. Federal Law restricts this device to sale by or on the order of a physician or properly licensed practitioner.

IPN$_1$N$_2$

Ingress Protection



CSA Symbol



CE Mark



Authorised Rep in the European Community



Catalogue Number



Serial Number



Lithium - ion Recycling Symbol



Recycle Symbol (Taiwan)



UL Recognized Component



Manufacturer



Not Intended for Use in Ground Transport



Not Intended for Use in Air Transport



Keep hands clear



Battery Charged



Battery Charging



Battery Waiting to Charge



Error Charging Battery

Copyright Datascope Corp.



Helium



RoHS Compliance



Helium Tank

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1 FEATURES AND CONTROLS

This section of the Operating Instructions identifies and describes each feature and control of the IABP. See System Operation in section 2 for more detailed instructions.

1.1 GENERAL SYSTEM OVERVIEW

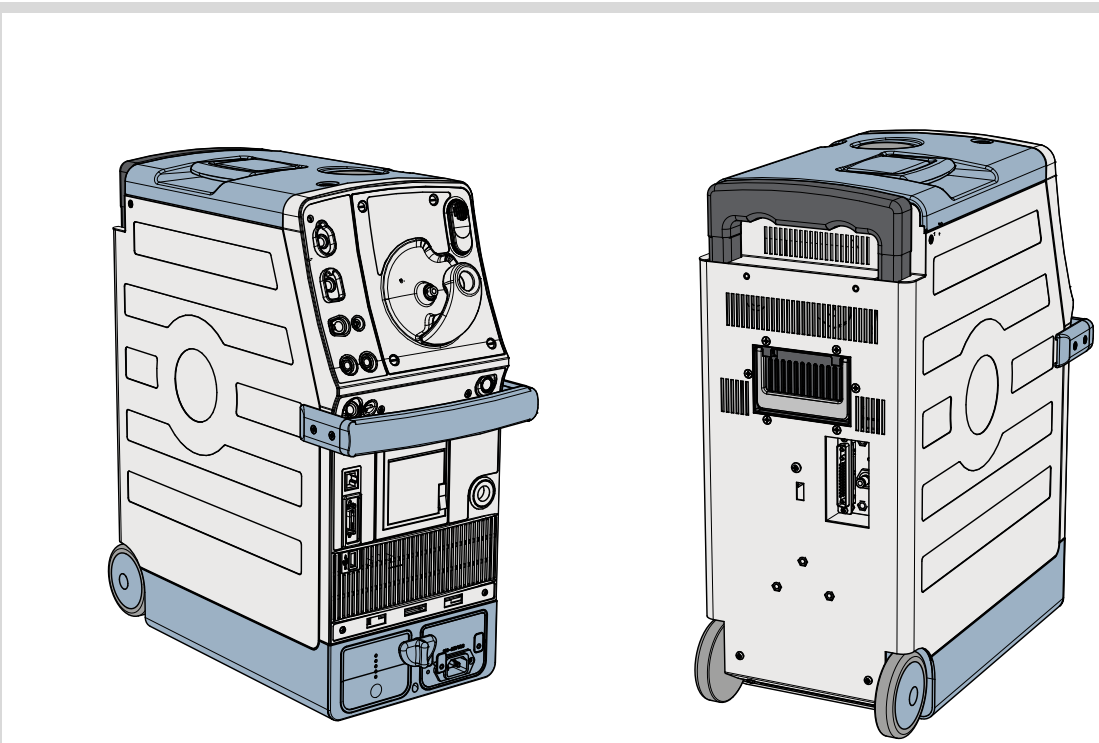


Figure 1-1: General Views of the IABP

Note:
All graphics in this section are for illustrative purposes and do not represent actual clinical conditions.

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1.2 MONITOR DISPLAY

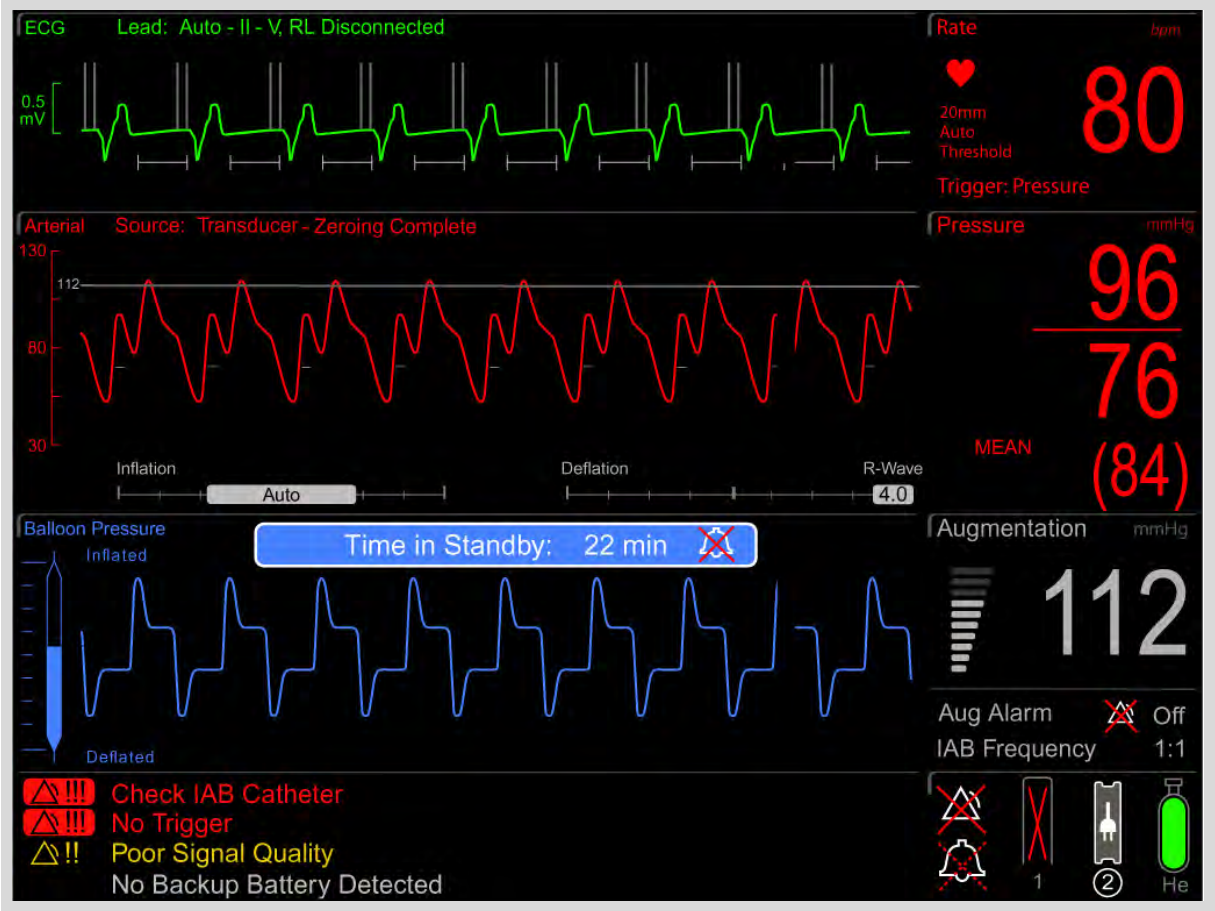


Figure 1-2: Example Monitor Display layout
The example is provided for illustrative purposes and does not represent actual clinical conditions.

Depending on the current **Balloon Waveform** setting in the **Display** preferences menu (described in section 1.3.13.1), the IABP displays either two waveforms (ECG and Arterial Pressure) or three waveforms (ECG, Arterial Pressure, and Balloon Pressure). The ECG, Arterial Pressure and Balloon Pressure Waveforms are located respectively from top to bottom in the Monitor Display. Each waveform is plotted from left to right with new data replacing old data.

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1.2.1 ECG WAVEFORM

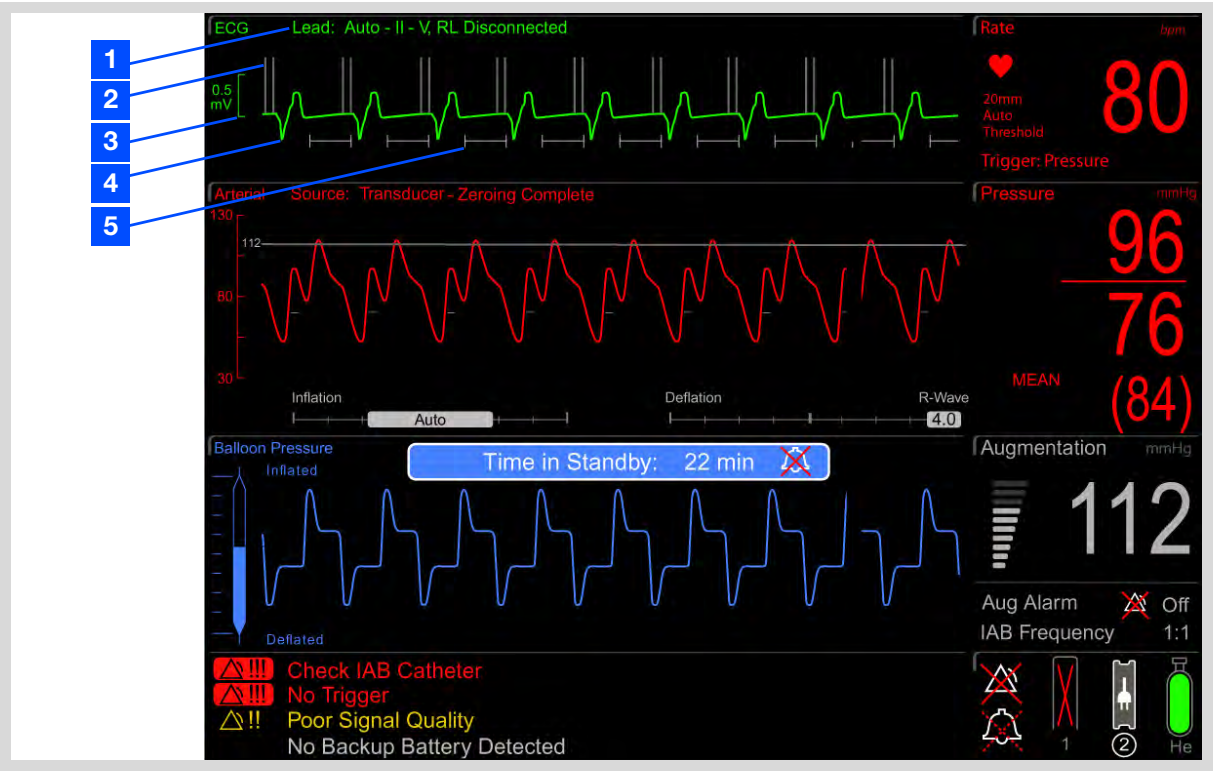


Figure 1-3: Example ECG Waveform
The example is provided for illustrative purposes and does not represent actual clinical conditions.

1. ECG Lead:

This field displays the selected (active) ECG signal source and its status.

In **Auto** OPERATION MODE, the system automatically selects an ECG signal source (**I**, **II**, **III** or **External**). This field displays the current auto-selected (active) ECG signal source. For example: **Lead: Auto - II**.

In **Semi Auto** OPERATION MODE, the user selects an ECG signal source (**I**, **II**, **III**, **aVR**, **aVL**, **aVF**, **V** or **External**). This field displays the current user-selected (active) ECG signal source, which is based on connected electrodes. For example: **Lead: II**

- The RA, LA, and LL electrodes are required to obtain an ECG signal regardless of ECG signal source. If any of these leads should fault, this field displays a lead fault message. For example: **Lead: II - RA Faulted**. This message indicates the current selected ECG signal source, and faulted lead(s) which needs to be replaced to acquire an ECG signal.

- The RL, and V electrodes are only required to utilize the optional augmented and chest ECG signal sources (**aVR**, **aVL**, **aVF**, or **V**). They are not required to obtain an ECG signal. If any of these leads should fault, this field displays a lead disconnected message. For example: **Lead: aVR - RL Disconnected**. This message indicates the current selected ECG signal source, and faulted lead(s), which needs to be replaced to enable the lost ECG signal source(s).

- When an External source is selected and a cable is not present, the text **Lead: External - No Cable** is displayed.

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2. Pacer Spikes:

When using Pacer Triggering (see section 2.1.5.1), the ECG Waveform area displays Pacer Spikes which are gray vertical lines that start at the ECG Waveform and extend upwards.

3. ECG Scale:

The ECG Scale is located immediately to the left of the displayed ECG Waveform. It is provided to facilitate determination of ECG amplitude. The bar indicator is 1 centimeter in height and the annotation indicates the current scale factor for the displayed ECG Waveform.

CAUTION

The displayed ECG signal is automatically scaled (amplified) for optimal screen presentation. Due to the automatic scaling, low ECG amplitudes may appear to be of normal amplitude when displayed. Judgments concerning ECG amplitude should be made with reference to the annotated scale.

4. ECG Waveform:

This is the ECG Waveform. It is plotted from left to right. The oldest data is erased, and is replaced by new data. To facilitate identification of the newest data, a vertical erase bar is drawn. The newest data is to the left of the bar and the oldest is to the right.

5. ECG Markers:

Through their length and placement below the ECG Waveform, these horizontal lines indicate the calculated inflation (assist) interval. Display of these markers is enabled or disabled with the **ECG Markers** setting in the **Display** preferences menu (section 1.3.13.1).

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1.2.2 TRIGGER RATE PARAMETER

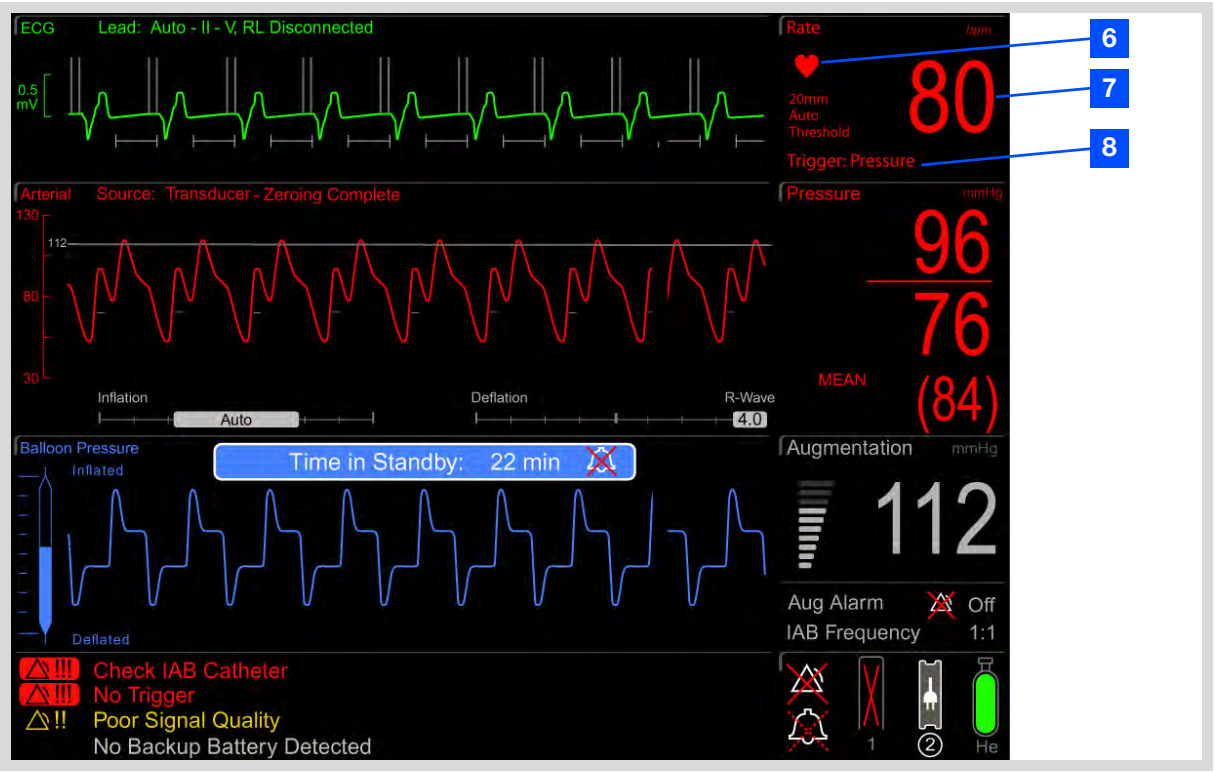


Figure 1-4: Example Trigger Rate parameter
The example is provided for illustrative purposes and does not represent actual clinical conditions.

The color used in the Trigger Rate parameter area will vary with the active trigger source as listed in the following table:

Trigger Source	Color used in the Trigger Rate Parameter Area
ECG, Pacer V/AV, and Pacer A	ECG Waveform color
Pressure	Arterial Pressure Waveform color
Internal	Blue

6. Trigger Indicator:

- When **ECG**, arterial **Pressure**, **Pacer V/AV** or **Pacer A** trigger source is selected, this indicator is displayed as a heart shaped icon that blinks On and Off with each detected trigger event.

- When **Internal** trigger is selected, this indicator is displayed as a diamond shaped icon that blinks On and Off with each internally generated trigger event.

7. Heart Rate:

This field is a numeric display of the current average heart rate in beats per minute (bpm). The IABP displays a zero (**0**) when the heart rate drops below 15 bpm, and "- - -" when signal is not present or invalid. See Heart Rate Meter in section 7.5 for specifications.

8. Trigger Source:

This field displays the active trigger source. The possible display items for this field include: **ECG**, **Pressure**, **Pacer A**, **Pacer V**, **Pacer A/V**, or **Internal**.

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When **Pressure** is the selected trigger source, the pressure **Threshold** value (in mm) and its current threshold setting (**Auto** or **Manual**) will be displayed. For example: **20mm Auto Threshold** or **20mm Manual Threshold**. The pressure **Threshold** value ranges from 7 to 30 mm (See FIGURE 1-5).

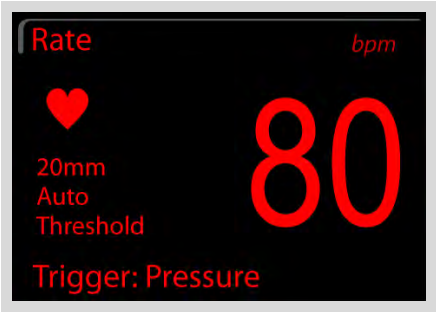


Figure 1-5: Example Pressure trigger source

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1.2.3 ARTERIAL PRESSURE WAVEFORM

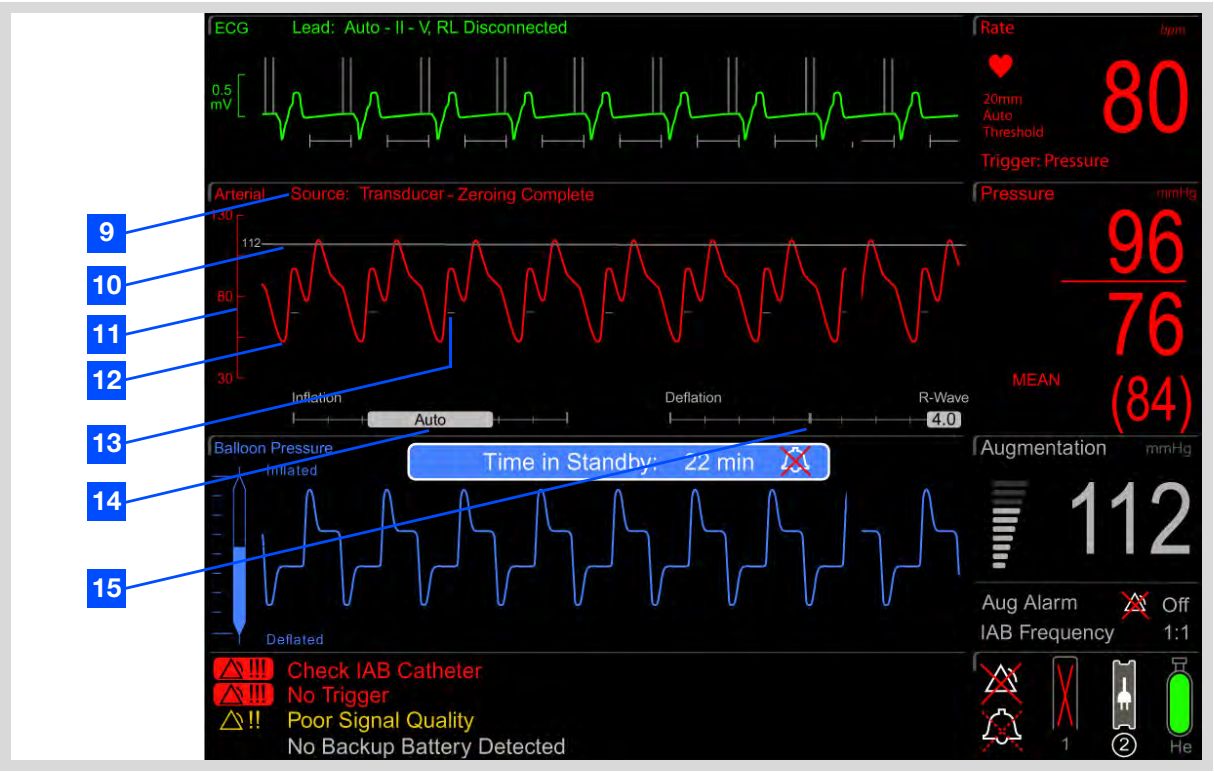


Figure 1-6: Example Arterial Pressure Waveform
The example is provided for illustrative purposes and does not represent actual clinical conditions.

9. Pressure Source:

This field displays the currently selected arterial pressure signal source and additionally its status if applicable. The current pressure signal source setting in the **Sources** menu (described in section 1.3.7.1) determines the item displayed in this field as follows:

- When the Pressure Source is set to **Direct**, the field will display either **Fiber-Optic** or **Transducer** (depending on the type of **Direct** pressure signal source that is connected). A connected and functional Fiber-Optic IAB takes priority over a directly connected arterial pressure transducer as the **Direct** pressure signal source. The Fiber-Optic IAB Sensor Connector must be disconnected to activate the direct pressure transducer input.

- When the Pressure Source is set to **Ext** in the **Sources** menu, this field will display **External**, indicating that an **External** pressure signal source (such as a bedside monitor) is providing the signal.

- In cases where a transducer or **External** pressure signal source is not present, the message **No Cable** is displayed. In the presence of a transducer that has not been successfully zeroed, the message **Not Zeroed** is displayed. If the Transducer has been successfully zeroed the message **Zeroing Complete** is displayed for a period of 10 seconds.

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10. Reference Line with Numeric Pressure Readout:

This user controlled, horizontal cursor is used to measure the arterial pressure of any point on the Arterial Pressure or Balloon Pressure Waveforms. In the presence of valid pressure indices a numeric value that represents the corresponding pressure at the reference line position (in mmHg) is displayed to the left of the line. When the reference line position is in the Balloon Pressure Waveform area the numeric value will display 2 dashes "--". The display and position of this line are controlled from the **Reference Line Control** area (described in section 1.3.15). When the Reference Line is initially activated it is positioned at the Mean Pressure value, and can be moved using the Up and Down Arrow keys. If the Mean Pressure is not available the Reference Line is positioned at the mid-point of the Arterial Pressure scale.

11. Arterial Pressure Waveform Scale:

The Arterial Pressure Waveform Scale is located to the left of the displayed Arterial Pressure Waveform. The scale is a vertical line with five equidistant tick marks. The numeric annotations denote the maximum, median, and minimum arterial pressures displayed within the viewable waveform area. The units are measured in mmHg and the displayable range of values is 0 to 300 mmHg. The scale is provided to facilitate determination of arterial pressure amplitude. When an uncalibrated or not zeroed signal is recorded by the system, the Arterial Pressure Waveform Scale does not show numeric annotations.

CAUTION:

The displayed AP signal is automatically scaled (amplified) and offset for optimal screen presentation. Because of automatic scaling, low AP amplitudes may appear to be of normal amplitude when displayed. Judgments should be made with reference to the annotated scale, patient arterial pressure parameter display.

12. Arterial Pressure Waveform:

This is the Arterial Pressure Waveform. It is plotted from left to right. The oldest data is erased, and is replaced by new data. To facilitate identification of the newest data, a vertical erase bar is drawn. The newest data is to the left of the bar and the oldest is to the right.

In **Standby** mode, the approximate interval of assist is continuously calculated and displayed by highlighting the appropriate interval on the Arterial Pressure Waveform.

During assist, Inflation Interval Highlighting is not displayed. To temporarily view Inflation Interval Highlighting while assisting, press the **Inflation Interval** key from within the **Display** preferences menu (described in section 1.3.13.1). Pressing **Inflation Interval** will cause Inflation Interval Highlighting to display for 15 seconds, which can be refreshed by pressing the **Restart Timer** key.

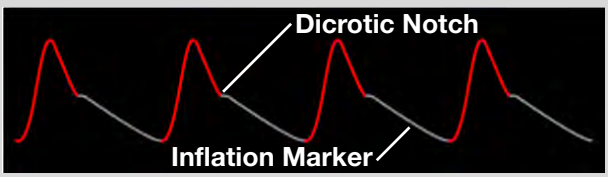


Figure 1-7: Example Highlighted Inflation Interval

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CAUTION:

The highlighted inflation interval marker should not be used to set timing. Timing should be set by examination of the Arterial Pressure Waveform.

13. Arterial Pressure Trigger Event Marks:

When arterial **Pressure** is the selected trigger source, small horizontal lines are added to the Arterial Pressure Waveform. These arterial pressure trigger event markers provide a visual indication of the current arterial pressure trigger threshold on the upstroke of the systole. These markers do not indicate the exact moment of the trigger event. They are slightly delayed in time.

14. Inflation Timing Indicator:

This graphical indicator provides visual feedback for the selected time duration between the trigger event and the start of inflation. The Inflation Timing Indicator ranges from -4.0 to 4.0 for the **Semi Auto** OPERATION MODE.

In **Semi Auto** OPERATION MODE, the indicator is controlled by the Inflation Timing Controls in the **Timing** menu (item 1, section 1.3.10).

In **Auto** OPERATION MODE, the word **Auto** is displayed at the center of the indicator to denote that inflation timing is automatically set and no operator intervention is required.

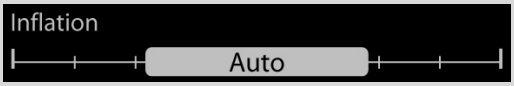


Figure 1-8: Inflation Timing Indicator in Auto OPERATION MODE

15. Deflation Timing Indicator:

This graphical indicator provides visual feedback for the selected time at which deflation occurs. The Deflation Timing Indicator ranges from -4.0 to 4.0 for the **Semi Auto** and **Auto** OPERATION MODE.

In **Semi Auto** OPERATION MODE, the indicator is controlled by the Deflation Timing Controls in the **Timing** menu (item 2, section 1.3.10).

The Deflation Timing Controls are active in all operation modes with the exception of a **Pressure** trigger source while in **Auto** OPERATION MODE. In this case, the word **Auto** is displayed at the center of the indicator to denote that deflation timing is automatically set and no operator intervention is permitted.

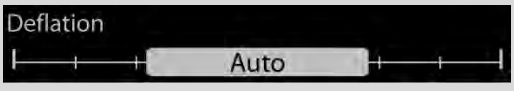


Figure 1-9: Deflation Timing Indicator in Auto OPERATION MODE

With an **ECG** trigger source while in the **Auto** OPERATION MODE, user modification of the automatically established deflation point is permitted but NOT required. Unlike inflation timing, deflation timing practices can vary considerably and this option allows users to tailor deflation to personal or institutional preference.

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The Deflation Timing Indicator also aids in distinguishing when the pump is operating in R-Wave Deflation mode.

Manual R-Wave Deflation mode is activated by manually moving the Deflation Timing Indicator to its extreme right (late) position. The label **R-Wave** will be displayed.



Figure 1-10: Deflation Timing Indicator in Manual R-Wave Deflation

The informational message **R-Wave Deflate** will also be displayed. Manual activation of R-Wave Deflation mode will always override automatic control.

Auto R-Wave Deflation is indicated by the Deflation Timing Indicator automatically repositioning itself to the extreme right (late) position and displaying the label **Auto R-Wave**. This mode may be manually activated from the **Pump Options** menu (described in section 1.3.13.4) or automatically activated whenever unpredictable rhythm patterns such as atrial fibrillation are detected.



Figure 1-11: Deflation Timing Indicator in Auto R-Wave Deflation

The informational message **Auto R-Wave Deflate** is also displayed. Any manual movement of the deflation timing indicator or the resumption of a predictable rhythm when in Auto R-Wave Deflation will return the timing indicator and the deflation timing to its previous value. The pump then continues monitoring for unpredictable rhythms.

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1.2.4 ARTERIAL PRESSURE PARAMETER

Peak systolic, end diastolic, and mean pressures are displayed in mmHg (See FIGURE 1-12). The valid displayable range for all arterial pressure numeric values is 0 to 300 mmHg inclusive. If the arterial pressure numeric value is greater than 300 mmHg, “>300” will be displayed. If the arterial pressure is invalid, uncalibrated, or not zeroed, 3 dashes “- - -” will be displayed in place of the numeric value. During assist, if the IAB Frequency is set at **1:2** or **1:3**, the unassisted peak systolic pressure and unassisted end diastolic pressure will also be displayed (See FIGURE 1-13).



Figure 1-12: Example Arterial Pressure Parameter



Figure 1-13: Example Arterial Pressure Parameter with Unassisted Values

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1.2.5 BALLOON PRESSURE WAVEFORM

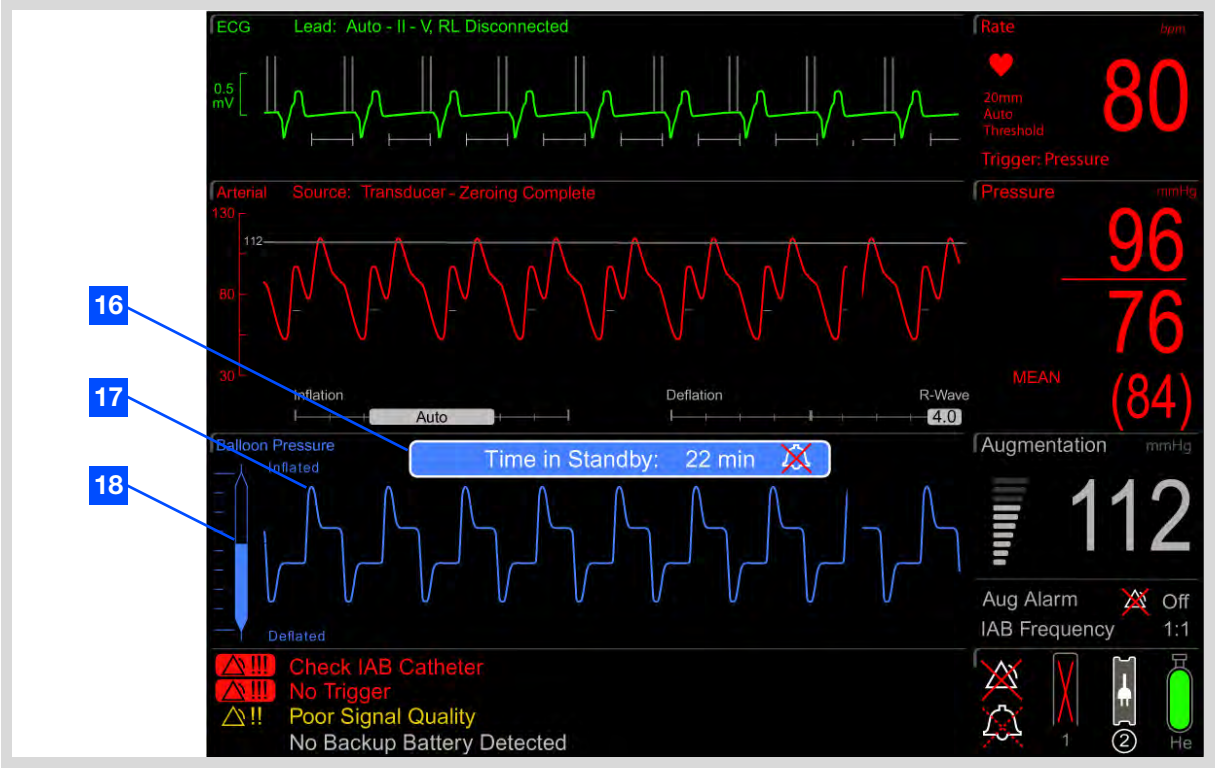


Figure 1-14: Example Balloon Pressure Waveform
The example is provided for illustrative purposes and does not represent actual clinical conditions.

16. Time In Standby:

Time in Standby (in minutes) is displayed only when the IABP is in **Standby** mode. The timer display starts when the IABP enters **Standby** mode for any reason and is cleared when assist is re-initiated. If the IABP is in **Standby** mode for less than 1 minute, the message **<1 min.** is displayed until the elapsed time in **Standby** mode is 1 minute or greater.

If the IABP remains in **Standby** mode for an elapsed time of 10 minutes, the **Prolonged Time in Standby** informational message is continuously displayed in the Message Display Area. The **Standby Advisory Tone** is provided as a reminder that a risk of thrombosis exists if the IAB remains deflated for extended time periods. If the **Standby Advisory Tone** is **Off** in the **Audio** preferences menu (described in section 1.3.13.2), the **Audio Alarm Off** icon is displayed to remind the user that no audio tone will be sounded.  The **Standby Advisory Tone** automatically defaults to the **On** position at start-up.

17. Balloon Pressure Waveform:

This is the Balloon Pressure Waveform. It is plotted from left to right. The oldest data is erased, and is replaced by new data. To facilitate identification of the newest data, a vertical erase bar is drawn. The newest data is to the left of the bar and the oldest is to the right.

18. IAB Status Indicator with Scale Markers:

The IAB Status Indicator depicts the inflation and deflation of the Intra-Aortic Balloon during assist. No quantitative measurement is intended, nor should it be inferred.

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1.2.6 AUGMENTATION PARAMETER

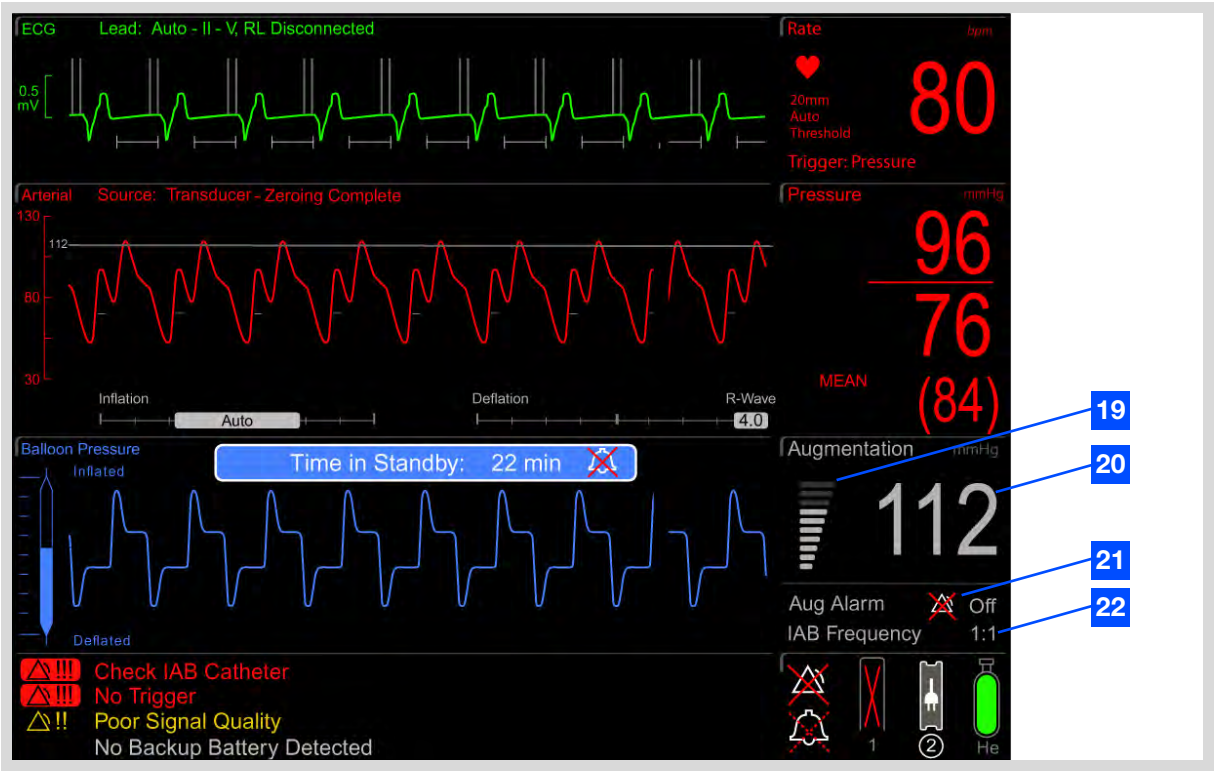


Figure 1-15: Augmentation parameter
The example is provided for illustrative purposes and does not represent actual clinical conditions.

19. Augmentation Indicator:

The relative selected level of augmentation is indicated by the number of displayed segments. This indicator is often used during the process of weaning a patient from IAB therapy, where the augmentation level is gradually reduced over time. The augmentation level displayed with the Augmentation Indicator is additionally displayed in the **Augmentation** menu (described in section 1.3.9).

20. Augmentation Value:

Indicates peak augmented diastolic pressure in mmHg. The valid displayable range is 0 to 300 mmHg inclusive. If the arterial pressure numeric value is greater than 300 mmHg, “>300” will be displayed. The augmented display will be blank if:

- the IABP is in **Standby** mode
- the pressure is uncalibrated
- the Fiber-Optic IAB is not connected
- the pressure transducer is not zeroed
- a pressure transducer is not connected
- an **External** pressure signal source is selected and the external cable plug is not inserted

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21. Aug (Augmentation) Alarm:

This field indicates the diastolic **Augmentation Alarm** limit in mmHg. This value is always displayed when the alarm is enabled. If the alarm is disabled, **OFF** is displayed with the **Alarm Inhibited** icon. 

Approximately 3 minutes after the initiation of assist and in the presence of valid pressure indices, verify that the Aug Alarm is automatically set approximately 10 mmHg less than the patient's augmented diastolic pressure.

22. IAB Frequency:

This is the current IAB Frequency setting. The IAB Frequency is selected using the controls in the **IAB Frequency** menu (described in section 1.3.8).

1.2.7 MESSAGE DISPLAY AREA

This area can display up to 4 alarms or informational messages of any type. In their priority order they are: Technical Alarms, High Priority Alarms, Medium Priority Alarms, Low Priority Alarms, and Informational Messages. All are displayed in their predetermined priority order within each class, higher priorities being displayed above lower priorities. When there are more than 4 alarms or Informational messages, the lower priorities will not be displayed. As higher priority conditions are corrected, the corresponding alarm or informational message is cleared allowing room for the next message to be displayed. Pressing the **Help Available** key will display the Help Screen area for single and multiple alarms as described in section 1.3.14. See Help Screen Area in section 1.3.14 for more information.

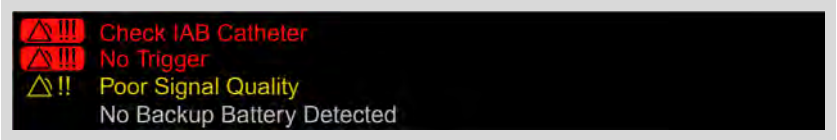


Figure 1-16: Example Alarm and Informational Messages

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1.2.8 ICON AND INDICATOR AREA

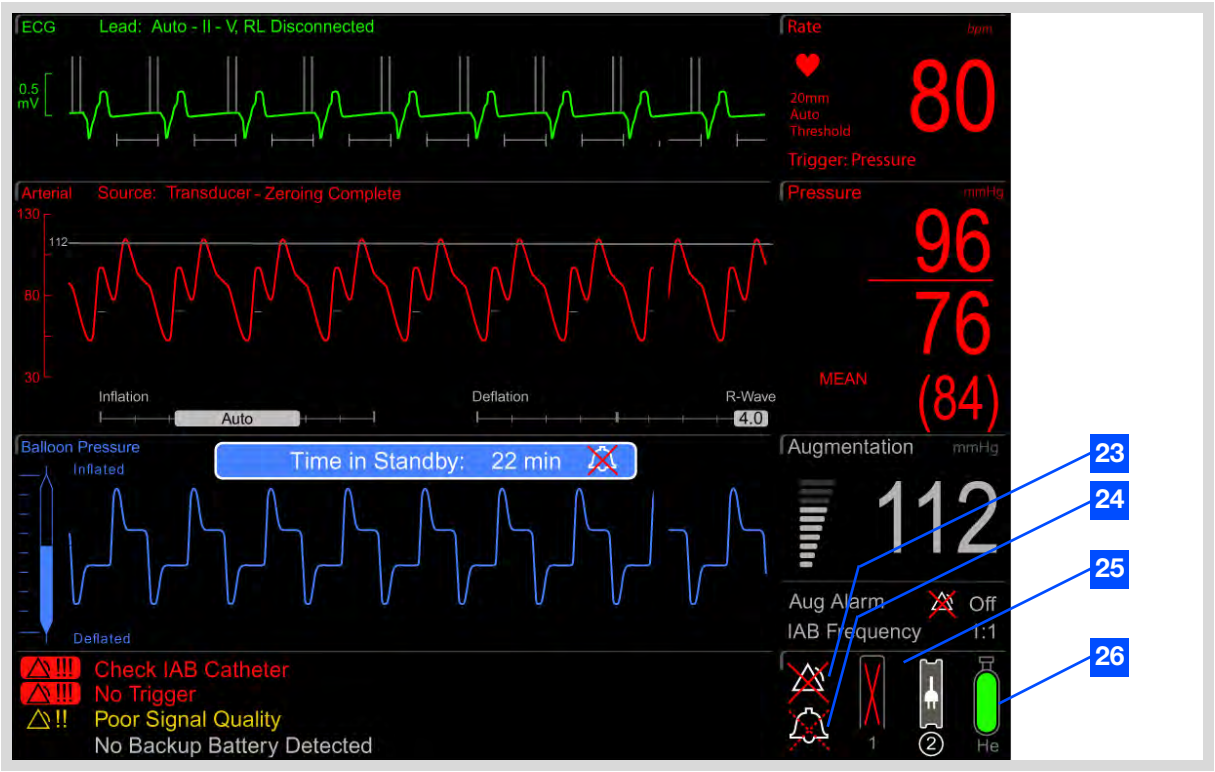


Figure 1-17: Example Icon Area
The example is provided for illustrative purposes and does not represent actual clinical conditions.

23. Alarm Inhibited Icon:

The alarm inhibited icon has two states.


When alarms have been set to **Off**, the alarm inhibited icon is displayed with a cross of solid lines.


When alarms have been temporarily paused, the alarm inhibited icon is display with a cross of dotted lines.

24. Audio Paused Icon:

This icon is displayed when the alarm tones have been temporarily muted with the **Pause Audio** key. Visual indicators of the alarm condition remain active.

25. Battery Icon Display Area:

The indicator numbers **1** and **2** beneath the icons in the Battery Icon Display Area correspond to the Battery Bay where each battery or the transport power supply is installed.

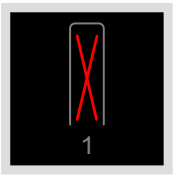
The Battery Icon Display Area displays different icons depending on the current power configuration of the IABP, and inform the user when the IABP is using AC or battery power. Also, when a battery is installed in a Battery Bay, these icons inform the user of the current state of charge of each installed battery, and via the indicator numbers which battery, if running on battery power, is currently in use.

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Described below are the different icons appearing in the Battery Icon Display Area:

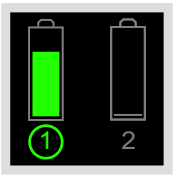
■ Empty Battery Bay Icon:

An empty Battery Bay is depicted in the Battery Icon Display Area by a box with a cross through it.

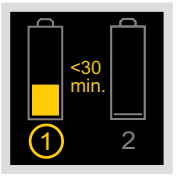


■ Battery Icon:

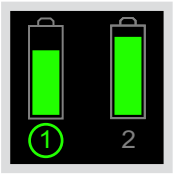
When a battery is installed in a Battery Bay, an icon depicting the battery's current status is displayed. As the charge level of the battery decreases, the battery icon will reflect this by incrementally decreasing the colored level inside the battery icon. Similarly, as the charge level of the battery decreases, the battery icon's colored level will transition from green to yellow to red. When a battery is depleted, and no longer available for use, the battery icon will appear gray. When AC power is not in use, the battery denoted by a circle around its battery indicator number, is the battery that is currently in use.



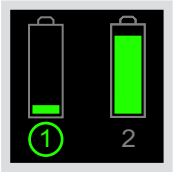
Additionally, when the cumulative remaining charge for both batteries reaches less than 30 minutes, the Battery Icon Display Area will display the approximate time remaining in 5 minute intervals starting at <30 min.



When the IABP is running on battery power, and multiple charged batteries are installed in the Battery Bays, the approximate charge level of both batteries is displayed. However, only the battery in the circled Battery Bay is currently in use. As a battery becomes depleted, the IABP will automatically transition to the next installed charged battery. In this situation, the battery icon's fill will not transition from green to yellow to red if there is a charged battery ready for use in the other Battery Bay.

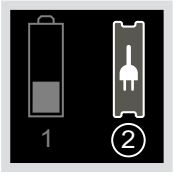


When the IABP detects an unusable battery in a Battery Bay, the attention icon ⚠ will be superimposed over the battery icon, with a corresponding message displayed in the Message Display Area.



■ Transport Power Supply Icon:

When a Transport Power Supply is installed and in a Battery Bay and plugged into an AC receptacle, the Transport Power Supply icon with AC plug is displayed, informing the user that the Transport Power Supply is installed, and the IABP is currently running on AC power. When the IABP is running on AC power from the Transport Power Supply, any installed batteries will be grayed out.



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When the IABP detects that the installed Transport Power Supply is not plugged into an AC power receptacle, or when a problem has been detected with an in-use Transport Power Supply, the attention icon will be superimposed over the Transport Power Supply. Additionally, when a problem has been detected with a Transport Power Supply, a corresponding message is displayed in the Message Display Area. When the Transport Power Supply is not plugged into an AC power receptacle, the AC plug icon is not displayed on the Transport Power Supply icon.

Installed batteries can only be charged from a Transport Power Supply when the Transport Power Supply is plugged into an AC receptacle, and the IABP is powered off.

Note:
The Low Battery alarm is displayed when 30 minutes or less of internal battery operating time remains. When this message is displayed, the battery symbol is displayed as empty. See the User Maintenance chapter for additional information.

26. Helium Indicator:

This icon indicates the approximate amount of remaining helium. When the helium tank is full, the Helium Indicator displays as a full green tank. As helium is depleted, the Helium Indicator will reflect this by incrementally decreasing the amount it is filled. When the amount of helium remaining in the tank becomes low, the Helium Indicator fill color switches from green to red, and will continue to decrease until the tank is empty.

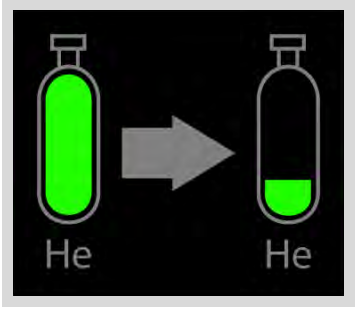


Figure 1-18: Example Helium Indicator transition from a full state to just before it is low

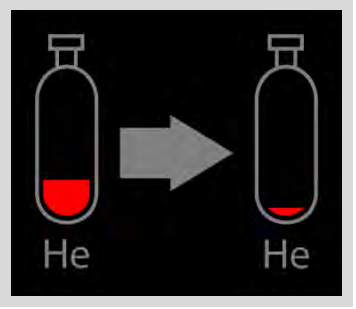


Figure 1-19: Example Helium Indicator transition from low to the empty state

Note:
A Low Helium informational message is displayed when the helium tank becomes low, and the Helium Indicator shows red and requires refilling.

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1.3 TOUCHSCREEN

This section of the Operating Instructions identifies and describes each feature and control in the Touchscreen. See System Operation in section 2 for use instructions.

CAUTION:

The Touchscreen is a pressure sensitive surface that should not be in contact with sharp objects or harsh chemicals.



Figure 1-20: Example Touchscreen

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1.3.1 OPERATION MODE KEYS

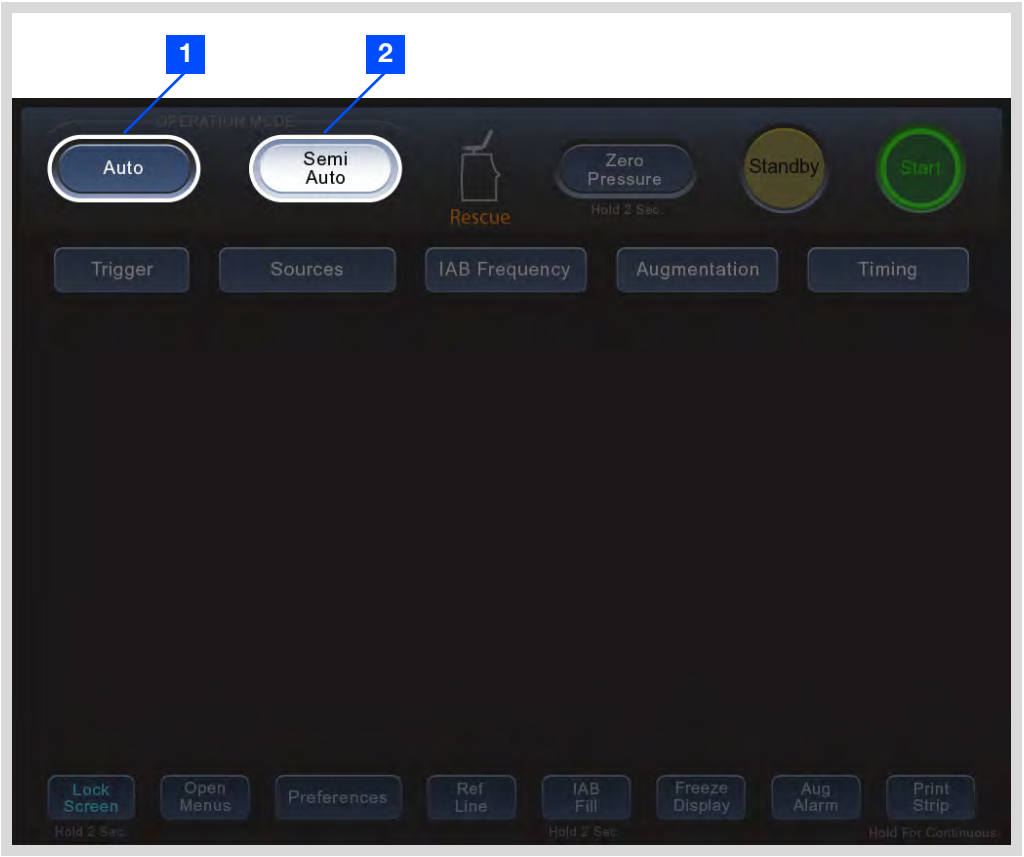


Figure 1-21: Example OPERATION MODE Keys

NOTE
An active mode key is displayed on a white background. An inactive mode key is displayed on a dark blue background.

The IABP has two operation modes, **Auto** (for simplicity) and **Semi Auto** (for versatility). The currently active mode is indicated by a white background on the corresponding mode key. The default operation mode is **Auto**. Selection of any OPERATION MODE key cancels the previous selection.

1. Auto Key:
This key places the IABP in the **Auto** OPERATION MODE. For more information see Auto Operation Mode in section 2.1.2.1.

2. Semi Auto Key:
This key places the IABP in the **Semi Auto** OPERATION MODE. For more information see Semi Auto Operation Mode in section 2.1.2.2.

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1.3.2 IABP CONFIGURATION ICON



The IABP Configuration Icon shows the current mode of configuration for the IABP, Hybrid Mode or Rescue Mode.

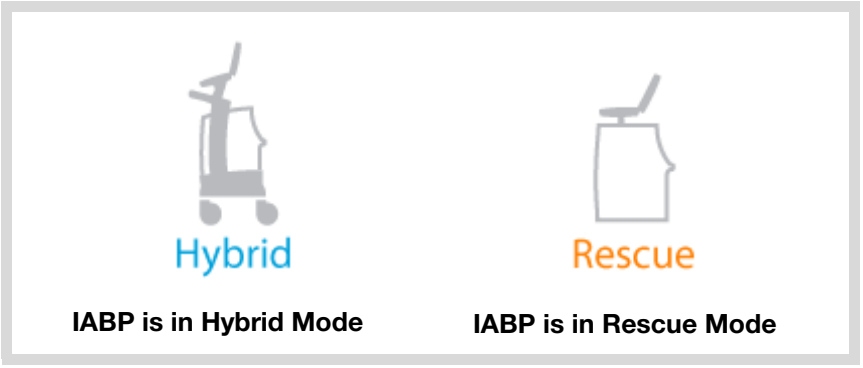


Figure 1-22: Example Configuration Icon Hybrid and Rescue modes

- Hybrid Mode – The Rescue unit is docked into the Hospital Cart.
- Rescue Mode – The IABP is in Rescue configuration and is not docked into the Hospital Cart.

If the IABP is set up in the Hybrid Mode and the Rescue Mode icon is displayed, ensure that the Rescue unit is securely docked into the Hospital Cart. Upon transitions from Rescue to Hybrid the IABP will sound three audio tones of increasing volume, upon transitions from Hybrid to Rescue the IABP will sound three audio tones of decreasing volume. Upon all transitions between Hybrid and Rescue the IABP will blink the icon for approximately 6 seconds.

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1.3.3 CALIBRATE PRESSURE/ZERO PRESSURE KEY



This key is applicable only for the **Direct** pressure signal sources, which include either the Fiber-Optic IAB or arterial pressure transducer (e.g., IAB inner lumen/radial artery).

The label for this key varies between **Calibrate Pressure** and **Zero Pressure** depending on the type of **Direct** pressure signal source that is connected to the IABP.



Figure 1-23: Example Calibrate Pressure and Zero Pressure keys

- When a Fiber-Optic IAB is connected, this key will be labeled **Calibrate Pressure**.
- When an arterial pressure transducer is connected, this key will be labeled **Zero Pressure**.

1. Calibrate Pressure Key:

This key initiates calibration of the Fiber-Optic IAB while the IABP is assisting.

2. Zero Pressure Key:

This key zeros the arterial pressure transducer while the transducer is vented.

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1.3.4 STANDBY KEY



Pressing this key while the IABP is assisting will suspend assist, and place the IABP into **Standby** mode (indicated by an illuminated key).



Figure 1-24: Example Standby key

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1.3.5 START KEY



If the IABP is not already assisting, pressing this key will cause the IABP to begin assisting if allowed by the current settings. To indicate that the IABP is assisting, this key flashes in time with trigger detection. If the IABP is already assisting with **Pressure** as the selected trigger source, momentarily pressing this key will issue an arterial pressure re-sync request to the system, initiating an instantaneous re-synchronization of timing during which a single beat is unassisted.

Pressing this key at power-up automatically initiates the IABP's rapid start feature. This feature expedites the start of IAB assist. The rapid start feature automatically performs the following steps:

- Automatically purges and fills the IAB, and calibrates the Fiber-Optic IAB if connected.
- Starts assist and automatically increases augmentation to maximum.



Figure 1-25: Example Start key

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1.3.6 TRIGGER MENU



Figure 1-26: Example Trigger menu

This menu enables selection of the following trigger sources: **ECG**, **Pressure**, **Pacer V/AV**, **Pacer A** and **Internal**.

Regardless of the operation mode, the active trigger source is indicated by a white background on the corresponding trigger key. It is also displayed in the trigger source field in the Rate parameter area to the right of the ECG Waveform area (item 8, section 1.2.2). In **Auto** OPERATION MODE, all trigger keys will be grayed out and disabled.

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1.3.7 SOURCES AND THRESHOLDS MENUS

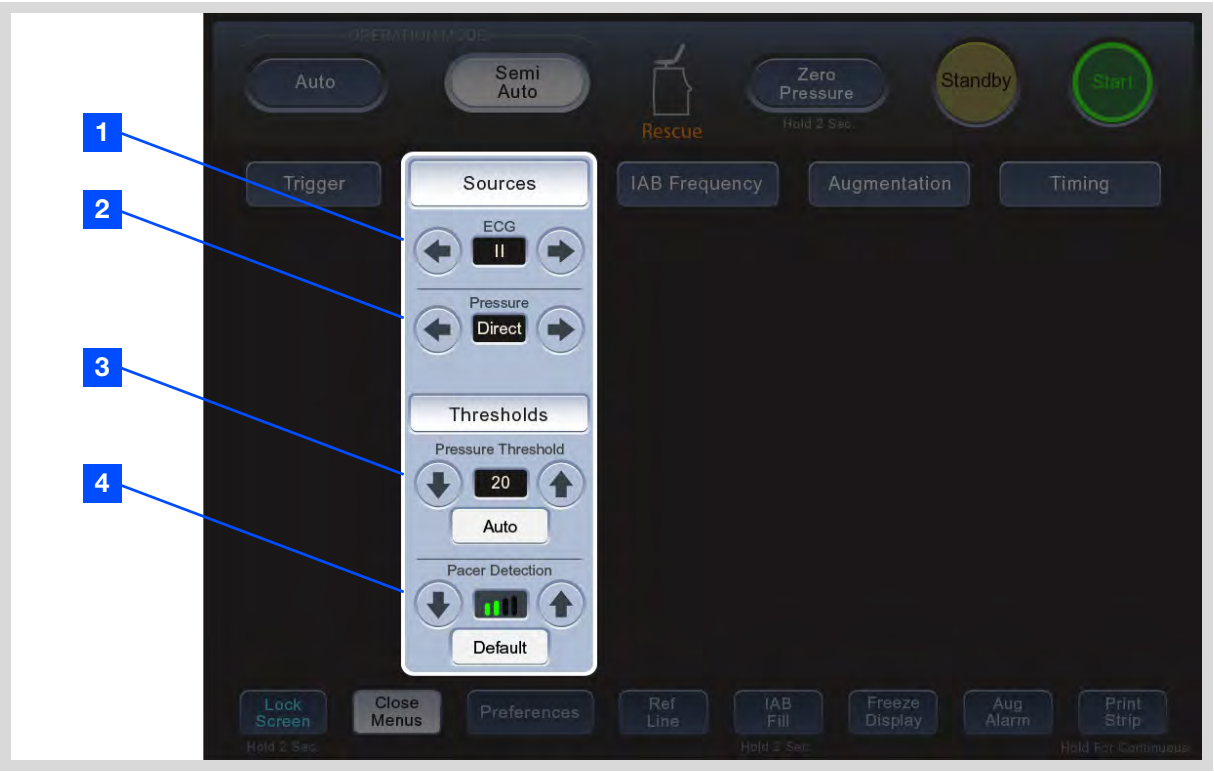


Figure 1-27: Example Sources and Thresholds menus

1.3.7.1 SOURCES MENU

1. ECG Lead Source:

- When the IABP is in **Semi Auto** OPERATION MODE, the Left and Right Arrow keys enable the selection of the available ECG signal source (**I**, **II**, **III**, **aVR**, **aVL**, **aVF**, **V** or **Ext**), which is based on connected electrodes. The current setting is displayed between the scroll keys.

- When the IABP is in **Auto** OPERATION MODE, the word **Auto** is displayed between the Left and Right Arrow keys with no other selections being possible. In this mode, the active ECG signal source is automatically selected by the IABP (**I**, **II**, **III** or **Ext**).

2. Pressure Source:

The Left and Right Arrow keys enable the selection of the Pressure Source (**Direct** and **Ext**). The current setting is displayed between the Left and Right Arrow keys and determines the item displayed in the Source field of the Arterial Pressure Waveform (described in section 1.2.3).

In the AUTO operation mode, the operator can manually change the pressure source. If the pressure source selected by the operator becomes unavailable or its trigger is lost, the IABP will automatically select an alternative pressure source, if available.

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1.3.7.2 THRESHOLDS MENU

Note:
The Sources menu must be open to access the Thresholds menu.

3. Pressure Threshold:

- In **Semi Auto** OPERATION MODE with **Pressure** as the active trigger source, the Up and Down Arrow keys enable the increase or decrease of the Pressure Threshold in increments of 1 mmHg between 7 and 30 mmHg. The current setting is displayed between the Up and Down Arrow keys.

- In **Auto** OPERATION MODE, the word **Auto** is displayed between the Up and Down Arrow keys with no other selections being possible.

4. Pacer Detection Level:

The Pacer Detection Level can be adjusted with the Up and Down Arrow keys in any operation mode and with any active trigger source. There are 4 levels of pacer detection, each graphically represented by segments of increasing size in the display between the Up and Down Arrow keys. The Pacer Detection can be reset to its default level **2** at any time by selecting the **Default** key.

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1.3.8 IAB FREQUENCY MENU

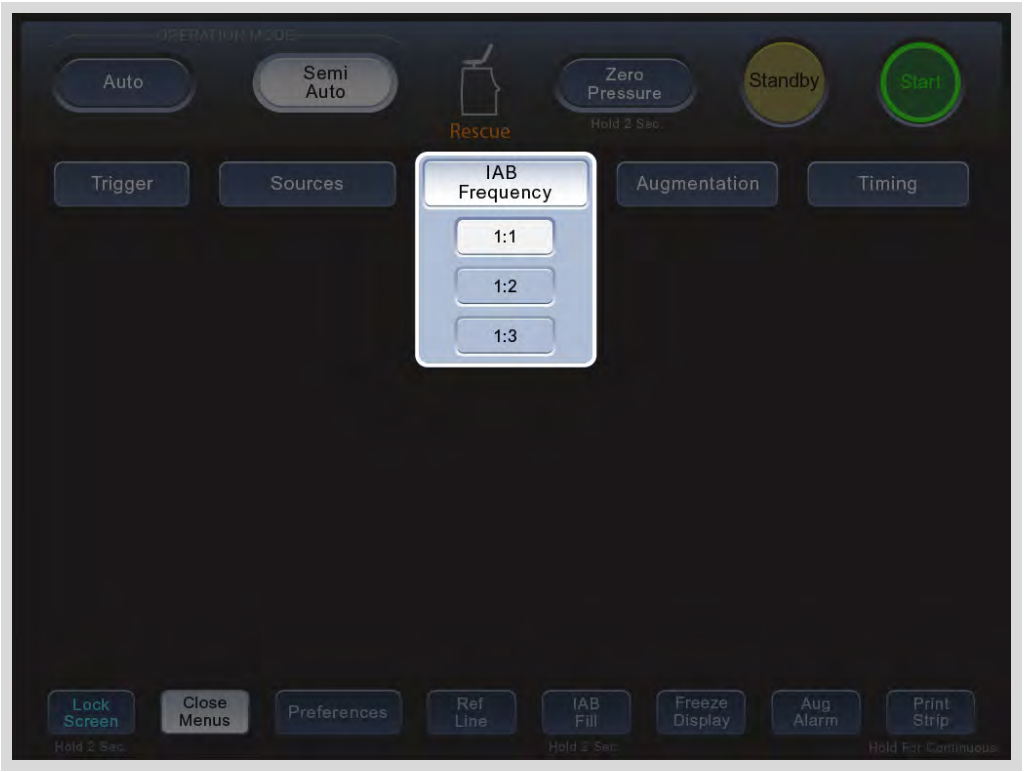


Figure 1-28: Example IAB Frequency menu

Available selections are:

- **1:1** - Every beat assisted
- **1:2** - Every other beat assisted
- **1:3** - Every third beat assisted

The currently active IAB Frequency is indicated by a white background on the corresponding key. The default IAB Frequency is **1:1**.

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1.3.9 AUGMENTATION MENU



Figure 1-29: Example Augmentation menu

The Augmentation menu consists of a display of the current Augmentation level and Up and Down Arrow keys to adjust this level in any operation mode and with any active trigger source. When the Augmentation menu is active, the Arrow keys enable the increase or decrease of the Augmentation level in increments of 1 unit between 1 and 10 units. The 10 levels of Augmentation are each graphically represented by segments of increasing size in the display to the left of the Up and Down Arrow keys.

If the Augmentation level is at the highest (Max) position, the Up Arrow key will gray out, signifying that the Augmentation level is at its peak setting, and cannot be increased any higher. Similarly, if the Augmentation level is at the lowest (Off) position, the Down arrow key will gray out, signifying that the Augmentation level is at its lowest setting, and cannot be decreased any lower.

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1.3.10 TIMING MENU



Figure 1-30: Example Timing menu

The Timing menu consists of timing controls for the inflation and deflation timing period of the IAB.

1. IAB Inflation Timing Controls:

The IAB Inflation Timing Controls are used to adjust the time duration between the trigger event and the beginning of the IAB inflation. Each time a control is pressed, the inflation point is moved 1 increment. Pressing and holding a control causes the inflation point to move in successive increments until the control is released.

- These controls are active only in the **Semi Auto** OPERATION MODE. They are disabled in **Auto** OPERATION MODE, where inflation timing is automatically set.

- The **Inflation** Timing Indicator (item 14, section 1.2.3) moves in response to any user adjustment to inflation timing.

2. IAB Deflation Timing Controls:

The IAB Deflation Timing Controls are used to adjust the time at which the start of IAB deflation occurs. Each time a control is pressed, the deflation point is moved 1 increment. Pressing and holding a control causes the deflation point to move in successive increments until the control is released.

Detecting the early occurrence of a cardiac cycle will produce an immediate start to deflation, overriding the scheduled deflation point. see Deflation Timing Indicator: in section 1.2.3.

- These controls are active in the **Semi Auto** OPERATION MODE.

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- Deflation is automatically set in the **Auto** OPERATION MODE and the timing controls are disabled except when **ECG** triggering is active. In this case, user modification of the automatically established deflation point is permitted but NOT required. Unlike inflation, deflation timing practices can vary considerably and this option provides flexibility in tailoring deflation to personal or institutional preference.

- The Deflation Timing Indicator (item 15, section 1.2.3) moves in response to any user adjustment to deflation timing.

- The Deflation Timing Controls also allow the user to change the deflation timing mode. Moving the Deflation Timing Indicator to its extreme right (late) position activates R-Wave Deflation mode. The label **R-Wave** will be displayed on the Deflation Timing Indicator, and the informational message R-Wave Deflate will be displayed in the Message Display Area. R-Wave Deflation mode delays deflation of the IAB until the occurrence of the next valid R-Wave trigger event.

- The IABP will automatically enact Auto R-Wave Deflate whenever unpredictable rhythm patterns such as atrial fibrillation are detected. The Deflation Timing Indicator will automatically reposition itself to the extreme right (late) position and display the label **Auto R-Wave**.

1.3.11 LOCK/UNLOCK SCREEN KEYS

The Touchscreen can be “locked” as a guard against unintended contact. This lock can be manually activated. In addition, the system design includes an automatic lock feature.



Figure 1-31: Example Lock Screen

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While the Touchscreen is in the locked state, any items that are currently displayed will be “grayed out”, but will not be closed or otherwise affected. In addition the entire Touchscreen area will be bordered by the cyan color of the **Unlock Screen** key and the following text will be superimposed in the center of the Touchscreen:



AUTOMATIC LOCK/UNLOCK

At initial startup, after the IABP has initiated an assist cycle, the Touchscreen will automatically lock after 2 minutes of inactivity. To unlock the Touchscreen, momentarily press the **Unlock Screen** key.

In the presence of any High Priority, Medium Priority, Low priority or Technical Alarm, the Touchscreen will automatically unlock and remain unlocked for the duration of the alarm condition.

MANUAL LOCK/UNLOCK

To manually lock the Touchscreen, press and hold the **Lock Screen** key for 2 seconds.

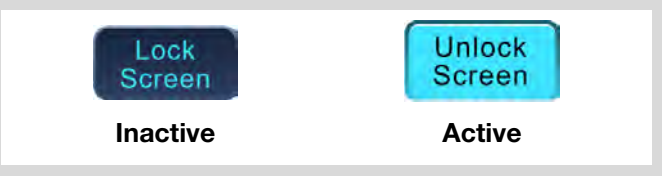


Figure 1-32: Example Lock/Unlock Screen key

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1.3.12 OPEN/CLOSE MENUS KEYS



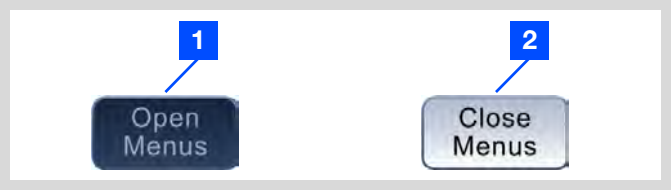


Figure 1-33: Open/Close Menus keys

1. Open Menus:

This key is only available when there are no open menus. If there are no open menus, pressing this key opens the **Trigger**, **Sources**, **IAB Frequency**, **Augmentation**, and **Timing** menus. The **Thresholds**, and **Preferences** menus remain closed.

2. Close Menus:

This key is available if there is one or more of the following menus open on the Touchscreen; **Trigger**, **Sources**, **Thresholds**, **IAB Frequency**, **Augmentation**, **Timing**, or **Preferences**. Pressing this key closes all open menus.

NOTE

The **Open/Close Menus** key functionality will have no effect on the Help Screen.

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1.3.13 PREFERENCES KEY



Figure 1-34: Preferences key

Selecting the **Preferences** key opens the **Preferences** menu which provides access to the **Display**, **Audio**, **Printer**, and **Pump Options Preferences** menus for user customization. By default, the **Display** preferences menu is always the first menu shown when the **Preferences** menu is opened. While the **Preferences** menu is open, all other menus will be temporarily hidden from view. Once the **Preferences** menu is closed, any menus that were previously displayed will be reopened.

Note:
If the **Preferences** menu is closed by using the **Close Menus** key, any open menus hidden from view by the **Preferences** menu will be subsequently closed.

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1.3.13.1 DISPLAY PREFERENCES MENU

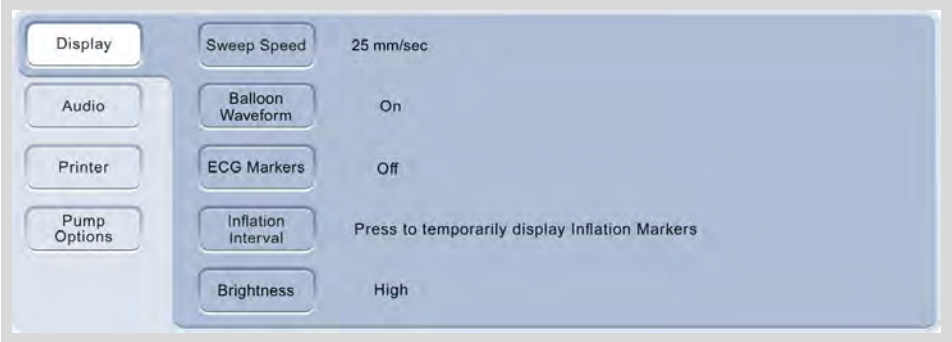


Figure 1-35: Example Display preferences menu

The **Display Preferences** menu choices **Sweep Speed**, **Balloon Waveform**, **ECG Markers**, **Inflation Interval**, and **Brightness** are described as follows:

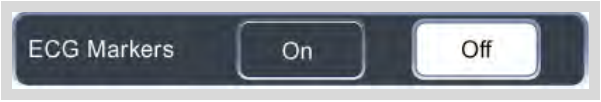
- **Sweep Speed:** Sets the sweep speed of the display's waveforms and printer. The choices are: **25 mm/sec**, and **50 mm/sec**. The default is **25 mm/sec**.



- **Balloon Waveform:** Enables or disables the display of the Balloon Pressure Waveform. The choices are: **On** and **Off**. The default is the most recent setting. See item 17 in section 1.2.5 for information on the Balloon Pressure Waveform.



- **ECG Markers:** Enables or disables the display of the ECG Markers. The choices are: **On** and **Off**. The default is the most recent setting. See item 5 in section 1.2.1 for information on the ECG markers.



- **Inflation Interval:** While in the Assist Mode, press this key to view the period of diastolic augmentation on the Arterial Pressure Waveform for 15 seconds, which can be refreshed by pressing the **Restart Timer** key. The marked and highlighted portion identifies the approximate balloon inflation period. When the timer expires, the **Inflation Interval** menu automatically closes.



CAUTION:

The highlighted inflation interval marker should not be used to set timing. Timing should be set by examination of the Arterial Pressure Waveform.

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■ **Brightness:** Sets the brightness of the Monitor Display and Touchscreen. The choices are: **Auto**, **Low**, **Medium**, and **High**. The default is **High**.



Note:
Choosing **Auto** brightness causes the IABP to adjust the Monitor brightness based on the ambient light.

1.3.13.2 AUDIO PREFERENCES MENU



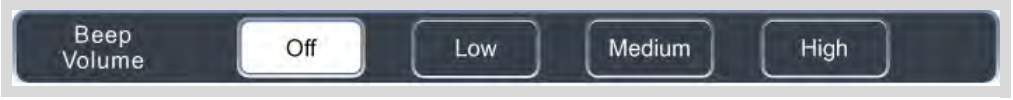
Figure 1-36: Example Audio preferences menu

The **Audio Preferences** menu choices **Alarm Volume**, **Beep Volume**, and **Standby Advisory Tone** are described as follows:

■ **Alarm Volume:** Used to adjust the volume of the alarms. Eight (8) volume levels are graphically represented by segments of equal width in the display between the increment/decrement keys. The lowest Alarm Volume level is **1**, and the Alarm Volume cannot be turned off. The default is level **4**. With each press of an increment/decrement key, a sample tone is generated for operator feedback.



■ **Beep Volume:** Sets the level of the QRS trigger beep. The choices are: **Off**, **Low**, **Medium**, and **High**. The default is **Off**.



■ **Standby Advisory Tone:** Enables or disables the **Prolonged Time in Standby** advisory tone. The choices are: **On** and **Off**. The default is **On**.



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1.3.13.3 PRINTER PREFERENCES MENU

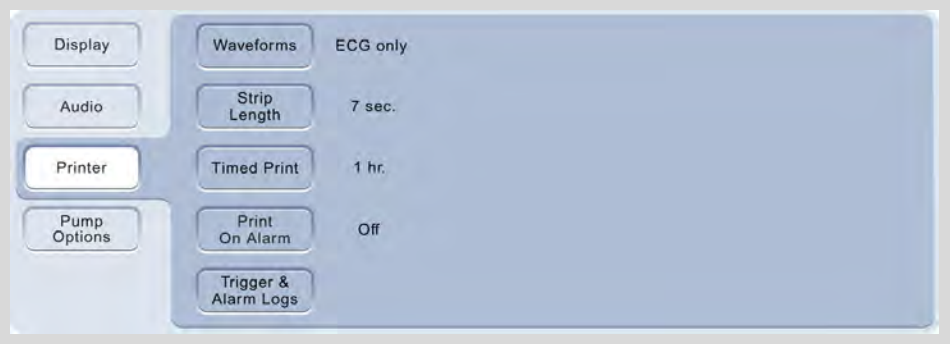


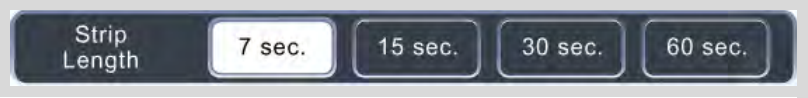
Figure 1-37: Example Printer preferences menu

The **Printer Preferences** menu choices **Waveforms**, **Strip Length**, **Timed Print**, **Print On Alarm**, and **Trigger & Alarm Logs** are described as follows:

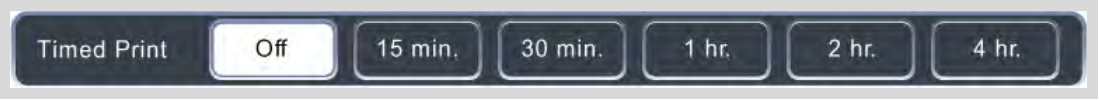
- **Waveforms:** Defines the vertical layout of the waveforms for the print strip. The choices are: **ECG & A. P.**, **ECG & Balloon**, **A. P. & Balloon**, **ECG Only**, **A. P. Only**, and **Balloon Only**. The default is **ECG & A. P.** See section 2.6.2 for specific details on printer formats.



- **Strip Length:** Defines the time duration of the print strip. The choices are: **7 sec.**, **15 sec.**, **30 sec.**, and **60 sec.** This is set to **7 sec.** at initial system power up, but the default is the most recent setting.

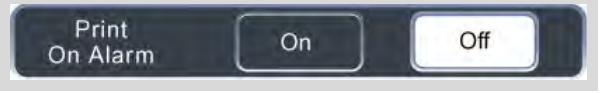


- **Timed Print:** Sets the interval for automatically printed strips. The choices are: **Off**, **15 min.**, **30 min.**, **1 hr.**, **2 hr.**, and **4 hr.** The default is **Off**.



- **Print On Alarm:** Enables or disables the **Print On Alarm** feature which automatically prints a strip during alarm conditions as follows:
  - For trigger related alarms - ECG and Arterial Pressure Waveforms are printed.
  - For pneumatic related alarms - Arterial Pressure and Balloon Pressure Waveforms are printed.

  The choices are: **On** and **Off**. The default is **Off**.



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- **Trigger & Alarm Logs:** Pressing the **Print Now** key initiates an immediate printout of a time and date stamped history of the 10 most recent trigger settings and alarms.

  Additionally, the 10 most recent trigger settings and alarms are maintained after the unit is powered down or experiences a total loss of power.



1.3.13.4 PUMP OPTIONS MENU



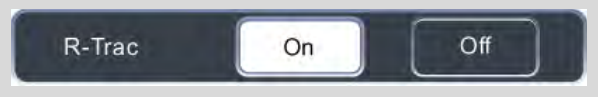
Figure 1-38: Example Pump Options menu

The **Pump Options** menu choices **Catheter Alarms**, **R-Trac**, **Set Time & Date**, and **Network Connections** are described as follows:

- **Catheter Alarms:** Enables or disables the catheter alarms. The choices are: **Catheter Alarms On**, **Gas Loss Alarm Off**, and **Pause Catheter Alarms**. The default is **Catheter Alarms On**. The **Pause Catheter Alarms** setting is only enacted for 60 minutes, then the operator must reassess and re-enact, if desired. To activate **Pause Catheter Alarms** the operator must press and hold the **Pause Catheter Alarms** key for 2 seconds.



- **R-Trac:** Enables or disables the automatic activation of R-Wave Deflation for tracking unpredictable rhythm patterns. The choices are: **On** and **Off**. The default is **On**.

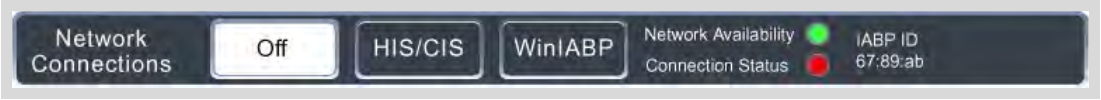


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- **Set Time & Date:** Sets the current time and date. Time is displayed in a 24-hour format with a two-digit hour and a two-digit minute. Date is displayed as a four-digit year followed by a two-digit month and a two-digit day. Up and Down Arrow keys control adjustment of all fields. Once the time and date are selected, press the **Accept** key to save and apply changes.



- **Network Connections:** Enables or disables external data communications for electronic medical records (HIS/CIS) or remote console viewing support (Win-IABP). Only one form of external data communication may be selected at a time. The choices are: **Off**, **HIS/CIS**, and **WinIABP**. The default is **Off**.



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1.3.14 HELP SCREEN AREA

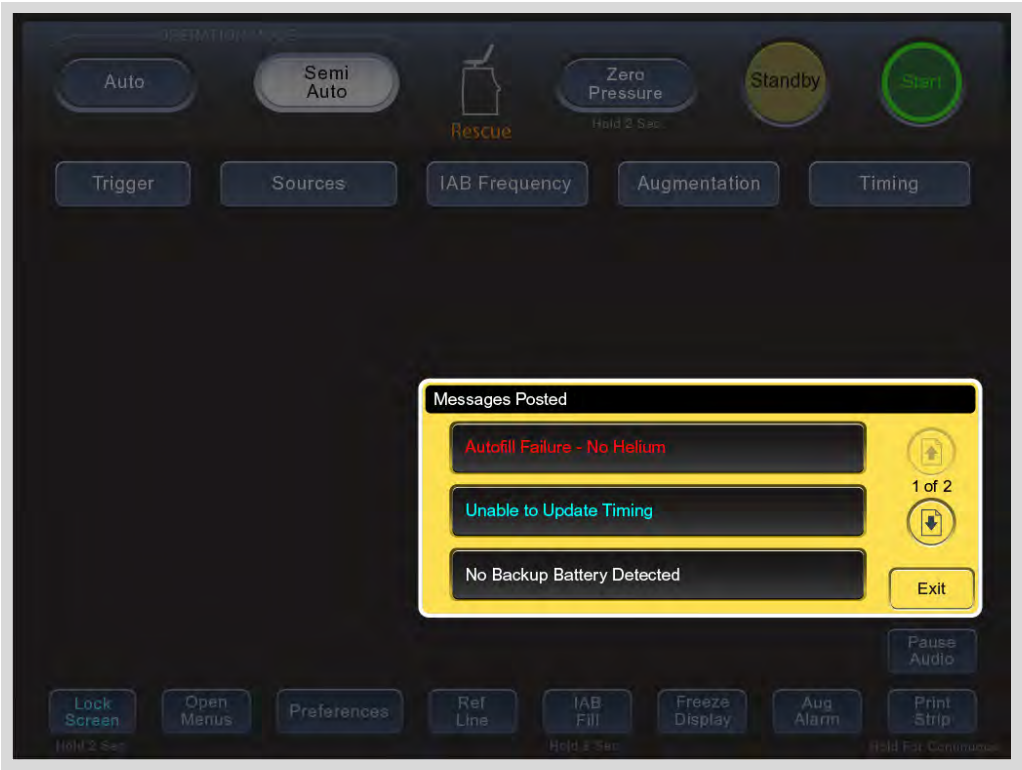


Figure 1-39: Example Help Screen area

Beyond displaying the same alarms and informational messages as the Message Display Area described in section 1.2.7, this area provides access to the Help Screens that are detailed in section 2.4.1. Unlike the Message Display Area, this area can display ALL of the current alarms/informational messages in their predetermined priority order within each classification, higher priorities being displayed above lower priorities. The priority order is as follows: Technical Alarms, High Priority Alarms, Medium Priority Alarms, Low Priority Alarms, and informational Messages. Pressing the **Help Available** key will display the Help Screen area for single and multiple alarms. As conditions are corrected, the corresponding alarm or informational message is cleared unless the Help Screen is currently being viewed.



Figure 1-40: Help Available key

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SINGLE ALARM

If only a single alarm or informational message exists that has a corresponding Help Screen, the corresponding Help Screen will be immediately displayed when the Help Available key is pressed (see the example in FIGURE 1-41).

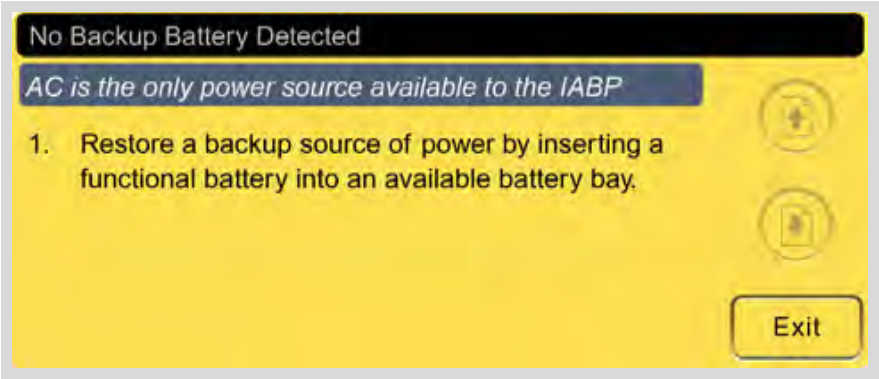


Figure 1-41: Example single alarm Help Screen

MULTIPLE ALARMS

If multiple alarms or informational messages exist, a multiple alarm display will be provided in the Help Screen area (see the example in FIGURE 1-42) to allow the user to select specific Help Screens for the list of active messages. Each listed alarm or informational message is actually a key that, when selected, displays the associated single alarm Help Screen.

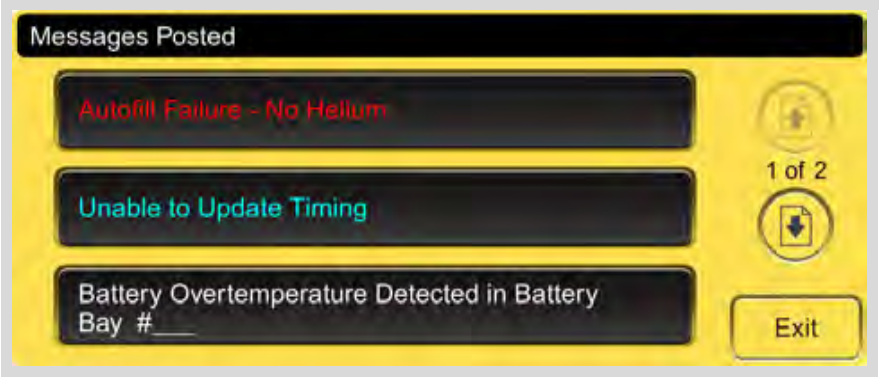


Figure 1-42: Example multiple alarm Help Screen

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1.3.15 REFERENCE LINE CONTROL AREA



Figure 1-43: Example Reference Line Control area

Selecting the **Ref Line** key opens the Reference Line control area and displays the reference line (item 10 in section 1.2.3) at the Mean Pressure value or if the Mean pressure is not available, the middle of the Arterial Pressure Waveform. The Up and Down Arrow keys in this area are used to move the reference line to the desired measurement point on the waveform. If the Reference Line is at the highest position on the Monitor Display, the Up Arrow key will gray out, signifying that the Reference Line cannot be moved any higher. Similarly, if the Reference Line is at the lowest position on the Monitor Display, the Down Arrow key will gray out, signifying that the Reference Line cannot be moved any lower. The selected numeric pressure value is displayed between the Up and Down Arrow keys on the Reference Line Control area as well as to the left of the Reference Line on the Monitor Display.The Up and Down arrow keys can be pressed to move the Reference line. When either of the Arrow keys is held continuously the movement of the Reference line will increase in order to traverse the waveform areas quickly

Note:
The reference line may also be moved into the Balloon Pressure Waveform area where the numeric pressure value in the Reference Line Control area is replaced with 2 dashes “- -”, and the numeric pressure value to the left of the Reference Line is not displayed.

Note:
If the arterial pressure is invalid, uncalibrated, or not zeroed, the numeric pressure value in the Reference Line Control area is replaced with 2 dashes “- -”, and the numeric pressure value to the left of the Reference Line is not displayed.

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1.3.16 IAB FILL KEY



Figure 1-44: IAB Fill key

Press and hold this key for 2 seconds to initiate the autofill process. If pumping is in progress, pumping will be suspended. The autofill process will purge and replace the shuttle gas (IAB and extension catheter) with pure helium, and re-calibrate the Fiber-Optic IAB, if appropriate.

The message **Autofill Complete** will be posted once an autofill is complete and will remain posted until pumping is resumed.

Since the IABP automatically purges and replaces the shuttle gas every 2 hours, operator intervention is not normally required. Consequently, this key is used infrequently. Typically, it is used in conjunction with an alarm when the Help Screens suggest corrective action for alarms.

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1.3.17 FREEZE/UNFREEZE DISPLAY KEY



Figure 1-45: Freeze/Unfreeze Display Key

Press this key to freeze all traces on the Monitor Display. Press it again to unfreeze the traces. This key is disabled when the recorder is activated. The Display will automatically unfreeze if the user is adjusting IAB Timing, or if the **Print Strip** key is pressed.

If the **Print Strip** key is pressed while the waveform traces are frozen, the waveform section that was captured by the Freeze Display will be printed out (see section 2.7).

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1.3.18 AUG (AUGMENTATION) ALARM CONTROL AREA



Figure 1-46: Augmentation Alarm Control area

This function allows the user to adjust the alarm limit (the pressure in mmHg that will trigger the Augmentaton Alarm) for diastolic augmentation. The Augmentation Alarm limit is automatically set approximately 3 minutes after initiation of assist (if using an arterial pressure transducer, it must be zeroed). The automatic Augmentation Alarm limit is determined by an adaptive process which sets the alarm to 10 mmHg below the patient's augmented diastolic pressure.

To reset or change the Augmentation Alarm limit, press the **Aug Alarm** key. The up and down arrow keys enable the increase or decrease of the Augmentation Alarm limit in increments of 2 mmHg between 60 and 200 mmHg. The current setting is displayed between the up and down arrow keys. The up and down arrow keys can be pressed and held to set the Augmentation Alarm Limit. When either of the arrow keys is held continuously the movement of the Augmentation Alarm Limit value will increase in order to set the limit quickly. If the Augmentation Alarm was previously set and has then been set to **Off** by the operator, pressing either the up and down arrow key will automatically set the Augmentation Alarm 10 mmHg below the patient's augmented diastolic pressure.

To disable the Augmentation Alarm, use the up and down arrow keys to move past the upper or lower ends of the range to set the alarm limit to **Off**.

Note:
The Augmentation Alarm, when used properly, serves as an important backup to internal monitoring alarms. Due to the dynamic nature of the shuttle gas system, alarms associated with gas loss and the IAB catheter do not operate under severe patient conditions (see section 2.4 for more details). By setting the Augmentation Alarm, the system monitors the level of assist and will alert the user in the event of a decrease in augmentation pressure.

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1.3.19 PAUSE AUDIO KEY



Figure 1-47: Pause Audio key

Press the **Pause Audio** key to temporarily suspend an active audible alarm for 60 seconds. This control does not override the alarm. If an alarm condition is not corrected within 60 seconds the audible alarm is enabled again. Alarm messages will remain displayed with the visible attributes active while the associated audible tone is temporarily disabled. In the event that a new alarm condition occurs while audible alarms are suspended, the alarm tone will be immediately reactivated. Additionally, audio can be immediately resumed by pressing the **Pause Audio** key during the 60 second paused audio period. The label for the Pause Audio key will be displayed as **Pause Audio** when the audio is enabled and **Audio Paused** when the audio is disabled.

Note:
Use of the Help Available key is recommended in the troubleshooting of alarm conditions.

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1.3.20 PRINT STRIP KEY



Figure 1-48: Print Strip key

To initiate printing based on the settings in the **Printer** preferences key (described in section 1.3.13.3), momentarily press the **Print Strip** key. See Printing in section 2.6 for information about defining the format of the printout.

- For a continuous print strip, press and hold the **Print Strip** key for 2 seconds.
- To stop printing, press the **Print Strip** key again. Printing will stop after the print trailer information has been printed.

Note:
If the waveform display is frozen, pressing the Print Strip key will unfreeze frozen waveforms.

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1.4 ALTERNATE POWER-UP MODE

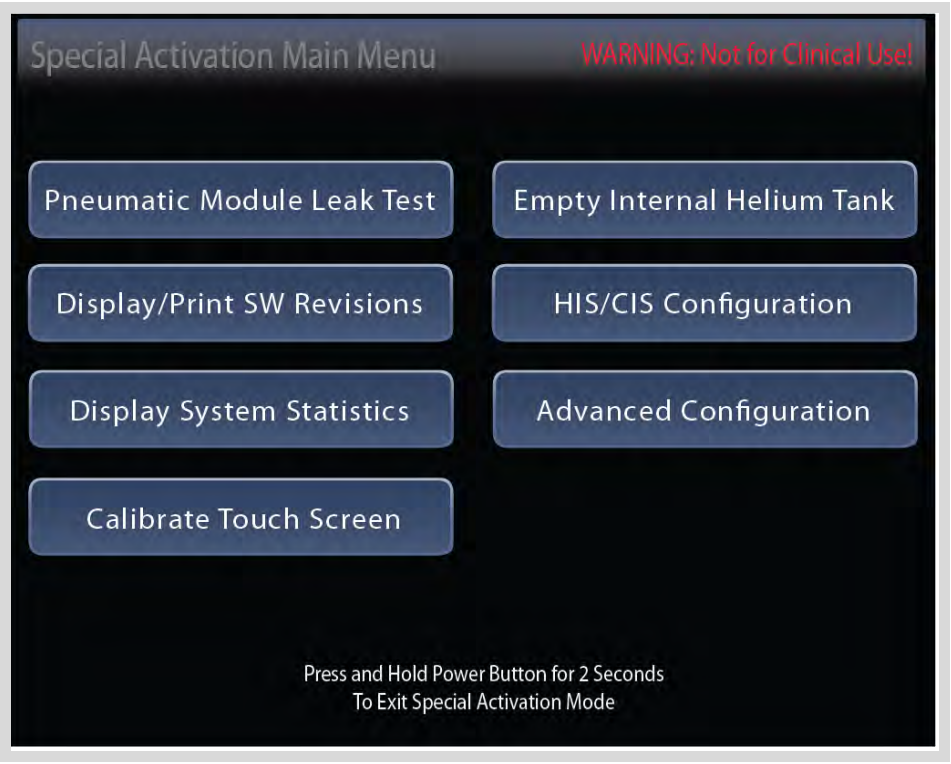


Figure 1-49: Example Special Activation Main Menu

During the power-up sequence of the IABP, certain functions can be enabled by powering-up the IABP in an alternate power-up mode. To enter the alternate power-up mode, start with the IABP turned off. While pressing and holding the **Low Level BP Output – Vent Button** (item 3, section 1.5.1), press and release the green **IABP Power Button** on the back panel (item 13, section 1.5.1) while continuing to hold the **Low Level BP Output – Vent Button** until the **Special Activation Main Menu** is displayed. Once the **Special Activation Main Menu** is displayed release the **Low Level BP Output – Vent Button**.

From the **Special Activation Main Menu**, the user can access to the following functions:

Pneumatic Module Leak Test:

Pressing this key opens the **Pneumatic Module Leak Test** screen. This test checks the integrity of the Pneumatic Module. Datascope Corp. recommends that this test be run before or after each use. For detailed information on performing the **Pneumatic Module Leak Test** see section 2.2.

Display/Print SW Revisions:

From this menu, the user can view the revisions of all software currently installed on the IABP. The user additionally has the option to print a list of all currently installed software revisions using the IABP's printer (item 14, section 1.5.1) by pressing the **Print Software Revisions** key.

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Display System Statistics:

From this menu the user can view the accumulated statistics of, Safety Disk Assist Cycles, Safety Disk Replacement Date, and Total System Hours. The user additionally has the option to print a list of all current System Statistics using the IABP's printer (item 14, section 1.5.1) by pressing the **Print System Statistics** key.

Calibrate Touchscreen:

Pressing this key opens the **Touch Screen Calibration** screen. Pressing the **Start Calibration Routine** key will begin the calibration procedure. During this procedure, the user will be prompted to press four targets  to complete Touchscreen calibration. The targets are displayed in each corner of the Touchscreen in the following order: Upper Left, Upper Right, Lower Right, and Lower Left. After all four targets have been pressed the user will be prompted to touch two additional targets to verify the calibration. For detailed information on calibrating the Touchscreen see section 4.9.

Empty Internal Helium Tank:

When commercially shipping **CARDIOSAVE Rescue** the internal helium tank **MUST** be emptied prior to shipping. Pressing this key opens the **Empty Internal Helium Tank** screen. Pressing the **Empty Internal Helium Tank** key will empty all of the Helium out of the internal tank. The user has the option to stop the emptying of the Helium tank by pressing the **Abort Emptying Helium Tank** key.

HIS/CIS Configuration:

From this menu the user can view or set the IP Address of the HIS/CIS Server.

Advanced Configuration:

Pressing this key opens the **Advanced Configuration** menu of the IABP. To access the **Advanced Configuration** menu, the user is required to enter a specialized key sequence. This menu should only be accessed by MAQUET Factory Trained and Certified Service Personnel.

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1.5 PUMP MODULE

1.5.1 BACK PANEL

Note:
All signal input and signal output ports are intended only for connection to specified equipment.

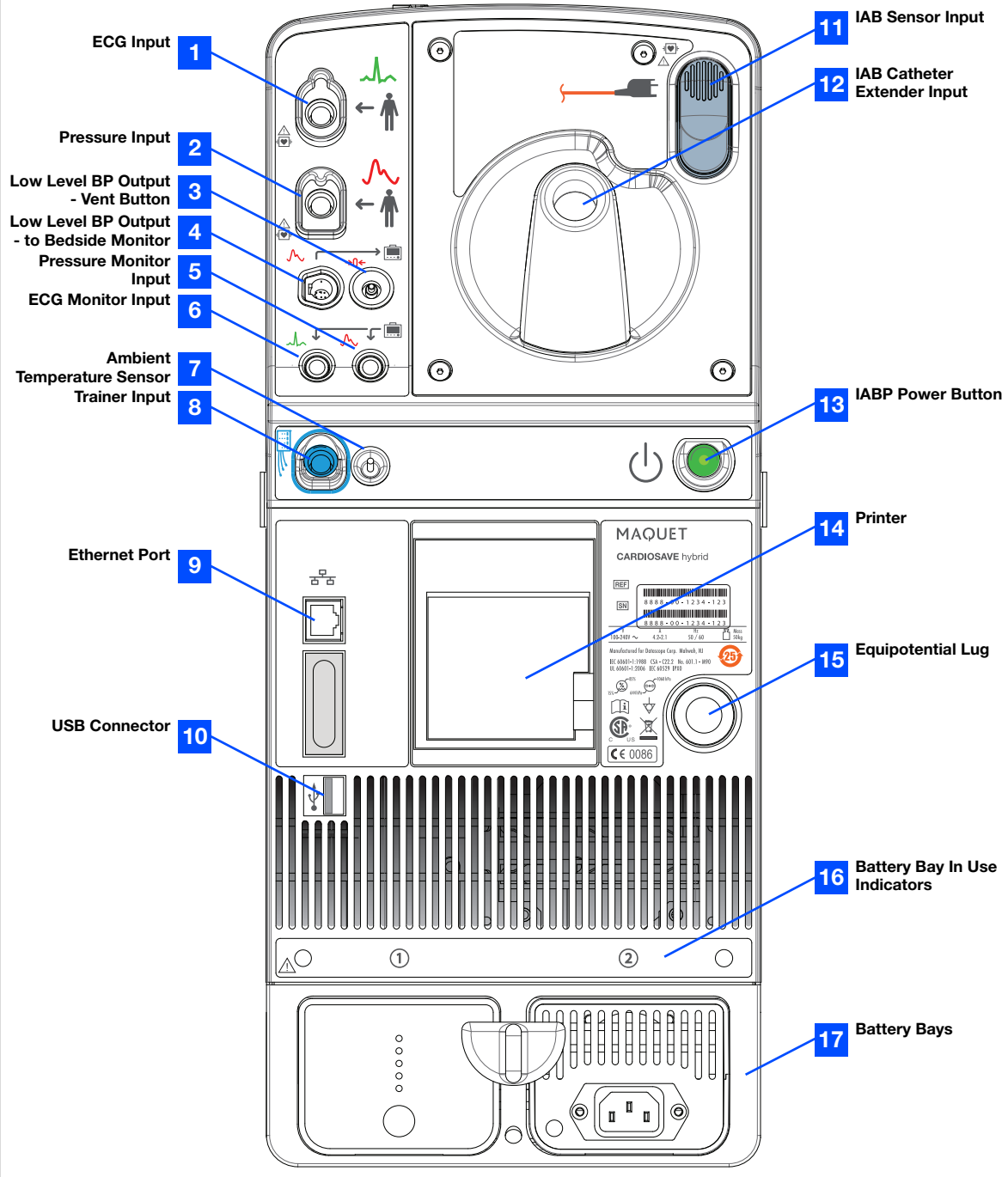


Figure 1-50: Back Panel

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1. ECG Input:

A 12-pin connector used for attaching patient cables. This connection is electrically isolated for patient safety.

2. Pressure Input:

A 12-pin connector used for attaching Datascope Corp. specified physiologic pressure transducers. This connection is electrically isolated for patient safety.

3. Low Level BP Output - Vent Button:

This button facilitates the zeroing process required for proper calibration of the arterial pressure channel of an attached bedside monitor. When pressed, the Low Level Output signal will simulate that of an atmospheric vented transducer. Venting will be simulated for 15 seconds to provide adequate time to zero the pressure channel on the bedside monitor. The pressure signal will then be restored automatically to permit monitoring through the bedside and centralized monitoring systems.

Note:
When using a Fiber-Optic IAB, prior to auto-calibration of the IAB sensor or upon loss of IAB sensor calibration, the IAB sensor Output is set to 0 mmHg. This indicates that the IAB sensor channel is not calibrated and permits the user to zero the pressure channel of an attached bedside monitor. The Vent button is enabled only after the IAB sensor has successfully auto-calibrated and affects only the IAB sensor Output signal.

4. Low Level BP Output - to Bedside Monitor:

This output connector is used to provide an electrical signal from the IAB to the physiologic pressure transducer input on the patient's bedside monitor for both Fiber-Optic and conventional arterial pressure signals. It is a patient isolated, defibrillation proof output which is designed to mimic the electrical behavior of a physiologic pressure transducer. The output signal provides a standard sensitivity of 5μV/V/mmHg. The Low Level Output is the ONLY recommended method for slaving pressure to the bedside monitor.

Prior to zeroing the AP Pressure Input, this output is set to 0 mmHg. Similarly, prior to auto-calibration of the IAB sensor or upon loss of IAB sensor calibration, this output is set to 0 mmHg. This indicates that the Low Level channel is not calibrated and permits the user to ZERO the pressure channel of an attached bedside monitor. When zeroing of the pressure input, or auto-calibration of the IAB sensor is complete, pressure indices will be displayed in accordance with section and the arterial waveform will be active at the Low Level BP Output. The Low Level BP Output may then be zeroed by using the Low Level BP Output - Vent button described in item 3 of this section.

5. Pressure Monitor Input:

A 1/4” stereo phone jack which permits the IABP to display and trigger from a pressure signal acquired from an external monitor. See External Monitor Interfacing in section 5.1 for additional information. The assumed scale factor of the incoming signal is 1V/100 mmHg.

6. ECG Monitor Input:

A 1/4” stereo phone jack which permits the IABP to display and trigger from an ECG signal acquired from an external monitor. See External Monitor Interfacing in section 5.1 The assumed scale factor of the incoming signal is 1V/1mV.

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7. Ambient Temperature Sensor:

The Ambient Temperature Sensor measures the outside ambient temperature of the IABP. This sensor should remain unobstructed during system operation.

8. Trainer Input:

A 12-pin connector provides power, and the appropriate timing signal required to synchronize the System Trainer.

9. Ethernet Port:

This port provides external data communications for electronic medical records (HIS/CIS) or remote console viewing support (Win-IABP).

10. USB Connector:

Reserved for Datascope Corp. use only.

11. IAB Sensor Input:

This optical connector is used to attach the IAB sensor cable (orange cable from a MAQUET/Datascope Corp. Fiber-Optic IAB) to the p.ump's pressure sensor module. The connector is protected by a sliding shutter which must be moved aside to facilitate cable attachment. With on hand, grasp the Fiber-Optic sensor connector as shown in FIGURE 2.5, with the red triangle visible on top, refer to section 2.1.4.1.1.

12. IAB Catheter Extender Input:

Used for connection of the IAB catheter extender.

13. IABP Power Button:

This is the Power Button for the Pump Console and Monitor. Operation of this button does not affect the status of the internal battery charger.

14. Printer:

See Printing in section 2.6 for detailed printing information.

15. Equipotential Lug:

A connector used to equalize the voltage potential which may exist between the IABP and earth ground or other hospital equipment.

16. Battery Bay In Use Indicators:

There are two Battery Bay indicators, one over each Battery Bay, which indicate which bay is currently in use by the IABP. The indicator will illuminate green if the IABP is charging a battery, or operating from power supplied by the corresponding Battery Bay.

Note:
Depending on current battery charge level, the system may take up to 30 seconds to detect battery status and begin charging the battery.

17. Battery Bays:

The Battery Bays provide the IABP with the ability to operate from a portable power source. They have a common physical lock which prevents simultaneous removal of both power sources.

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1.6 BATTERY STATUS LEDS

Each battery has five (5) LEDs on the back which indicate the battery's approximate state of charge. Each LED represents approximately 20% charge. For example, one (1) illuminated LED informs the user that the battery has approximately 0-20% charge remaining, while five (5) illuminated LEDs informs the user that the battery has approximately 80-100% charge remaining.

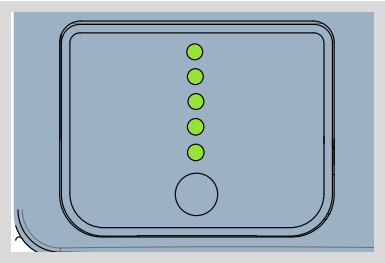


Figure 1-51: Battery is 80-100% Charged

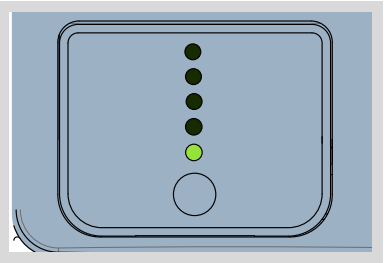


Figure 1-52: Battery is 0-20% Charged

To view the battery status, press the button located on the front of the battery. The LEDs will illuminate informing the user of the battery's approximate state of charge.

The following table describes the possible battery status LED configurations:

LED configurations	Approximate State of Charge
1 Flashing	0 - 10%
1 Illuminated	10% - 20%
2 Illuminated	20% - 40%
3 Illuminated	40% - 60%
4 Illuminated	60% - 80%
5 Illuminated	80% - 100%

Additionally, the battery status LEDs will be illuminated when the battery is charging. However, in this state, the LED representing the current state of charge will continuously flash informing the user that the battery is charging.

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1.7 DEFAULT SETTINGS

If the system is switched off for less than 3 minutes, user settings and system preferences are automatically retained by the system's internal memory. If the system is off for more than 3 minutes, it will automatically restore default settings. The system's default settings are listed in the following tables:

1.7.1 USER SETTINGS

Item Name	Default Value
OPERATION MODE:	Auto
ECG Scale:	1 mV
Trigger Source:	ECG
ECG Lead:	II
Internal Rate:	80
Pressure Source:	Fiber-Optic
Pressure Thresholds:	Auto
Pacer Detection:	Auto
IAB Frequency:	1:1
Augmentation:	0
Inflation Timing:	Auto
Deflation Timing:	Auto
Reference Line:	Off
Aug Alarm:	Off (See section 1.3.18 for more information on the functions of the Aug Alarm)

SYSTEM PREFERENCES

DISPLAY:

Item Name	Default Value
Sweep Speed:	25 mm/sec
Balloon Waveform:	As Last Set
ECG Markers:	As Last Set
Brightness:	High

AUDIO:

Item Name	Default Value
Alarm Volume:	4
Beep Volume:	Off
Standby Advisory Tone:	On

PRINTER:

Item Name	Default Value
Waveforms:	ECG & A. P.
Strip Length:	7 sec.
Timed Print:	Off
Print On Alarm:	Off

PUMP OPTIONS:

Item Name	Default Value
Catheter Alarms:	Catheter Alarms On
R-Trac:	On
Set Time & Date:	As Last Set
Network Connections:	Off

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2 SYSTEM OPERATION

Prior to operating the IABP, the user must be familiar with its controls and functions (see the “Features And Controls” starting in Section 1) and have a thorough knowledge of intra-aortic balloon pumping.

2.1 OPERATION INSTRUCTIONS

2.1.1 POWER-UP PROCEDURE

1. If using a Transport Power Supply, attach the power cord, appropriate for the country of use, securely into the Transport Power Supply power receptacle.

   Plug the power cord into a compatible grounded AC receptacle. In the U.S., use only receptacles marked as **Hospital Grade**. Do not use an adapter to eliminate the plug’s connection to ground. If auxiliary equipment is used with the IABP, insure that the equipment is also properly grounded.

   If operating on battery power, ensure that the batteries are fully charged, and sufficient additional batteries are available.

2. Should a Pneumatic Module Leak Test be desired, execute the test steps in section 2.2. Otherwise, continue on to step **3**.
3. Press the IABP Power Button (item 13 section 1.5.1) to turn the IABP on.
4. The IABP will now perform a self-test of all subsystems. Verify that the **System Test OK** message appears in the Message Display Area on the Monitor Display.

In the event that any electrical or pneumatic test fails, the message **Power-Up Test Fails Code # ___** is displayed on the Monitor. The code number indicates which test has failed in the system. Power cycle the system (power down for a minimum of 10 seconds) and if the message repeats, record the code number and contact MAQUET Service.

2.1.1.1 CONFIRM HELIUM PRESSURE

1. Ensure that the Helium Indicator on the Monitor Display indicates that an adequate volume of helium exists in the helium tank.
2. Ensure that the **Low Helium** Informational message is not displayed in the Message Display Area. If the **Low Helium** message is displayed, use the Helium Refilling Station to refill the internal helium tank as described in section 4.2.

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2.1.2 OPERATION MODES

The choice of operation mode strongly affects the IABP's functionality and the layout of the user interface. For example, when the operation mode is set to **Auto**, many of its controls are not required and are therefore disabled. Conversely, when the operation mode is set to **Semi Auto**, the same controls are enabled.

	Auto	Semi Auto
Trigger and Lead Source	Auto	User selection
IAB Timing	Auto	User sets initial timing, then periodically assesses and adjusts
Lost Trigger or Lead Source	Auto detect new source	IABP alarms, and user adjusts

OPERATION MODE keys select the automation and control for the application of therapy to the patient. Selection of any OPERATION MODE key cancels the previous selection. When transitioning from **Auto** to **Semi Auto** OPERATION MODE, assist is suspended, and the IABP is placed in **Standby** mode. Assist may be resumed by pressing the **Start** key. When transitioning from **Semi Auto** to **Auto** OPERATION MODE, assist will automatically continue.

2.1.2.1 AUTO OPERATION MODE

Press the **Auto** key to place the IABP in the **Auto** OPERATION MODE. When the IABP is operating in **Auto** OPERATION MODE, operation is completely automatic.

- The IABP automatically selects the most appropriate ECG lead and trigger source (**ECG** or **Pressure**). Then the IABP automatically sets inflation and deflation timing. No operator intervention is required. While **ECG** is the selected trigger source, deflation timing can be fine tuned via use of the IAB Deflation Timing Controls.

- In this fully automatic mode, there is no operator selection or override of the trigger source. In the event that the trigger source is lost, the IABP automatically selects the next best available trigger source and re-times the IABP, if appropriate. Similarly, if a superior trigger source is made available, it is automatically selected and timing is reset. **ECG** is the preferred trigger source.

- The IABP's software algorithms automatically track changes in patient heart rate or rhythm and adjust the inflation and deflation points accordingly. When the patient's rhythm is not adequately predictable, and a valid ECG trigger source is available, R-Wave deflation is automatically selected. The IABP continually monitors the patient's rhythm and selects R-Wave deflation when it is the most appropriate. This is indicated via the Deflation Timing Indicator (item 15, section 1.2.3) automatically repositioning itself to the extreme right (late) position and displaying the label **Auto R-Wave**, and the **Auto R-Wave Deflate** informational message on the Message Display Area.

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- Assist is automatically suspended when making the transition from **Auto** OPERATION MODE to **Semi Auto** OPERATION MODE. Resume assist by pressing the **Start** key.

WARNING:

If possible, use ECG or Arterial Pressure trigger during CPR. This facilitates synchronization of the assist to the rate and rhythm of chest compressions. In Auto OPERATION MODE, the ECG (R-Wave) or Arterial Pressure signal will automatically be selected as the trigger source. Choice is dependent upon relative signal quality. If neither the ECG nor the Arterial Pressure signals produce adequate trigger reliability to allow for Auto Operation, the IABP may be triggered by its own internal clock. Select Semi Auto OPERATION MODE and set the Trigger Source to Internal.

2.1.2.2 SEMI AUTO OPERATION MODE

Press the **Semi Auto** key to place the IABP in the **Semi Auto** OPERATION MODE.

- In this operation mode, the operator selects the most appropriate ECG lead, and trigger sources. On start-up, the IABP defaults to **ECG** as the trigger source, and **Lead II** as the ECG lead. However, the user may adjust these selections to the user desired trigger and ECG lead sources. Then the operator sets IAB Inflation and Deflation Timing. Software algorithms automatically track changes in patient heart rate or rhythm and adjust the inflation and deflation points accordingly making beat to beat adjustments.

- When the patient's rhythm is not adequately predictable, and a valid ECG trigger source is available, R-Wave deflation is automatically selected. The IABP continually monitors the patient's rhythm and selects R-Wave deflation when it is the most appropriate. The status message **Auto R-Wave Deflate** is displayed when R-Wave Deflation has been selected.

- In this operation mode, loss of the trigger source will result in the alarm message **No Trigger** being displayed along with an audio tone. Trigger source selection is not automated, it is the responsibility of the operator.

- Assist is automatically suspended when making the transition from **Auto** OPERATION MODE to **Semi Auto** OPERATION MODE. This is done to emphasize the need for operator intervention when entering this operation mode. The operator should re-assess timing when the trigger source is changed. Assist may be resumed by pressing the **Start** key.

- Similarly, when a new trigger source is selected, and timing has not been set by the operator, the IABP will immediately suspend assist and enter **Standby** mode. This is done to emphasize the need for initial operator intervention when changing trigger sources. The operator should re-assess timing when trigger sources are changed. Assist may be resumed by pressing the **Start** key.

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2.1.3 ECG ACQUISITION

A high quality ECG signal is desirable to ensure optimal triggering. An ECG signal can be acquired either directly from skin electrodes or indirectly as a high-level output from a compatible external monitor. See External Monitor Interfacing in section 5.1 for additional information on interfacing requirements when using external monitor sources.

Direct ECG signal acquisition requires an ECG patient cable, lead wires and skin electrodes. Use only the MAQUET/Datascope Corp. supplied patient cable and leads to minimize noise.

The type of skin electrode and application technique are major factors in determining the quality of the signal obtained. Use of high quality electrodes is recommended. These are designed to acquire an ECG signal with excellent baseline stability, recovery from defibrillation and minimum artifact from patient movement.

In order to permit acquisition of high quality ECG signals with minimal noise and fewer dropouts, the following techniques for electrode use are recommended:

- Shave or choose a hairless electrode site on the patient.
- Prep the electrode site properly as recommended by the electrode manufacturer.

Note:
This can involve cleansing the skin thoroughly with alcohol to remove skin oils followed by drying with a rough towel or use of an electrode prepping agent.

- The use of Wet-Gel electrodes is recommended because, in general, they provide a better quality electrical contact immediately after being placed on the skin.
- If Solid-Gel (hydrogel) electrodes must be used, apply to the patient as early as possible to allow the electrical contact to improve prior to therapy.
- Since prolonged exposure to air can dry out electrodes, do not remove from the packaging for extended periods prior to application to the patient.
- Do not use electrodes with expired date codes, or from punctured, ripped, or pre-opened packaging.
- Consider using specialized low-impedance electrodes or electrodes with larger electrical contact areas where possible, especially, for patients with dry skin, poor circulation, or diabetes.

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2.1.3.1 USE OF ECG SKIN ELECTRODES

WARNING:

Use only MAQUET/Datascope Corp. ECG lead wires with the ECG Patient Cable. The use of any other lead wires may cause the system to function improperly.

1. When acquiring an ECG signal directly from skin electrodes:

   a. Ensure that the patient lead wires are securely inserted into the yoke of the MAQUET/ Datascope Corp. supplied ECG trunk cable. Connect each patient lead wire to a skin electrode. The following table shows the number of ECG Electrodes vs. Leads available. The recommended minimum number of electrodes is four (4) to provide optimal lead selection triggering options.

(#) ELECTRODES USED (AHA)	(#) ELECTRODES USED (IEC)	(#) ECG LEADS AVAILABLE
RA, LA, LL	R, L, F	I, II, III
RA, LA, LL, RL	R, L, F, N	I, II, III, aVR, aVL, aVF
RA, LA, LL, RL, V	R, L, F, N, C	I, II, III, aVR, aVL, aVF, V

   b. Attach electrodes to the patient at the appropriate locations, as shown.

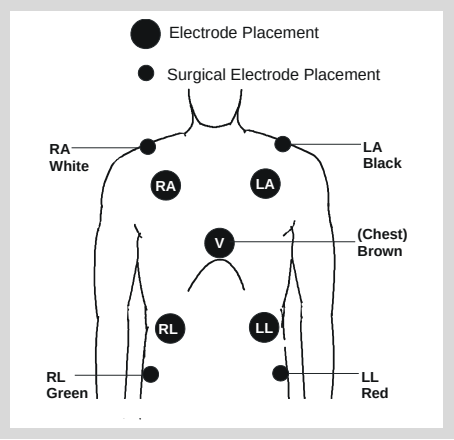


Figure 2-1: Electrode Placement AHA

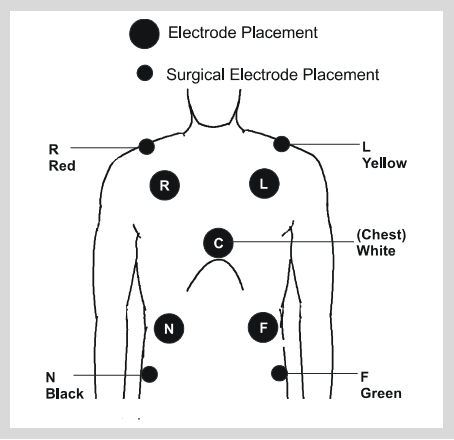


Figure 2-2: Electrode Placement IEC

   c. Plug the ECG patient cable into the back panel ECG Input connector (item 1, section 1.5.1).

   d. Check that an ECG Waveform is present on the Monitor Display and that the ECG Lead field on the Monitor Display (item 1, section 1.2.1) indicates the desired lead. Also confirm consistent triggering.

2. In **Auto** OPERATION MODE the IABP will automatically select a lead that provides reliable triggering (either **I**, **II**, **III** or **External**). If an alternate lead choice is desired then:

   a. Place the IABP in **Semi Auto** OPERATION MODE, and from the **Trigger** menu, set the trigger source to **ECG**.

   b. From the **Sources** menu, set the desired ECG lead (**I**, **II**, **III**, **aVR**, **aVL**, **aVF**, **V** or **Ext**), which is based on connected electrodes.

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2.1.3.2 ECG OUTPUT FROM AN EXTERNAL BEDSIDE MONITOR

1. When using a high-level ECG output from an external monitor, plug the interface cable into the ECG Monitor Input (item 6, section 1.5.1).
2. Select the external monitor input by setting the ECG signal source to **Ext** in the **Sources** menu (item 1, section 1.3.7.1).
3. Verify that the ECG Lead field on the Monitor Display (item 1, section 1.2.1) reads **External** and that a good quality ECG Waveform is displayed. Also check for consistent ECG triggering.

2.1.3.3 ECG TROUBLESHOOTING

Symptom	Possible Causes	Recommended Corrective Action
Noisy ECG	Faulty electrodes/electrode leads.	Check electrode contact; replace electrodes
Noisy ECG Baseline	Unit not configured for proper line frequency.	Contact MAQUET Service.
Intermittent ECG	Faulty electrodes/electrode leads/patient cable.	Check electrode contact; replace electrodes. Check or replace patient cable.
Lead Fault message on the display	ECG patient lead fault.	Check electrode contact; replace electrodes. Check or replace patient cable.
Motion Artifact	Faulty electrodes.	Check electrode contact replace electrodes.
Weak ECG Signal	Electrode position or poor quality.	Try alternate lead configurations (Lead II generally provides the largest R-Wave).
ESU interference	Poor electrode placement, poor ECG cable orientation or wrong ECG lead wires.	Verify correct electrode placement. Use for guidance on appropriate electrode location. If in the O.R., use ECG operating room lead wires with ESI noise filtering. See Accessories in section 6 for more detail.
	Interfaced to monitor without ESU suppression.	Use direct ECG electrodes with ECG operating room lead wires.

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2.1.4 ARTERIAL PRESSURE ACQUISITION

An arterial pressure signal can be acquired either directly, or indirectly as a high-level output from a compatible external monitor. See External Monitor Interfacing in section 5.1 for additional information on interfacing requirements when using external monitor sources.

Sources of direct arterial pressure acquisition are either a Fiber-Optic IAB or an external arterial pressure transducer (e.g., IAB inner lumen/radial).

2.1.4.1 DIRECT ARTERIAL PRESSURE

Connection requirements between the balloon catheter and the pump console differ depending on the choice of balloon.

- When using a MAQUET/ Datascope Corp. Fiber-Optic IAB, an optical connection is used to provide an arterial pressure signal to the IABP Fiber-Optic IAB Connection.
- When using a Conventional IAB, an external arterial pressure transducer (e.g., IAB inner lumen/radial) is required to provide an arterial pressure signal to the IABP Conventional IAB Connection.

Note:
The IAB catheter instructions for use take precedence regarding its insertion, set-up and use. The following steps provide general guidance regarding the attachment of MAQUET/Datascope Corp. IABs to the pump.

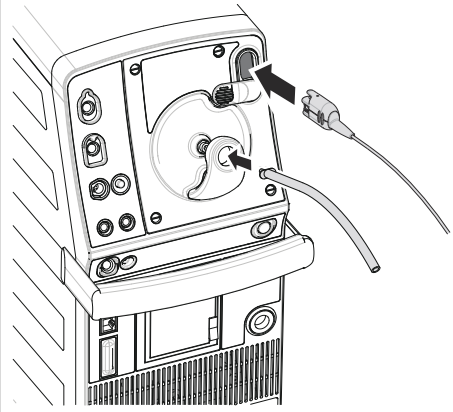


Figure 2-3: Fiber-Optic IAB Connection

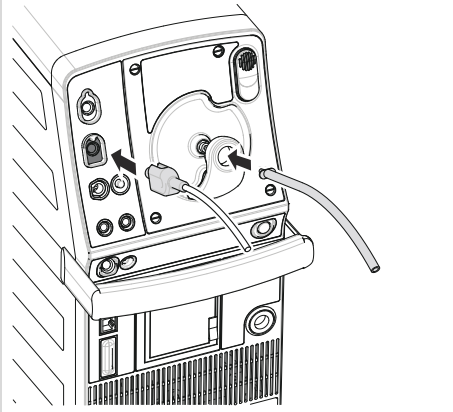


Figure 2-4: Conventional IAB Connection

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2.1.4.1.1 FIBER-OPTIC IAB

CAUTION:

Do not touch the exposed end of the Fiber-Optic IAB cable, or permit it to contact other surfaces. This could damage or contaminate the sensor connection.

1. With one hand, grasp the Fiber-Optic Sensor Connector as shown in Grasping the Fiber-Optic sensor connector, with the red triangle visible on top.

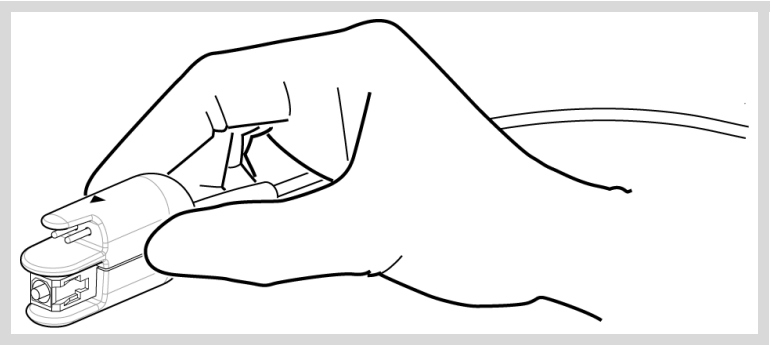


Figure 2-5: Grasping the Fiber-Optic sensor connector

2. Remove and discard the protective cover from the Fiber-Optic IAB connector. Do not to touch the exposed end of the Fiber-Optic cable.
3. With the other hand, open the protective shutter that covers the opening for the IAB Sensor Input (item 11, section 1.5.1) by rotating it to the left.
4. Insert the Fiber-Optic IAB connector into the IAB Sensor Input until it “clicks”.

Note:

Ensure that the red triangles on the Fiber-Optic IAB Sensor Connector and on the back panel are in alignment.

5. Connect the Fiber-Optic IAB catheter's male luer fitting to the female luer fitting on the MAQUET/ Datascope Corp. catheter extender. Connect the male luer fitting of the MAQUET/Datascope Corp. catheter extender to the IAB Catheter Extender Input luer fitting (item 12, section 1.5.1).

CAUTION:

To ensure reliable operation of the Autofill system and proper IAB inflation pressures, it is important that the combined total volume of the IAB’s membrane and extracorporeal tubing, plus the catheter extender tubing, is not altered. Using tubing of a different length or internal diameter from that supplied with MAQUET/Datascope Corp. IAB products will change IAB inflation pressure levels and may result in Autofill failures. Consequently, such practices must be avoided.

Note:

The Pneumatic Module will support all of MAQUET/Datascope Corp. adult intra-aortic balloons.

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6. Depending on the current operation mode, the response of the IABP will vary as follows:

Auto OPERATION MODE

- If the Fiber-Optic IAB is the only valid arterial pressure source connected to the IABP, the Pressure Source displayed in the Sources menu (item 2, section 1.3.7.1) is automatically set to **Direct**, the label **Fiber-Optic** is displayed in the Pressure Source field on the Arterial Pressure Waveform (item 9, section 1.2.3), and the Fiber-Optic IAB is used as the preferred Pressure Source.

- If another valid source of arterial pressure is connected to the IABP prior to the connection of the Fiber-Optic IAB, the Fiber-Optic IAB automatically takes precedence as the preferred Pressure Source once the Fiber-Optic IAB is tested and validated by the IABP.

Semi Auto OPERATION MODE

- Ensure that the Pressure Source is set to **Direct** in the Source menu (item 2, section 1.3.7.1).

- Once the Pressure Source is set to **Direct**, the arterial pressure signal from the Fiber-Optic IAB is automatically detected by the IABP, and used as the pressure source.

- If an arterial pressure transducer is connected to the IABP, and is being used as the arterial pressure source, the Fiber-Optic IAB automatically takes precedence as the preferred pressure source.

- The label **Fiber-Optic** is displayed in the Pressure Source field on the Arterial Pressure Waveform (item 9, section 1.2.3).

7. An automatic calibration of the Fiber-Optic IAB will occur once assist is initiated.

Note:
If Fiber-Optic IAB calibration fails, the system will attempt to recalibrate after 5 minutes if the IABP is assisting. If the recalibration attempt also fails subsequent calibration attempts will occur as regularly scheduled.

Note:
After a Fiber-Optic IAB calibration failure, the “Unable to Calibrate Fiber-Optic Sensor” informational message will be displayed while the sensor is connected and selected as the arterial pressure signal source.

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2.1.4.1.2 ARTERIAL PRESSURE TRANSDUCER

Note:
The instructions provided with the IAB catheter take precedence regarding the set-up and flush of the arterial pressure transducer. The following steps provide general guidance regarding the acquisition of the arterial pressure signal from the pressure transducer.

1. Insert the Blood Pressure Transducer Adapter cable (P/N 0012-00-1815) into the Pressure Input (item 2, section 1.5.1). Refer to section 6.1.1.1 for more details about interfacing the BP Transducer Adapter cable.
2. To establish a monitoring site, utilize the inner lumen of the intra-aortic balloon or utilize an alternate arterial pressure site (i.e. radial). Aortic pressure monitoring is recommended for managing patients on IABP therapy.
3. Connect the arterial pressure site to an arterial pressure line (which includes a transducer), then connect the appropriate pressure cable to the transducer and connect it to the IAB.
4. Depending on the current operation mode, the response of the IABP will vary as follows:

Note:
If a Fiber-Optic IAB is connected to the IABP, the Fiber-Optic IAB takes precedence over the arterial pressure transducer as the direct arterial pressure source, and must be disconnected in order to use the transducer.

Auto OPERATION MODE

- If the arterial pressure transducer is the only valid arterial pressure source connected to the IABP, the Pressure Source displayed in the Sources menu (item 2, section 1.3.7.1) is automatically set to **Direct**, the label **Transducer** is displayed in the Pressure Source field on the Arterial Pressure Waveform (item 9, section 1.2.3), and the transducer is used as the preferred Pressure Source.
- If an external source of arterial pressure is connected to the IABP prior to the connection of the transducer, the external arterial pressure source will continue to function as the preferred pressure source until the transducer is zeroed. The Pressure Source must be set to **Direct** when zeroing the transducer.

Semi Auto OPERATION MODE

- Ensure that the Pressure Source is set to **Direct** in the Source menu (item 2, section 1.3.7.1).
- Once the Pressure Source is set to **Direct**, the arterial pressure signal from the arterial pressure transducer is automatically detected by the IABP, and used as the pressure source.
- The label **Transducer** is displayed in the Pressure Source field on the Arterial Pressure Waveform (item 9, section 1.2.3).

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5. Zero the pressure transducer as follows:

   Initially, the message **Not Zeroed** is displayed in the Pressure Source field on the Arterial Pressure Waveform (item 9, section 1.2.3), indicating the need to zero the transducer.

   a. Vent the transducer to atmosphere.

   b. Press and hold the **Zero Pressure** key for a minimum of two (2) seconds. An audible click will sound and the automatic zero process is performed. (The zeroing function accommodates pressure transducers with offsets of up to ±120 mmHg). All of the numeric pressure values at the right side of the Monitor Display will show zero (±2 mmHg) when zeroing is successful, and the message **Transducer - Zeroing Complete** briefly displays in the Pressure Source field on the Arterial Pressure Waveform.

      The displayed patient blood pressure parameters are only valid if the transducer has been properly zeroed. If the transducer has not been zeroed (i.e. the process is unsuccessful), then three (3) dashes "- - -" will be displayed in all numeric fields of the Arterial Pressure Parameter area. The three (3) dashes "- - -" will also be displayed if the offset of the transducer exceeds the valid limit of ±120 mmHg (this might occur in cases where the transducer is defective).

Note:
If the transducer offset exceeds ±120 mmHg, it will not be possible to automatically zero the transducer. The message "Not Zeroed" indicates this is a fault condition. If this occurs, the transducer should be considered incompatible or defective and should not be used.

To prevent zeroing the transducer at inappropriate times, the **Zero Pressure** key is disabled when:

- Pulsatility is detected on the Arterial Pressure Waveform
- The transducer is disconnected
- The Pressure Source is set to **Ext** (External)

6. Close the pressure transducer vent to atmosphere. Verify that the Arterial Pressure Waveform is displayed and that the digital peak systolic, end diastolic, and mean pressures are displayed in the Arterial Pressure parameter area.

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2.1.4.2 PRESSURE OUTPUT FROM AN EXTERNAL BEDSIDE MONITOR

This brief procedure presumes that a monitoring line has already been established and that the external monitor has already been zeroed.

1. Plug the interface cable from the external monitor into the Pressure Monitor Input (item 5, section 1.5.1).
2. Depending on the current operation mode, the response of the IABP will vary as follows:

Auto OPERATION MODE

- If the external bedside monitor is the only valid arterial pressure source connected to the IABP, the Pressure Source displayed in the Sources menu (item 2, section 1.3.7.1) is automatically set to **Ext**, the label **External** is displayed in the Pressure Source field on the Arterial Pressure Waveform (item 9, section 1.2.3), and the external bedside monitor is used as the preferred Pressure Source.

- If a valid direct pressure source is connected to the IABP prior to the connection of the external bedside monitor, the direct pressure source will continue to function as the preferred Pressure Source. If the external source is the desired pressure source, the direct pressure source should be disconnected. The user may also manually switch to the external source by selecting **Ext** in the Source menu.

Semi Auto OPERATION MODE

- Set the Pressure Source to **Ext** in the Source menu (item 2, section 1.3.7.1).

- Once the Pressure Source is set to **Ext**, the arterial pressure signal from the external bedside monitor is automatically detected by the IABP, and used as the pressure source.

- The label **External** is displayed in the Pressure Source field on the Arterial Pressure Waveform (item 9, section 1.2.3).

3. Verify that a good quality pressure waveform is displayed.

CAUTION:

Blood pressure transducers used with the IABP shall meet the standard for interchangeability and performance as defined by ANSI/AAMI BP22:1994/(R) 2006, Blood Pressure Transducers.

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2.1.4.3 PRESSURE SOURCE TROUBLESHOOTING

2.1.4.3.1 FIBER-OPTIC IAB

Symptom	Possible Causes	Recommended Corrective Action
The Fiber-Optic cable is attached, but no signal is displayed.	The Fiber-Optic cable is not making a secure connection in the IAB sensor Input Receptacle.	Remove the Fiber-Optic sensor connector and reinsert it into the IAB sensor Input making sure that the connector is fully seated.
The pressure indices measured from the Fiber-Optic IAB differs from indices measured by an arterial pressure transducer.	The other pressure source is monitoring the pressure at a different location from the Fiber-Optic IAB.	None required
	Environmental conditions may have changed since the last calibration	If appropriate, re-zero the other pressure source, and recalibrate the Fiber-Optic IAB by pressing the **Calibrate Pressure** key while the pump is assisting.
No pressure indices are displayed.	The system cannot accurately display indices, since the sensor has not been calibrated.	If you have just inserted the Fiber-Optic IAB, the pump will automatically calibrate once assist starts. If the Fiber-Optic IAB calibration failed due to low pressure pulsatility, a calibration may be manually invoked after pulsatility increases by pressing the **Calibrate Pressure** key while the pump is assisting.

2.1.4.3.2 ARTERIAL PRESSURE TRANSDUCER

Symptom	Possible Causes	Recommended Corrective Action
The waveform from the direct arterial pressure transducer input is not available on the pump.	The direct arterial pressure transducer input is not active when a Fiber-Optic IAB sensor cable is connected.	Remove the Fiber-Optic IAB sensor cable from the pump.
The Arterial Pressure Waveform has continuous low amplitude high frequency noise which can affect auto operation.	The pressure monitoring tubing may be in contact with the pump console, coupling in vibration from the pump's compressor.	Re-route the pressure monitoring tubing so that it does not directly contact the pump console. Consider relocating the transducer and flush bag to a separate IV pole.
The Arterial Pressure Waveform is over-damped or the pulse height is unusually low.	The pressure monitoring tubing may have excessive bubbles or may have too much compliance.	Flush the pressure line to remove any bubbles. Use a maximum of 8 feet of tubing (preferably 5 feet), and maintain the pressurized flush bag at 300 mmHg.

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2.1.5 SELECTION OF TRIGGER SOURCE

Trigger sources are automatically selected in **Auto** OPERATION MODE. In **Semi Auto** OPERATION MODE, the trigger source must be selected from the **Trigger** menu. The alarm message **No Trigger** will be displayed along with an audio tone if a missing or invalid trigger source is selected. See Trigger Menu in section 1.3.6 for more information.

Note:
In Semi Auto OPERATION MODE, assist is automatically suspended when making the transition from one trigger source to another. This is done to remind the operator to assess timing and, if necessary, adjust the Inflate and Deflate timing controls to optimize therapy prior to resuming assist. Resume assist by pressing the Start key.

2.1.5.1 ECG TRIGGER

When **ECG** is the trigger source, the IABP triggers on the patient's R-Wave. This is indicated by a heart shaped icon in the Trigger Rate parameter area that blinks On and Off with each detected trigger event (item 6, section 1.2.2). The ECG signal source can be from patient electrodes or from an external patient monitor. The trigger software adapts the detection threshold to changes in QRS amplitude and suppresses motion artifact.

- If a pacer pulse is detected while **ECG** is the trigger source, it will be ignored and the IABP will still trigger on the patient's R-Wave. Detected pacer pulse signals are enhanced to display as Pacer Spikes on the ECG Waveform (item 2, section 1.2.2). If necessary, pacer pulse detection sensitivity may be increased or decreased by adjusting the Pacer Detection Level from within the **Thresholds** menu (see item 4 in Section 1.3.6.2).

- In **Auto** OPERATION MODE, the best available ECG signal source (**I**, **II**, **III**, or **Ext**) is automatically selected. If these sources are exhausted, then **Pressure** may be automatically selected as the trigger source. An automatic change in trigger source can be provoked by electro-surgical noise, motion artifact or loss of electrodes.

- In **Semi Auto** OPERATION MODE, the ECG signal source (**I**, **II**, **III**, **aVR**, **aVL**, **aVF**, **V** or **Ext**) can be changed with the Left and Right Arrow keys in the **Sources** menu (item 1, section 1.3.7.1).

- In all cases, the ECG lead field (item 1, section 1.2.1) displays the current active ECG lead.

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2.1.5.2 PRESSURE TRIGGER

When **Pressure** is the trigger source, the IABP triggers on the patient's arterial blood pressure.

Note:
This is generally a less preferred trigger source in the presence of a good ECG signal. When possible, an **ECG** trigger source should be used.

The IABP will trigger on the systolic upstroke of the patient's Arterial Pressure Waveform. The signal source can be either the **Direct** Fiber-Optic IAB, **Direct** arterial pressure transducer (e.g., IAB inner lumen/radial artery), or an **External** pressure signal.

- To facilitate rapid start-up while using an arterial pressure transducer as the **Pressure** trigger source, assist can be initiated without zeroing the transducer. However, zeroing is necessary to support the numeric display of patient arterial pressure parameters.

- In **Auto** OPERATION MODE, the best available arterial pressure signal source is selected. Preference is given to the Fiber-Optic IAB. If the fiber-optic cable is not connected, preference is given to the direct arterial pressure transducer. If it is unavailable, the external arterial pressure signal source is automatically selected. If all potential valid signal sources are lost, the alarm message **No Trigger** will be displayed along with an audio tone. An automatic change in trigger source can be provoked by electro-surgical noise, motion artifact or loss of electrodes.

- In **Auto** OPERATION MODE, the pressure signal source can be manually selected. If the operator-selected pressure signal source becomes unavailable or its trigger is lost, the IABP will automatically select an alternate pressure signal source, if available.

- In **Semi Auto** OPERATION MODE, the pressure signal source for the arterial **Pressure** trigger source (**Direct** or **Ext**) is selected with the Left and Right Arrow keys in the **Sources** menu (item 2, section 1.3.7.1).

2.1.5.2.1 PRESSURE THRESHOLD

Note:
When **Pressure** is the selected trigger source, the Pressure Threshold value (in mm) and its current mode setting (**Auto** or **Manual**) will be displayed in the trigger source field (item 8, section 1.2.2).

- In **Auto** OPERATION MODE, the IABP identifies and triggers on the upstroke of the systolic pressure pulse. This upstroke is identified as a positive upturn in arterial pressure. The IABP continuously optimizes and adapts the trigger threshold to changes in the systolic pulse height, (i.e., pressure trigger threshold is automatic). The approximate trigger level is indicated on the Arterial Pressure Waveform by arterial pressure trigger event marks (item 13, section 1.2.3), which are displayed as horizontal tick marks beside the arterial pressure upstroke. The user cannot influence the pressure threshold level while in the **Auto** OPERATION MODE.

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- In some clinical settings or circumstances, a fixed sensitivity may be advantageous. In **Semi Auto** OPERATION MODE with **Pressure** as the active trigger source, the Pressure Threshold **UP** and **DOWN** Arrow keys enable the increase or decrease of the Pressure Threshold value in increments of 1 mmHg between 7 and 30 mmHg. The current setting is displayed between the **UP** and **DOWN** Arrow keys (see item 3, section 1.3.6.2). The Pressure Threshold Mode will now be displayed as **Manual** in the Trigger Source Field (item 8, section 1.2.2).

WARNING:

If the Manual pressure trigger threshold option is used, the threshold must be adjusted whenever persistent changes in systolic pulse height occur. Height changes may be due to changing patient conditions or may occur following the pump's initial calibration of a Fiber-Optic IAB. Always reevaluate inflation and deflation timing after making adjustments to the trigger threshold for any reason.

2.1.5.2.2 USE OF PRESSURE TRIGGER

The IABP is designed to trigger on the upstroke of systole and ignore rises in arterial pressure attributed to the augmenting action of the IAB. This protective refractory mechanism is very useful in blocking false diastolic trigger events, but it can mask very premature pulses associated with instantaneous rises in heart rate. The IABP can detect and adapt to rises in rate. However, extreme changes, such as rate doubling, can result in every other systole remaining invisible to detection. Alternate beat triggering is apparent when the displayed heart rate is half the patient’s actual rate. This condition is rare, but if observed can be immediately corrected by pressing the **Start** key. This will suspend assist for a single beat and restore proper trigger detection. If no user action is taken, proper triggering will be restored at the 60 second automatic synchronization check point.

2.1.5.2.2.1 AUTOMATIC SYNCHRONIZATION CHECKS IN PRESSURE TRIGGER

An important feature of the IABP is the pressure trigger's 60 second periodic synchronization check. Every minute, when the IAB Frequency is **1:1**, pumping is suspended for a single beat. This permits the patient's natural systolic pulse and interval parameters, unaltered by the action of the IAB, to be checked. This check periodically ensures that the refractory and IAB timing intervals are being properly determined and, if necessary, corrects these intervals.

This automatic synchronization check can also be user initiated at any time by momentarily pressing the **Start** key while assist is active. This provides the capability to immediately re-synchronize triggering and timing in the rare event that a loss of synchronization is observed. When a synchronization check is initiated by pressing the **Start** key, the timer for the next check is automatically reset to 60 seconds.

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2.1.5.2.2.2 DYSRHYTHMIAS WHILE IN PRESSURE TRIGGER

The IABP will automatically adapt to sustained random dysrhythmias, such as atrial fibrillation. Such rhythms lack a predictable pattern and will produce early systolic ejections that can unavoidably overlap with balloon deflation, impairing stable and consistent systolic pulse detection. The IABP automatically detects such rhythms and minimizes the probability of overlap.

In **Semi Auto** OPERATION MODE, an **Irregular Pressure Trigger Detected** informational message is displayed and an alert tone is briefly activated. This message indicates to users that the system has automatically compensated by deflating earlier to avoid interfering with systolic ejection. Consequently, the user should NOT attempt to adjust the IAB deflation control. Adjustments to deflation timing could compromise trigger performance when the patient finally resumes a regular rhythm and the system automatically reverts back to standard timing.

WARNING:

When pressure is being used as the trigger source, balloon deflation should always be adjusted to be complete at the upstroke of systole. Late deflation timing causes a reduction in, and delay in detection of, systolic pulse pressure. The system relies on a prominent and timely systolic upstroke for consistent, reliable pressure triggering. Any overlap of balloon deflation and systolic ejection, while pressure is the trigger source, could cause triggers to be late or missed, potentially resulting in loss of synchronization.

WARNING:

Pressure triggering is NOT recommended for use when sustained irregular cardiac rhythms or tachyarrhythmia's are present. Remember to adjust deflation early enough so that deflation is completed prior to systole and to provide continuous observation while triggering from a pressure source. If an "Irregular Pressure Trigger Detected" informational message appears, DO NOT attempt to adjust the deflation control as the system will automatically compensate by deflating earlier to avoid interfering with systolic ejection.

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2.1.5.3 PACER V/AV TRIGGER

When **Pacer V/AV** is the trigger source, the IABP automatically determines if a Ventricular or Atrio-Ventricular pacemaker is present. In either case, the IABP triggers on the pacer's ventricular pulse. It ignores the patient's QRS and arterial pulse, if applicable, and the trigger source field (item 8, section 1.2.2) will display **Pacer V** or **Pacer A/V** as appropriate. **Pacer V/AV** trigger mode is available only in **Semi Auto** OPERATION MODE.

- The use of **Pacer V/AV** triggering requires that the patient is either 100% V paced or 100% A/V paced and captured (i.e., no demand pacing). The ECG signal source can be from patient skin electrodes or an external ECG signal.

- **Pacer V/AV** is often selected as the trigger source when the patient is paced and the resultant QRS response is too weak to be a reliable trigger source (e.g., operating room usage).

2.1.5.3.1 PACER DISCRIMINATION CRITERIA

- **Pacer V:**
  The system recognizes the presence of a ventricular pacer provided the ventricular pacing interval is fixed and the rate is less than 180 bpm.

- **Pacer A/V:**
  The system recognizes the presence of an atrial-ventricular sequential pacer provided the A-V interval is between 50 - 250 ms. However, the A-V interval must be shortened in a physiologic manner for proper pacer detection at higher pacing rates (up to 180 bpm).

When using **Pacer V/AV** as the trigger source, ensure that the IABP is reliably recognizing the Pacer Spikes. If a ventricular pacer is used, be sure an enhanced ventricular pacer pulse is observed on each cardiac cycle.

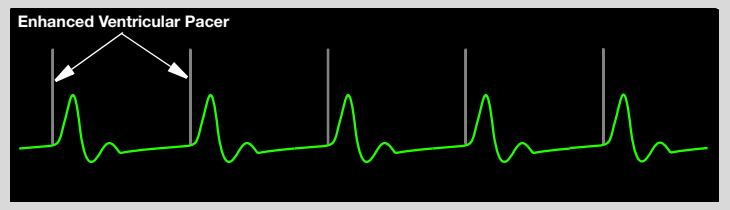


Figure 2-6: Pacer V

If an atrial-ventricular sequential pacer (AV Pacer) is in use, then 2 enhanced pacer pulses must be observed on each cardiac cycle.

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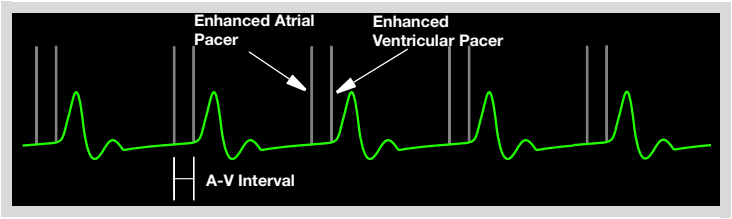


Figure 2-7: Pacer A/V

If either the atrial or ventricular pacing pulses are not being detected or are detected inconsistently, then consider adjusting the Pacer Detection level (item 4, section 1.3.6.2).

The system triggers selectively on the ventricular pulse for either type of pacer, provided there is 100% paced rhythm (i.e., no demand pacing). If the conditions for either pacer type are not met, a trigger alarm occurs and the message **Check Pacer Timing** is displayed.

Note:
Pacer V/AV trigger will not function in the presence of ESU Interference. Assist will be suspended temporarily and will resume automatically when interference subsides. The **Trigger Interference** alarm message is displayed when ESU interference is detected when **Pacer V/AV** is the trigger source.

2.1.5.4 PACER A TRIGGER

When **Pacer A** is the trigger source, the patient's QRS is actually used as the trigger event. The IABP will trigger on the patient's R-Wave and reject interference from atrial pacer artifact. The ECG signal source can be either patient electrodes or an external ECG signal. This mode is recommended for use only when the tails of an atrial pacer interfere with R-Wave detection. Either fixed or demand atrial pacers can be used in this mode. **Pacer A** trigger mode is available only in **Semi Auto** OPERATION MODE.

2.1.5.5 INTERNAL TRIGGER

Internal triggering is used when there is no mechanical cardiac cycle, (i.e., cardio-pulmonary bypass or asystole). When using **Internal** as the trigger source, the IABP will trigger at a fixed rate as defined by the Internal Rate Control (see FIGURE 1-26 in section 1.3.6). The Up and Down Arrow keys of the Internal Rate Control enable the increase or decrease of the Internal Rate in increments of 5 bpm between 40 and 120 bpm. The current setting is displayed between the Up and Down Arrow keys. The trigger source field (item 8, section 1.2.2) will display **Internal**. Internal trigger mode is available only in **Semi Auto** OPERATION MODE.

- **Internal** triggering is typically used in the OR during CABG procedures, when the patient is on bypass and no QRS is present. Assist is recommended when in full bypass to prevent clot formation on the IAB membrane.

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- When using **Internal** as the trigger source, the system continues to monitor for R-Wave activity via the ECG patient cable. If a viable QRS is present, this **Internal** triggering should not be used. If a valid R-Wave is detected while in this mode, the IAB is automatically deflated (to prevent asynchronous assist), and the alarm message **ECG Detected While Using Internal Trigger** will be displayed along with an audio tone. If reliable R-Wave activity has resumed then the system should be switched back to the **ECG** trigger source for proper timing.

WARNING:

Do not remain in the internal trigger mode when the patient is generating a cardiac output.

Note:

Internal trigger rate can only be changed when the trigger source is set to **Internal**.

2.1.5.6 TRIGGER TROUBLESHOOTING

Symptom	Possible Causes	Recommended Corrective Action
System does not trigger.	Valid Arterial Pressure (A.P.) and ECG trigger source does not exist, or are lost while in **Auto** OPERATION MODE.	Check integrity of all A.P. cable connections, optical or electrical. If arterial pressure transducer is in use, verify transducer was not left vented. Attach or reposition the electrode(s) and check the integrity of all ECG cable/lead connections.
	Pulse pressure inadequate for pressure triggering; ECG signal too small.	If arterial pressure transducer is in use, attempt to restore A.P. pulse height by flushing fluid circuit.
System triggers erratically.	Paced ECG acquired from an external monitor having limited bandwidth.	See External Monitor Interfacing in section 5.1.
	Pacer pulses are not being properly identified.	Adjust Pacer Detection level per section 1.3.6.2
	Large A-pacer tails in ECG trigger.	Select **Pacer A** trigger.
	Demand pacer in **Pacer V/AV** mode.	Select **ECG** or **Pressure** trigger.
	Pacer spike coincident with R-Wave.	Consider switching to Pressure Trigger mode (see section 2.1.5.2)
System triggers every other cardiac cycle in pressure trigger.	Pressure trigger needs resynchronization.	Quickly depress the **Start** key for re-synchronization.
System skips assist cycles in pressure trigger when operating in **Semi Auto** OPERATION MODE.	Deflation time is set too late.	If appropriate, readjust deflation timing and quickly depress the **Start** key for re-synchronization.

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2.1.6 SELECTION OF IAB FREQUENCY

Changes in IAB Frequency are commonly made to assess timing or reduce assist (i.e. wean patients from IAB therapy). The selection of IAB Frequency determines the ratio of heart beats that are assisted by the IAB. The selections are: **1:1**, every beat is assisted; **1:2**, one out of two beats are assisted; or **1:3**, one out of three beats are assisted. Select the desire IAB Frequency by pressing the appropriate key in the IAB Frequency menu (see FIGURE 1-28 in section 1.3.8).

The choice of IAB Frequency determines the manner in which the arterial pressure indices are computed and displayed. In **1:1** mode all beats are assisted and a single assisted value is displayed for each pressure index.

When either **1:2** or **1:3** is selected, both the assisted and unassisted peak systolic and end diastolic pressures are numerically displayed and may be printed, and are labeled accordingly. Detail of waveform showing assisted and unassisted pressure waveforms are shown below.

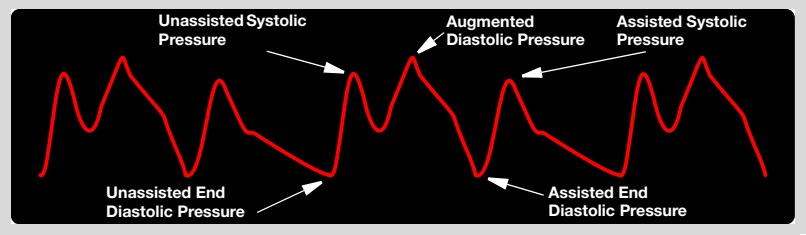


Figure 2-8: Detail of waveform showing assisted and unassisted pressure

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2.1.7 TIMING OF INTRA-AORTIC BALLOON

Timing refers to the positioning of the inflate and deflate points on the Arterial Pressure Waveform.

In the **Auto** OPERATION MODE the pump automatically initializes and continually adjusts timing. In **Semi Auto** OPERATION MODE the user must initialize and periodically check IAB timing.

In Standby mode, Inflation Interval Highlighting is displayed on the Arterial Pressure Waveform. The Inflation Interval Highlighting is an approximation of balloon inflation time.

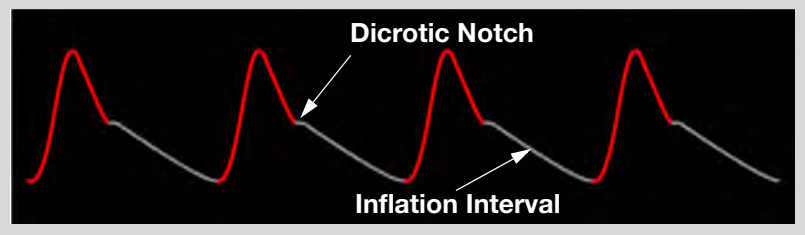


Figure 2-9: Example Highlighted Inflation Interval starting at the Dicrotic Notch

2.1.7.1 PROPER IABP TIMING

2.1.7.1.1 INFLATION

- Occurs at the dicrotic notch.
- Appears as a sharp “V”.
- Ideally diastolic augmentation rises above systole.

2.1.7.1.2 DEFLATION

- Occurs just prior to the next systolic event.
- Results in a reduction in the assisted end diastolic pressure.
- Results in a reduction in the assisted systolic pressures.

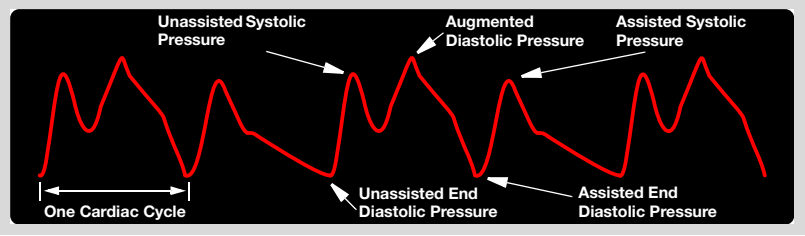


Figure 2-10: Sample waveform showing 1:2 IABP Frequency

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2.1.8 INITIATION OF ASSIST

1. Press the **Start** key and confirm that an autofill is in progress as indicated by the **Autofilling** message posted in the Message Display Area (section 1.2.7). The balloon catheter circuit will be purged and filled with the proper amount of helium. If the Fiber-Optic IAB is present, it will automatically be calibrated during the fill process. The message **Autofilling and Calibrating Fiber-Optic Sensor** will be posted in the Message Display Area.
   - Assist will begin following a successful autofill, indicated by the **Autofilling** message clearing and the **Start** key flashing in time with each inflation cycle.
   - In **Auto** OPERATION MODE, pumping will begin with the augmentation set at **Max** and timing will be established automatically.
   - In **Semi Auto** OPERATION MODE, pumping begins with augmentation reduced, the system then progressively increase augmentation on each successive pump cycle until the **Max** level is reached. This provides an opportunity for the user, prior to full IAB volume displacement, to make the necessary fine adjustments to timing. Refinement of balloon timing should now be performed to maximize augmentation and hemodynamic unloading.

Note:
The automatic augmentation feature may be disabled at any time by pressing either of the Up and Down Arrow keys in the Augmentation Menu (section 1.3.9) prior to, or during, the activation of this feature. Subsequent presses of the Up and Down Arrow keys will incrementally increase or decrease augmentation.

2. The Augmentation Alarm limit is displayed between the up and down arrow keys of the **Aug Alarm** Control area (described in section 1.3.18). Approximately 3 minutes after initiation of assist, verify that the Aug Alarm setting is approximately 10 mmHg less than the patient's augmented diastolic pressure. If an Arterial Pressure transducer is used, it must be zeroed for the Augmentation Alarm to set automatically.
3. If adjustment to the alarm limit is desired, press the **Aug Alarm** key. Then press the Up and Down Arrow keys to adjust the alarm limit.

Note:
The Augmentation Alarm, when used properly, serves as an important backup to internal monitoring alarms. Due to the dynamic nature of the shuttle gas system, alarms associated with gas loss and the IAB catheter do not operate under severe patient conditions (see section Alarm and Informational Messages for more details). By setting the Augmentation Alarm, the system monitors the level of assist and will alert the user in the event of a decrease in augmentation pressure.

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2.1.9 IAB FILL

The IABP will automatically pause assist in order to purge and refill the balloon catheter circuit with helium every two (2) hours. When the autofill cycle is completed, assist will automatically resume. An operator may initiate an autofill at anytime by pressing and holding the **IAB Fill** key. This will reset the 2 hour autofill timer. Should a 2 hour autofill time-out occur while in the **Standby** mode, an autofill will be performed one minute after returning to the Assist mode.

An autofill will automatically occur if local atmospheric pressure decreases or increases by 25 or 50 mmHg respectively, as may occur during air transport. These pressure changes will initiate autofills approximately every 1,000 feet of rise or 2,000 feet of drop in altitude to keep the balloon pressure acclimated to local conditions.

To maintain optimal augmentation, the lost helium (due to diffusion) is replaced one hour after each autofill cycle.

Note:
When the Fiber-Optic IAB is present, the pump will utilize the autofill cycles to update the calibration of the Fiber-Optic IAB. Timed Autofills will occur after the first hour of assist, after two (2) hours of assist and every two (2) hours thereafter.

To maintain optimal augmentation, the lost helium (due to diffusion) is replaced one hour after each autofill cycle

Note:
If the autofill procedure fails to purge and fill the Pneumatic Module properly, the message **Autofill Failure** will be displayed and an audible alarm will be activated. Corrective action can be obtained by pressing the Help Available key (See section Help Screens for information regarding help screens).

2.1.10 WEANING A PATIENT FROM IABP SUPPORT

Weaning may be accomplished by a gradual and progressive reduction in IAB frequency or IAB volume displacement (augmentation), or a combination of both.

When weaning, frequent assessment of hemodynamic parameters and patient condition is recommended.

WARNING:
When weaning by reduced IAB augmentation, do not reduce augmentation to a point at which the IAB status indicator moves less than 50%.

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2.2 PNEUMATIC MODULE LEAK TEST

This test checks the integrity of the Pneumatic Module. Datascope Corp. recommends that this test be run before or after each use. The test requires multiple interactions with the operator. Specifically during the course of the test, the operator is requested to plug the IAB Catheter Extender Input of the Pneumatic Module. The IABP prompts the user at the appropriate time for this action.

WARNING:

Pneumatic Module Leak Test MUST NOT be performed with the pump connected to a patient's IAB.

The user can run the Pneumatic Module Leak Test only when the IABP is in the alternate power-up mode. To enter the alternate power-up mode, start with the IABP turned off. While pressing and holding the **Low Level BP Output – Vent Button** (item 3, section 1.5.1), press and release the green **IABP Power Button** on the back panel (item 13, section 1.5.1) while continuing to hold the **Low Level BP Output – Vent Button** until the **Special Activation Main Menu** is displayed. Once the **Special Activation Main Menu** is displayed, release the **Low Level BP Output – Vent Button**.

To perform a Pneumatic Module Leak Test:

1. From the **Special Activation Main Menu**, press the **Pneumatic Module Leak Test** key.
2. Press the **Start Pneumatic Module Leak Test** key to initiate the test.
3. Using a non-locking luer cap (supplied in accessory kit), tightly plug the IAB Catheter Extender Input when the message **Please Plug IAB Port!** appears on the Touchscreen in the Instructions field.
4. The Status field will display the pneumatic tests that are currently being executed. When the tests are complete (in approximately 6 minutes), the message **PIM Leak Tests Complete** will be displayed.
5. If the system passes the test, the message **Pass** in green will be displayed in the Results field. Remove the luer cap and press and hold the **IAB Power Button** for 2 seconds to exit the **Special Activation Menu**. If IABP therapy is being started, then proceed with set-up of the pump.

   If the system fails the test, the message **Fail** in red will be displayed in the Results field. Check to ensure that the luer cap is tight, then repeat the leak test. If the test fails again, contact MAQUET Service.

If in doubt about the integrity of the Pneumatic Module, contact MAQUET Service.

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2.3 HELP SCREENS

Help screens are provided for consultation regarding alarm or informational message descriptions and alarm configuration. Help Screens are context sensitive and available based on the information displayed on the Monitor. For example: The Help Screens for alarm messages are only available while an alarm condition or informational message exists. When one or more alarm/informational message is present, the **Help Available** key will appear on the Touch Screen indicating that help is available for the current alarm/informational message(s). See Help Screen Area in section 1.3.14.

Navigating the Help Screens:

1. Press the **Help Available** key on the Touchscreen. The Help Screen will open and display all of the current alarms/informational messages in their predetermined priority order within each classification, higher priorities being displayed above lower priorities. The priority order is as follows: Technical Alarms, High Priority Alarms, Medium Priority Alarms, Low Priority Alarms, and Informational Messages.
2. If only a single alarm or informational message exists, the corresponding Help Screen will be immediately displayed. If multiple alarm or informational messages exist, a Multiple Alarm Display will be provided in the Help Screen Area. Each listed alarm or informational message is actually a key that, when selected, displays the associated Help Screen.
3. In the Help Screen, use the Page Up and Page Down keys to navigate through the available help information.
4. If the Help Screen is only displaying a single alarm or informational message, pressing the **Exit** Key will close the Help Screen. However, if a single alarm or informational message is being displayed, and there are multiple alarm or informational messages present, pressing the **Back** Key will close the current Help Screen, and display the Help Screen for multiple alarm or informational messages. If the Help Screen is displaying multiple alarm or informational messages, pressing the **Exit** key will close the Help Screen.

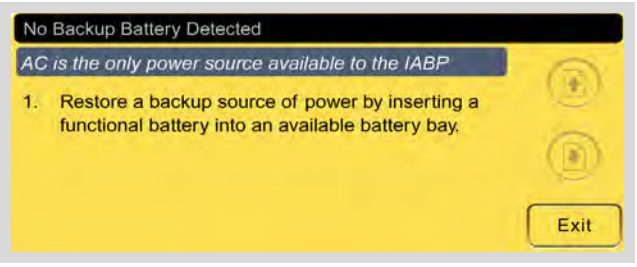


Figure 2-11: Example single alarm Help Screen

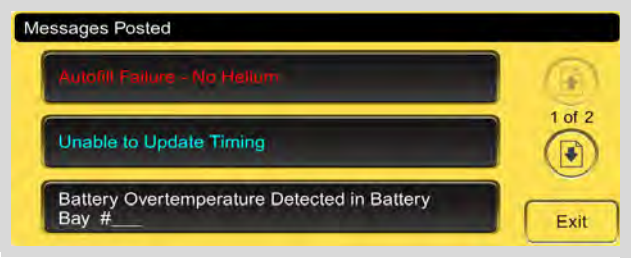


Figure 2-12: Example multiple alarm Help Screen

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2.4 ALARM AND INFORMATIONAL MESSAGES

The IABP utilizes both auditory and visual alarm signals to communicate the need for immediate Operator response, prompt Operator response, or Operator awareness. Auditory alarm signals (tone sequences) are primarily intended to attract the attention of the operator. They were carefully developed to communicate the urgency of the response, as well as the pump's location. Auditory signals are effective over a relatively broad range of operator positions.

CAUTION:

Do not set the alarm volume to such a low level that it cannot be readily heard over the ambient noise level of the venue in which the IABP is used.

Visual alarm signals consist of both symbols and text. The displayed information further reinforces the urgency of the alarm (color, flashing property and symbol shape) and also identifies the alarm via a specific text message. Textual information is legible at the operator's position, up to 1 meter from the front of the Monitor. Additionally, alarms are further complimented by an option to display context sensitive help information to aid in the understanding and guide in the resolution of the alarm condition.

Alarm and informational messages are grouped into the following categories in order to facilitate operator awareness and understanding: Technical Alarms, High, Medium and Low Priority Alarms, and Informational Messages. These messages are displayed based upon the priority of the condition(s) that prompted them.

Technical Alarms and High Priority Alarm messages are displayed first at the top of the Message Display Area on the Monitor Display. These alarms require the Operator's immediate response. Technical Alarms initiate a continuous alarm tone and suspend pumping. High Priority Alarms initiate the High Priority Alarm Tone, and, in a majority of cases, suspend pumping. If multiple alarm conditions are present, all of the current alarms/informational messages are displayed in their predetermined priority order within each classification, higher priorities being displayed above lower priorities. The associated Help Screens Area is organized to reflect the order of priority.

When Medium Priority Alarms are displayed, depending on IABP conditions, IAB assist will not be suspended and the Medium Priority Alarm tone is sounded. Medium Priority Alarms require the Operator’s prompt response.

When Low Priority Alarms are displayed, IAB assist is not suspended and the Low Priority Alarm tone is sounded. Low Priority Alarms require the Operator’s awareness.

Informational messages typically provide awareness of conditions that do not require immediate action and may persist for longer periods. These messages may also be accompanied by an infrequently repeated audio reminder tone.

Gas Loss and IAB Catheter alarm operation is maintained at heart rates up to 140 BPM*. However, one component of the IAB Catheter Alarms, detection of gas trapped in the safety disk, is suspended at 112 BPM to minimize nuisance alarms.

** The cited heart rates assume that the timing controls are at nominal mid-position.*

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WARNING:

The Augmentation Alarm, which is automatically set at power-up, provides back-up to IAB alarms (gas loss and IAB catheter alarms) at higher heart rates. Therefore, this alarm should not be manually disabled.

WARNING:

If more than one pump is being used in close proximity, ensure that the source of the alarm sound is correctly identified by confirming the corresponding visual indication.

Note:

The **CARDIOSAVE Rescue** maintains a non-volatile event log which is accessible in Service Diagnostics Mode. For more information, see the Service Manual.

2.4.1 TECHNICAL ALARMS

Technical Alarms are indications that an IABP electrical hardware failure has occurred. Technical Alarms are the highest priority alarms and sound a continuous tone. In all cases of Technical Alarms, pumping is suspended.

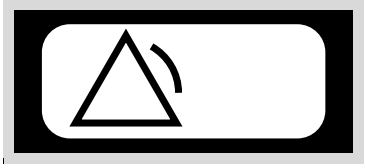


Figure 2-13: Technical Alarm Icon

Power-Up Test Fails Code #___
There is a start-up failure in a major subsystem of the IABP.
1 Note the code number displayed.
2 Turn the IABP OFF by pressing and holding the green IABP Power Button, located on the back panel, for 2 seconds.
3 Wait 10 seconds.
4 Turn the IABP ON by pressing and releasing the green IABP Power Button.
5 If the alarm message persists, switch to another MAQUET IABP if available and contact MAQUET Service.

Alarm Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: Failure of one or more electrical sub-system tests during system power-up diagnostics.
System Response: System is held in VENT Mode / IAB deflated.
Reset: Attempt to clear by cycling power OFF and ON.

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System Failure

There is a malfunction of the microprocessor.

1. Turn the IABP OFF by pressing and holding the green IABP Power Button, located on the back panel, for 2 seconds.
2. Wait 10 seconds.
3. Turn the IABP ON by pressing and releasing the green IABP Power Button.
4. If the alarm message persists, switch to another MAQUET IABP if available and contact MAQUET Service.

Alarm Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: Solenoid driver watchdog detected vacuum and / or pressure solenoid energized for approximately 2 seconds or vacuum valve is not activated within 2 seconds of pressure valve or IABP processor failure.
System Response: System is disabled and Pneumatic Module is vented to atmosphere / IAB deflated.
Reset: Attempt to clear by cycling power OFF and ON.

Internal Communication Failure

There was an internal communications failure.

1. Turn the IABP OFF by pressing and holding the green IABP Power Button, located on the back panel, for 2 seconds.
2. Wait 10 seconds.
3. Turn the IABP ON by pressing and releasing the green IABP Power Button.
4. If the alarm message persists, switch to another MAQUET IABP if available and contact MAQUET Service.

Alarm Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: Internal electronics communications failure.
System Response: System is disabled/IAB deflated.
Reset: Attempt to clear by cycling power OFF and ON.

System Over Temperature

The system has detected an over temperature condition.

1. Turn the IABP OFF by pressing and holding the green IABP Power Button, located on the back panel, for 2 seconds.
2. Wait 10 seconds.
3. Turn the IABP ON by pressing and releasing the green IABP Power Button.
4. If the alarm message persists, switch to another MAQUET IABP if available and contact MAQUET Service.

Alarm Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: An over temperature condition has been detected in the compressor assembly.
System Response: System is disabled and Pneumatic Module is vented to atmosphere / IAB deflated.
Reset: Attempt to clear by cycling power OFF and ON.

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2.4.2 HIGH PRIORITY ALARMS

High Priority Alarms indicate situations that require immediate Operator response. Pumping is suspended for the majority of High Priority Alarms. A red flashing alarm icon with three (3) exclamation points denotes the High Priority Alarm Icon. All High Priority Alarms have a uniform audio tone. The combination of five notes for High Priority Alarms is played in the following sequence: five notes a short pause, five notes a long pause and then this cycle repeats.



FIGURE 2-14 High Priority Alarm Icon

Gas Gain in IAB Circuit
A gas gain has been detected in the IAB circuit.
1 Verify all connections are leak free.
2 Press the START key to Autofill and resume pumping.
3 If alarm persists, contact MAQUET Service.

Alarm Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: Cumulative shuttle gas gain exceeds 5 cc, relative to the last autofill volume. Active when IAB inflation period >= 80 mSec and deflation period >= 250 mSec.
System Response: Vent / IAB deflated.
Reset: Message and Audio Tone cleared when: the START key is pressed and the Autofill is automatically initiated, or the IAB FILL key is pressed and held for 2 seconds.

Autofill Failure - No Helium
The Helium tank is closed.
1 Open the Helium tank.
The Helium tank is empty.
1 Replace the Helium tank.

Alarm Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: While using the IABP in its Hospital configuration, the IAB could not be automatically filled because of inadequate Helium gas supply.
System Response: Vent / IAB deflated.
Reset: Replace the Helium Tank then retry the autofill by pressing the START key, or by pressing the IAB FILL key for 2 seconds.

Autofill Failure - No Helium
There is insufficient Helium supply to perform an Autofill.
1 Connect the Helium Filling Station to the Transport Console to replenish the internal Helium gas supply.
2 If Helium Filling Station is unavailable, reinsert the Transport Console into the Hospital Cart to replenish the internal Helium gas supply.

Alarm Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: While using the IABP in its Transport configuration, the IAB could not be automatically filled because of inadequate Helium gas supply.
System Response: Vent / IAB deflated.
Reset: Replenish the Helium gas supply then retry the autofill by pressing the START key, or by pressing the IAB FILL key for 2 seconds.

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Autofill Failure - Blood Suspected

A leak is suspected in the IAB Catheter.

1. Check for evidence of blood in the tubing. If found, stop pumping and notify physician. Refer to IAB manufacturer's instructions for IAB removal.
2. If blood is not present, turn the IABP OFF by pressing and holding the green IABP Power Button for 2 seconds, wait 10 seconds, turn the IABP ON by pressing and releasing the green IABP Power Button.
3. Press the START key to refill the IAB and resume pumping.
4. If “AUTOFILL FAILURE - BLOOD SUSPECTED” message repeats and there is still no evidence of blood in the tubing, switch to another MAQUET IABP, if available.
5. Contact MAQUET Service.

Alarm Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: While the system was Autofilling, a leak in the IAB resulted in blood migration back to the system.
System Response: Vent / IAB deflated.
Reset: Attempt to clear by cycling power OFF and ON.

Autofill Failure

The IABP cannot fill the IAB catheter system.

1. Ensure that one correctly sized IAB extender tubing is tightly connected to the IAB and the IABP, and there are no restrictions in the tubing.
2. Check for evidence of blood in the IAB tubing. If found, stop pumping and notify physician. Refer to IAB manufacturer's instructions for IAB removal.
3. If blood is not present, press the START key to refill the IAB and resume pumping.
4. If the alarm message persists, switch to another MAQUET IABP if available.
5. Contact MAQUET Service.

Alarm Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: The Helium supply is adequate however the IAB could not be automatically filled.
System Response: Vent / IAB deflated.
Reset: Retry the autofill by pressing the START key, or by pressing the IAB FILL key for 2 seconds.

IAB Disconnected

The IAB catheter or extension tubing is disconnected.

1. Reattach the IAB catheter and extension tubing.
2. Press the START key to refill the IAB and resume pumping.

Alarm Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: Disconnection at IAB or extension catheter while in assist mode.
System Response: Vent / IAB deflated.
Reset: When the IAB is reconnected and an Autofill is initiated by pressing the START key, or the IAB FILL key is pressed and held for 2 seconds

High Drive Pressure

There may be a component failure in the pneumatic system.

1. Attempt to resume pumping by pressing the START key.
2. If the alarm message persists, switch to another MAQUET IABP if available.
3. Contact MAQUET Service.

Alarm Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: Regulated pressure from the compressor exceeds the acceptable operating range.
System Response: Standby / IAB deflated.
Reset: Resume assist by pressing the START key.

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IAB Catheter Restriction	
There is a restriction in the IAB catheter or tubing.	
1	Check the catheter tubing, extracorporeal tubing, and extender tubing for restriction, and relieve restriction if possible.
2	Press the START key to resume pumping.
The IAB membrane is not completely unfolded.	
1	Aspirate to assure blood is not returned through the extracorporeal tubing.
2	Using a syringe, manually inflate and deflate the IAB with 30 cc of air through the male Luer of the IAB.
3	Press the START key to Autofill and resume pumping.
The IAB remains in the sheath immediately after insertion.	
1	Check the markings on the IAB catheter to confirm that the balloon has fully exited the sheath. If the balloon has not fully exited the sheath, refer to the IAB catheter manufacturer's instructions for use to reposition the sheath relative to the IAB catheter.
2	Press the START key to resume pumping.

Alarm Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: See Probable Causes above.
System Response: Standby / IAB deflated.
Reset: Reset when assist is resumed by pressing the START key

Gas Loss in IAB Circuit	
A Helium loss has been detected due to a leak or high rate of diffusion in the IAB Circuit.	
1	Check for evidence of blood in the tubing. If found, stop pumping and notify physician. Refer to IAB manufacturer's instructions for IAB removal.
2	If blood is not detected, ensure that the IAB extender tubing is tightly connected to the IAB and the IABP. If appropriate, perform an Autofill by pressing and holding the IAB FILL key for 2 seconds, then press the START key to resume pumping.
3	If the patient is febrile or tachycardic, consider increasing the frequency of Autofills by initiating an Autofill prior to the regularly scheduled 2-hour Autofill.
4	If the alarm persists and there is no evidence of blood in the IAB tubing, consider setting the GAS LOSS ALARM to the OFF position via the PUMP OPTIONS menu from within the PREFERENCES MENU.

Alarm Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: Cumulative shuttle gas loss exceeds a nominal 5 cc/hr. dynamic limit. Active only when IAB inflation period >=80 mSec and deflation period >=250 mSec.
System Response: Vent / IAB deflated.
Reset: Message and Tone cleared when: the IAB FILL key is pressed and held for 2 seconds.

Low Vacuum	
There may be a component failure in the pneumatic system.	
1	If the alarm message persists, switch to another MAQUET IABP if available.
2	Contact MAQUET Service.

Alarm Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: Insufficient or no compressor vacuum.
System Response: Waiting to pump / IAB deflated.
Reset: Automatically when vacuum is restored.

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Trigger Interference
The system is detecting electro-surgical interference while in Pacer V/AV trigger mode.
1 Pumping automatically resumes when interference clears.
2 If the condition persists, select PRESSURE Trigger via the TRIGGER menu if appropriate.
3 Verify timing and press the START key to resume pumping.

Alarm Attributes:
Operation Mode: Semi Auto
Trigger Source: Pacer V/AV
Detailed Cause: Electro-Surgical Noise (ESU) detected while the Pacer trigger source is selected.
System Response: Waiting to pump / IAB deflated. A nominal 10 second alarm delay is incorporated to reduce false-positive nuisance alarms due to transient violations.
Reset: Automatically, when ESU interference stops. Or manually, by deselecting the Pacer trigger source.

Check Pacer Timing
The patient is not 100% paced.
1 Use ECG Trigger whenever the pacemaker is operating in a demand pacing mode.
2 Select ECG Trigger via the TRIGGER menu.
3 Press the START key to resume pumping.
The system is unable to distinguish between the intervals of an A-V Pacemaker.
1 A typical A-V interval (approximately 170 mSec) may have to be shortened when pacing rates exceed 130 to 135 BPM.
The rate on the V or A-V Pacemaker is set too high.
1 Verify that the pacing rate does not exceed 180 BPM.

Alarm Attributes:
Operation Mode: Semi Auto
Trigger Source: Pacer V/AV
Detailed Cause: Beat-to-beat pacing intervals vary by more than 6.25% or the V or A-V pacer rate is >180 bpm.
System Response: Waiting to pump / IAB deflated. A nominal 10 second alarm delay is incorporated to reduce false-positive nuisance alarms due to transient violations.
Reset: Automatically, when acceptable Pacer timing conditions are met. Or manually, by deselecting the Pacer Trigger.

No Trigger
Both the ECG and Arterial Pressure (A.P.) signals are absent or inadequate for triggering.
1 Attach or reposition the ECG electrode(s) and check the integrity of all ECG cable/lead connections.
2 Check integrity of all A.P. cable connections, optical or electrical. If transducer is in use, verify that the transducer was not left vented.
3 If an over damped A.P. signal is present, attempt to improve signal quality by aspirating and flushing the arterial pressure line.

Alarm Attributes:
Operation Mode: Auto
Trigger Source: ECG or Pressure
Detailed Cause: ECG and Arterial Pressure trigger are unavailable or are lost while in Auto OPERATION MODE.
System Response: Waiting to pump / IAB deflated. A nominal 10 second alarm delay is incorporated to reduce false-positive nuisance alarms due to transient violations.
Reset: Automatically, when trigger returns.

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No Trigger	
An electrode is detached or malpositioned.	
1	Reattach or reposition the ECG electrode(s).
There is inadequate signal acquisition.	
1	Select an alternate ECG lead or an External ECG signal via the SOURCES Menu.
An inappropriate trigger source has been selected.	
1	Select an alternate trigger source via the TRIGGER Menu. Resume pumping by pressing the START key.
Pacer pulses are not being detected while in Pacer V/AV Trigger mode.	
1	Enhance pacer pulse recognition by increasing the Pacer Detection level. First open the SOURCES Menu, then press the Pacer Detection UP ARROW key in the THRESHOLDS Menu until pacer pulses are enhanced on the ECG Waveform.

Alarm Attributes:
Operation Mode: Semi Auto
Trigger Source: R-Wave derived triggers (ECG & Pacer A) or Pacer Pulse derived (Pacer V/AV).
Detailed Cause: Trigger is unavailable or lost when either the ECG or Pacer Trigger modes are selected while assisting.
System Response: Waiting to pump / IAB deflated. A nominal 10 second alarm delay is incorporated to reduce false-positive nuisance alarms due to transient violations.
Reset: Automatically, when trigger returns.

Poor Signals Persist	
ECG triggering is too unreliable for Auto Operation due to poor ECG signal quality.	
1	Attempt to improve ECG signal by ensuring electrode contact and optimal placement. If necessary, change electrodes.
2	Check integrity of all cable/lead connections.
The Arterial Pressure (A.P.) waveform is absent, flat, or over damped.	
1	Check integrity of all cable connections, optical or electrical.
2	If a transducer is in use, verify the transducer was not left vented. If the waveform is still flat, attempt to clear the inner lumen by aspirating and flushing the arterial pressure line.
3	If unable to clear the inner lumen, cap the lumen. Provide an alternate A.P. source (i.e.: radial) by connecting and zeroing a standard transducer or by connecting an interface cable from the A.P. high level output of an external monitor to the IABP.
4	If signal problems persist, resume pumping by switching the OPERATION MODE to SEMI AUTO. Verify trigger and proper timing, and press the START key.

Alarm Attributes:
Operation Mode: Auto
Trigger Source: ECG
Detailed Cause: Both ECG and Arterial Pressure signal quality have been poor for a sustained period of time.
System Response: Waiting to pump / IAB deflated
Reset: Automatically upon detection of a good ECG or A.P. signal, or manually by switching to Semi Auto OPERATION MODE.

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No Pressure Trigger

The Arterial Pressure (A.P.) signal is absent or flat.

1. Verify that the desired Pressure Source has been selected, either Direct or External. Use the PRESSURE arrow keys via the SOURCES menu to select an appropriate Pressure Source.
2. Check integrity of all A.P. cable connections, optical or electrical. If transducer is in use, verify that the transducer was not left vented.
3. If a transducer is in use, attempt to clear inner lumen by aspirating and flushing the arterial pressure line. If not successful, cap the inner lumen. Provide an alternate A.P. source (i.e.: radial) by connecting and zeroing a standard transducer or by connecting an interface cable from the A.P. high level output of an external monitor to the IABP.

The patient's pulse pressure is inadequate for pressure triggering.

1. If a transducer is in use, aspirate and flush the arterial pressure line in an attempt to improve an over damped A.P. signal.
2. If appropriate, select a different trigger source via the TRIGGER Menu. Resume pumping by pressing the START key.
3. If Pressure trigger is required, reduce the Trigger Threshold Level by activating the THRESHOLDS Menu within the SOURCES Menu and using the PRESSURE THRESHOLD down ARROW key to decrease the Trigger Threshold Level.

Alarm Attributes:
Operation Mode: Semi Auto
Trigger Source: Pressure
Detailed Cause: Valid trigger is unavailable or lost when the Pressure trigger mode is selected (Not applicable to Auto OPERATION MODE).
System Response: Waiting to pump / IAB deflated. A nominal 10 second alarm delay is incorporated to reduce false-positive nuisance alarms due to transient violations.
Reset: Automatically, when a valid Pressure trigger is detected or an alternate trigger source is selected.

ECG Detected While Using Internal Trigger

A valid ECG is being detected while in the INTERNAL trigger mode.

1. Using the TRIGGER Menu, select a patient derived trigger source (such as ECG or PRESSURE).
2. Verify proper timing. Resume pumping by pressing the START key.

Alarm Attributes:
Operation Mode: Semi Auto
Trigger Source: Internal
Detailed Cause: ECG activity is detected persistently for 4-6 seconds while in the Internal Trigger mode.
System Response: Assisting however IAB is immediately deflated on each R-Wave detection.
Reset: Automatically, when ECG activity ceases. Manually, by deselecting Internal Trigger mode.

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Augmentation Below Limit Set	
There is a change in the patient's hemodynamic status.	
1	Assess the patient’s hemodynamic status and attempt to optimize.
2	If necessary, decrease the augmentation alarm limit to 8-10 mmHg below the patient’s diastolic augmentation pressure by pressing the AUG ALARM key and using the DOWN arrow key.
The augmentation alarm limit is set too high.	
1	Decrease the AUG ALARM limit to 8-10 mmHg below the patient's augmented diastolic pressure by pressing the AUG ALARM button and using the DOWN arrow key.
The AUGMENTATION level has been set too low	
1	Increase the IAB augmentation by pressing the UP arrow key via the AUGMENTATION Menu until the level reaches Max.
The IAB is positioned incorrectly.	
1	Verify placement and reposition if necessary.
There is a timing error.	
1	Assess for late inflation and early deflation timing and correct, if necessary.
There is a balloon leak.	
1	Check for blood in the tubing. If found, stop pumping and notify physician. Refer to the IAB manufacturer's instructions for IAB removal.

Alarm Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: Diastolic augmentation has dropped below the Augmentation Alarm limit.
System Response: Unaffected. A nominal 10 second alarm delay is incorporated to reduce false-positive nuisance alarms due to transient violations.
Reset: Automatically, when the augmentation rises above alarm limit.

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2.4.3 MEDIUM PRIORITY ALARMS

Medium Priority Alarms indicate situations in which a prompt Operator response is required. This class of alarm does not suspend pumping, but may indicate a need for corrective action. A yellow flashing alarm icon with two (2) exclamation points denotes the Medium Priority Alarm Icon. All Medium Priority Alarms have a uniform audio tone. The combination of three (3) notes for Medium Priority Alarms is played in the following sequence: three notes a pause and then this cycle repeats.



FIGURE 2-15 Medium Priority Alarm Icon

Fiber-Optic Sensor Failure
There is a failure in the communication of the Fiber-Optic Sensor signal with the IABP.
1 Firmly grasp the Fiber-Optic Sensor Connector using the raised grips. Remove it from the Fiber-Optic Sensor Input and reinsert until it clicks.
2 Check for visible kinks in the orange Fiber-Optic cable, if found relieve the kink.
3 If problem persists, disconnect the Fiber-Optic Sensor Connector.
4 Provide an alternate A.P. source (i.e.: radial) by connecting and zeroing a standard transducer or by connecting an interface cable from the A.P. high level output of an external monitor to the IABP.
5 If an external high level A.P. input is provided and the IABP is in SEMI AUTO operation mode, manually switch the IABP's pressure input to EXTERNAL using the PRESSURE ARROW keys via the SOURCES Menu. Confirm that the trigger and timing settings are set appropriately.
6 In the event that an alternate A.P. source cannot be provided, consider replacing the balloon.

Alarm Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: There is a failure in the communication of the Fiber-Optic Sensor signal with the IABP.
System Response: Pumping will continue while in ECG trigger, the Fiber-Optic pressure waveform and indices will not be available.
Reset: Upon removing the Fiber-Optic Sensor Connector.

Poor Signal Quality
ECG triggering is too unreliable for Auto Operation due to poor ECG signal quality.
1 Attempt to improve ECG signal by ensuring electrode contact and optimal placement. If necessary, change electrodes.
2 Check integrity of all cable/lead connections.
The Arterial Pressure (A.P.) waveform is absent, flat, or over damped.
1 Check integrity of all cable connections, optical or electrical.
2 If a transducer is in use, verify the transducer was not left vented. If the waveform is still flat, attempt to clear the inner lumen by aspirating and flushing the arterial pressure line.
3 If unable to clear the inner lumen, cap the lumen. Provide an alternate A.P. source (i.e.: radial) by connecting and zeroing a standard transducer or by connecting an interface cable from the A.P. high level output of an external monitor to the IABP.

Alarm Attributes:
Operation Mode: Auto
Trigger Source: ECG
Detailed Cause: Both ECG and Arterial Pressure signal quality is poor while in ECG trigger.
System Response: System continues to pump but may time conservatively.
Reset: Automatically upon detection of a good ECG or A.P. signal.

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No Pressure Source Available

No DIRECT or EXTERNAL arterial pressure (A.P.) source was detected.

1. If using a Fiber-Optic IAB, ensure that the Fiber-Optic Sensor Cable is connected. Once connected, a calibration will occur automatically in 20 seconds.
2. If a transducer is in use, ensure that the pressure cable is connected to the transducer and the IABP. If alarm persists, consider replacing the pressure cable.
3. If an A.P. source is still unavailable, consider providing an interface cable from the A.P. high level output of an external monitor to the IABP.

Alarm Attributes:
Operation Mode: Auto
Trigger Source: ECG or Pressure
Detailed Cause: Neither a direct or external pressure source was detected.
System Response: System continues to pump but may time conservatively.
Reset: Automatically, upon connection of a viable pressure source.

Low Battery

There is less than 30 minutes of battery operating time remaining.

1. Connect system to an AC power source.
2. If an AC power source is unavailable, insert a charged battery into the battery bay not currently in use.

Alarm Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: Cumulative reserve of both batteries falls below 30 minutes of operating time.
System Response: Unaffected.
Reset: Automatically removes message and turns off tone when an AC power source is restored or when a charged battery is inserted.

Catheter Alarms Paused - Enable AUG. ALARM

The Augmentation Alarm has been set to OFF while Catheter Alarms are Paused.

1. Set the AUG. ALARM to 10 mmHg below the patient's augmented diastolic pressure.
2. Adjust the Augmentation Alarm by pressing the AUG. ALARM key and using the ARROW keys.

Alarm Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: Catheter Alarms are Paused while the Augmentation Alarm is set to OFF.
System Response: Unaffected.
Reset: Once the user reactivates the Augmentation Alarm.

Over Temperature Condition Detected

An over temperature condition has been detected in the pneumatic system.

1. Switch the IAB FREQUENCY to 1:2 or 1:3 in an attempt to reduce the load on the pneumatic system, then switch to another MAQUET IABP if available.
2. Contact MAQUET Service.

Alarm Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: An over temperature condition has been detected in the pneumatic compressor.
System Response: Unaffected.
Reset: Automatically once the compressor temperature falls below the established over temperature threshold.

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Multiple AC Power Sources Detected

The IABP is connected to multiple AC power sources.

1 Disconnect the IABP from the unused AC power source(s).

Alarm Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: The system has detected that multiple AC power sources are connected to the IABP.
System Response: Unaffected.
Reset: Automatically, once the unused AC power source is disconnected.

Disconnect Trainer - Patient Cable(s) Connected

The System Trainer remains connected to the IABP and patient ECG / Pressure waveforms are detected.

1 Disconnect the System Trainer.

Alarm Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: A combination of Patient and Trainer cable(s) are connected to the IABP.
System Response: Triggering and timing response may be altered due to the inappropriate combination of trainer and patient signals.
Reset: Automatically, when the mix of trainer and patient cables is eliminated.

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2.4.4 LOW PRIORITY ALARMS

Low Priority Alarms are indications that Operator awareness is required. A cyan alarm icon with one exclamation point denotes the Low Priority Alarm Icon. All Low Priority Alarms have a uniform audio tone. The combination of two (2) notes for Low Priority Alarms is played in the following sequence: two notes a pause and then this cycle repeats.



FIGURE 2-16 Low Priority Alarm Icon

Unable to Update Timing	
Poor waveform quality.	
1	Check integrity of all A.P. cable connections, optical or electrical. If transducer is in use, verify that the transducer was not left vented.
2	If a transducer is in use, aspirate and flush the arterial pressure line in an attempt to improve an over damped A.P. signal.
3	Attach or reposition the ECG electrode(s) and check the integrity of all ECG cable/lead connections.
4	If not properly triggering or signal problems persist, switch OPERATION MODE to SEMI AUTO. Verify trigger and proper timing, resume pumping by pressing the START key.
The sustained heart rate is less than 30 BPM or greater than 150 BPM.	
1	Switch the OPERATION MODE to SEMI AUTO. Verify trigger and proper timing, resume pumping by pressing the START key.
Poor diastolic augmentation.	
1	If diastolic augmentation cannot be observed when AUGMENTATION level is set to MAX, attempt to improve the patient's hemodynamic status.

Alarm Attributes:
Operation Mode: Auto
Trigger Source: ECG or Pressure
Detailed Cause: See Probable Causes above.
System Response: Pumping is unaffected, conservative timing rules are applied. System increases frequency of attempts to update timing.
Reset: Automatic upon completion of a successful update, or entry into Standby.

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2.4.5 INFORMATIONAL MESSAGES

Informational Messages provide system information to the Operator. Informational Messages display textual messages and, in some cases, are accompanied by an infrequently-repeating audio reminder tone.

Prolonged Time in Standby
The IABP has been in STANDBY mode for an extended period of time.
1 Verify whether it is appropriate to resume pumping.
2 Press the START key to resume pumping. Note: MAQUET recommends that the IAB should not remain inactive (i.e. not inflating and deflating) for more than 30 minutes because of the potential for thrombus formation.

Message Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: Pump has been is Standby for at least 10 minutes.
System Response: Unaffected. A 30 second Double Beep will be sounded at 10, 15, and 20 minutes. Beyond 20 minutes the 30 second Double beep shall sound every 2 minutes until the message is cleared.
Reset: Message cleared by pressing START key.

Fiber-Optic Sensor Module Failure
There has been a failure of the internal Fiber-Optic Sensor Module in the IABP.
1 If a Fiber-Optic IAB is NOT in use, continue normal IABP use. Contact MAQUET Service for Fiber-Optic Sensor Module repair.
2 If a MAQUET Fiber-Optic IAB is in use, replace the IABP with another MAQUET IABP that supports the Fiber-Optic IAB.
3 If a replacement pump is NOT available, provide an alternate A.P. source (i.e.: radial) by connecting and zeroing a standard transducer or by connecting an interface cable from the A.P. high level output of an external monitor to the IABP.
4 If an external high level A.P. input is provided and the IABP is in SEMI AUTO operation mode, manually switch the IABP's pressure input to EXTERNAL using the PRESSURE ARROW keys via the SOURCES Menu. Verify trigger and proper timing.
5 Contact MAQUET Service for Fiber-Optic Sensor Module repair.

Message Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: There has been a failure of the Fiber-Optic Sensor Module in the pump console.
System Response: Pumping Unaffected, Auto timing may be conservative if an alternate Pressure source is not provided. Pressure indices may be displayed as dashes and an Audio Double Beep is sounded for 10 seconds at the onset of the message.
Reset: See corrective actions above.

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Irregular Pressure Trigger Detected	
The patient's rhythm is too variable to accurately predict the next systolic pressure trigger event.	
1	The System has automatically compensated by deflating earlier to avoid interfering with systolic ejection. Consequently, do NOT attempt to adjust the IAB DEFLATION control.
2	Confirm that the patient's ECG also indicates irregularity. If the rhythm disturbance persists, consider using ECG trigger for more reliable triggering.
The patient's rhythm is regular however IAB deflation is set too late, interfering with systolic detection.	
1	Confirm that the patient's ECG rhythm is regular. If so, adjust the IAB DEFLATION control earlier to improve consistency of the PRESSURE trigger.

Message Attributes:
Operation Mode: Semi Auto
Trigger Source: Pressure
Detailed Cause: Erratic Pressure Triggering due to either: 1) Patient arrhythmias 2) Late deflation is inhibiting pressure pulse detection.
System Response: System automatically bases deflation on shorter cardiac cycle intervals. This earlier deflation avoids interference with premature beats. An Audio Double Beep is initiated 60 seconds after the alarm is posted and sound for 4 seconds and repeat every 5 minutes while the message is posted.
Reset: Automatically, when trigger interval becomes regular.

Unable to Calibrate Fiber-Optic Sensor	
The patient's arterial pulse pressure is too low to reliably establish or update the Fiber-Optic Sensor calibration.	
1	When the patient's pulse pressure increases, attempt calibration by pressing the CALIBRATE PRESSURE key for 2 seconds while the IABP is in Assist mode.
2	If calibration was unsuccessful and pressure indices are required, provide an interface cable from the A.P. high level output of an external monitor to the IABP. Manually switch the IABP's pressure input to EXTERNAL using the PRESSURE ARROW keys via the SOURCES Menu. Verify trigger and proper timing.
3	If an external Pressure Source is not available, provide an alternate Direct A.P. source (i.e.: radial) by first removing the Fiber-Optic Sensor Connector and subsequently connecting and zeroing a standard transducer.
There is a restriction in the IAB catheter or tubing.	
1	Check the catheter tubing and relieve the restriction if possible.
2	Attempt calibration by pressing the CALIBRATE PRESSURE key for 2 seconds while the IABP is in the Assist mode.
3	If calibration was unsuccessful and pressure indices are required, provide an interface cable from the A.P. high level output of an external monitor to the IABP. Manually switch the IABP's pressure input to EXTERNAL using the PRESSURE ARROW keys via the SOURCES Menu. Verify trigger and proper timing.
4	If an external Pressure Source is not available, provide an alternate Direct A.P. source (i.e.: radial) by first removing the Fiber-Optic Sensor Connector and subsequently connecting and zeroing a standard transducer.

Message Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: The System was unable to establish or update Fiber-Optic Sensor calibration.
System Response: Pumping Unaffected, Pressure indices may be displayed as dashes.
Reset: Upon a valid calibration, or switch to an alternate A.P. Source.

Low Helium	
The Helium tank is closed.	
1	Open the Helium tank.
There are fewer than 24 Autofills of Helium remaining in the tank.	
1	Replace the Helium tank.

Message Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: While using the IABP in its Hospital configuration, the Helium gas supply dropped below a preset reserve as determined by tank pressure.
System Response: Unaffected. An Audio Double Beep is sounded for 30 seconds and repeats every 60 minutes while the message is posted.
Reset: Automatically when Helium supply is restored.

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Low Helium

There are fewer than 12 Autofills (approximately 1 day) of Helium remaining in the tank.

1. Connect the Helium Filling Station to the Transport Console to replenish the internal Helium gas supply.
2. If the Helium Filling Station is unavailable, insert the Transport Console into the Hospital Cart to replenish the internal Helium gas supply.

Message Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: While using the IABP in its Transport configuration, the Helium gas supply dropped below a preset reserve as determined by tank pressure.
System Response: Unaffected. An Audio Double Beep is sounded for 30 seconds and repeats every 60 minutes while the message is posted.
Reset: Automatically when Helium supply is replenished.

Gas Loss in IAB Circuit

A Helium loss has been detected due to a leak or high rate of diffusion in the IAB Circuit.

1. Check for evidence of blood in the tubing. If found, stop pumping and notify physician. Refer to IAB manufacturer's instructions for IAB removal.
2. If blood is not detected, ensure that the IAB extender tubing is tightly connected to the IAB and the IABP.
3. If the patient is febrile or tachycardic, consider increasing the frequency of Autofills by initiating an Autofill prior to the regularly scheduled 2-hour Autofill.

Message Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: The Gas Loss alarm has been overridden and the cumulative shuttle gas loss exceeded the nominal 5 cc/hr. dynamic limit. Active only when IAB inflation period >=80 mSec and deflation period >=250 mSec.
System Response: Unaffected since the alarm is overridden.
Reset: Message cleared when: the IAB FILL key is pressed and held for 2 seconds.

No Trigger

Both the ECG and Arterial Pressure (A.P.) signals are absent or inadequate for triggering.

1. Attach or reposition the ECG electrode(s) and check the integrity of all ECG cable/lead connections.
2. Check integrity of all A.P. cable connections, optical or electrical. If transducer is in use, verify that the transducer was not left vented.
3. If an over damped A.P. signal is present, attempt to improve signal quality by aspirating and flushing the arterial pressure line.

Message Attributes:
Operation Mode: Auto
Trigger Source: ECG or Pressure
Detailed Cause: No trigger has been detected while the IABP is in standby.
System Response: Standby / IAB is deflated. Informational Message posted on display, however the audible alarm is inhibited.
Reset: Automatically, when a valid trigger is detected or the START key is pressed.

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No Trigger	
An electrode is detached or malpositioned.	
1	Reattach or reposition the ECG electrode(s).
There is inadequate signal acquisition.	
1	Select an alternate ECG lead or an External ECG signal via the SOURCES Menu.
An inappropriate trigger source has been selected.	
1	Select an alternate trigger source via the TRIGGER Menu. Resume pumping by pressing the START key.
Pacer pulses are not being detected while in Pacer V/AV Trigger mode.	
1	Enhance pacer pulse recognition by increasing the Pacer Detection level. First open the SOURCES Menu, then press the Pacer Detection UP ARROW key in the THRESHOLDS Menu until pacer pulses are enhanced on the ECG Waveform.

Message Attributes:
Operation Mode: Semi Auto
Trigger Source: R-Wave derived triggers (ECG & Pacer A) or Pacer Pulse derived triggers (Pacer V/AV).
Detailed Cause: No trigger has been detected while the IABP is in standby.
System Response: Standby / IAB is deflated. Informational Message posted on display, however the audible alarm is inhibited.
Reset: Automatically, when a valid trigger is detected or the START key is pressed.

No Pressure Trigger	
The Arterial Pressure (A.P.) signal is absent or flat.	
1	Verify that the desired Pressure Source has been selected, either Direct or External. Use the PRESSURE arrow keys via the SOURCES menu to select an appropriate Pressure Source.
2	Check integrity of all A.P. cable connections, optical or electrical. If transducer is in use, verify that the transducer was not left vented.
3	If a transducer is in use, attempt to clear inner lumen by aspirating. If not successful, cap the inner lumen. Provide an alternate A.P. source (i.e.: radial) by connecting and zeroing a standard transducer or by connecting an interface cable from the A.P. high level output of an external monitor to the IABP.
The patient's pulse pressure is inadequate for pressure triggering.	
1	If a transducer is in use, aspirate and flush the arterial pressure line in an attempt to improve the quality of an over damped A.P. signal.
2	If appropriate, select a different trigger source via the TRIGGER Menu. Resume pumping by pressing the START key.
3	If Pressure trigger is required, reduce the Trigger Threshold Level by activating the THRESHOLDS Menu within the SOURCES Menu and using the PRESSURE THRESHOLD down arrow key to decrease the Trigger Threshold Level.

Message Attributes:
Operation Mode: Semi Auto
Trigger Source: Pressure
Detailed Cause: No trigger has been detected while the IABP is in standby.
System Response: Standby / IAB is deflated. Informational Message posted on display, however the audible alarm is inhibited.
Reset: Automatically, when a valid trigger is detected or the START key is pressed.

Fiber-Optic Sensor Calibration Postponed	
A non-scheduled calibration has been postponed because the patient's mean arterial pressure may be too low to pause assist.	
1	Assess the patient to determine if a brief pause in assist would be tolerated, and if appropriate, press the CALIBRATE PRESSURE key for 2 seconds, while Assisting, to initiate a calibration.
A non-scheduled calibration has been postponed because less than 15 minutes have elapsed since the last calibration.	
1	Assess the patient to determine if a brief pause in assist would be tolerated, and if appropriate, press the CALIBRATE PRESSURE key for 2 seconds, while Assisting, to initiate a calibration.
A non-scheduled calibration has been postponed because the IABP is in STANDBY.	
1	Resume Assist and press the CALIBRATE PRESSURE key for 2 seconds to initiate a calibration.

Message Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: See “Probable Causes” above.
System Response: Pumping is unaffected, Pressure indices may not be displayed.
Reset: Upon initiation of a calibration.

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Verify Proper Timing

No associated Help Screen.

Message Attributes:
Operation Mode: Semi Auto
Trigger Source: All
Detailed Cause: Reminder that the operator has changed the OPERATION MODE from Auto to Semi Auto or, the operator has changed trigger modes while in Semi Auto OPERATION MODE.
System Response: Standby / IAB deflated.
Reset: Automatically when the operator selects another OPERATION MODE or presses the START key.

Autofill Complete

No associated Help Screen.

Message Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: The System has successfully completed an autofill.
System Response: IAB deflated.
Reset: Message posted for 5 seconds.

Autofilling

No associated Help Screen.

Message Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: The System is in the process of automatically purging and refilling the IAB with Helium.
System Response: IAB deflated.
Reset: Message clears when autofill completes.

Calibrating Fiber-Optic Sensor

No associated Help Screen.

Message Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: The System is in the process of updating the calibration of the Fiber-Optic Sensor.
System Response: IAB partially inflates and deflates
Reset: Message clears when calibration completes.

Autofilling and Calibrating Fiber-Optic Sensor

No associated Help Screen.

Message Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: The System is in the process of automatically purging and refilling the IAB with Helium and updating the calibration of the Fiber-Optic Sensor.
System Response: IAB partially inflates and deflates
Reset: Message clears when autofill/calibration completes.

Calibration Only Available in Assist Mode

No associated Help Screen.

Message Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: Displayed when the operator attempts to initiate a calibration while the IABP is in Standby.
System Response: Unaffected. No action in response to pressing unavailable keys.
Reset: Message clears automatically after 5 seconds.

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Unable to Zero - Transducer Not Vented

No associated Help Screen.

Message Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: The user has attempted to zero the transducer in the presence of a pulsatile AP waveform.
System Response: Unaffected-zeroing of the transducer is not attempted
Reset: Message automatically clears in 5 seconds.

Catheter Alarms are Paused

The Gas Loss, Gas Gain and Catheter Restriction Alarms have been temporarily inactivated by the user.

1. After a 60 minute period, the Catheter Alarms will be automatically reactivated.
2. Ensure the AUG. ALARM has been set to 10 mmHg below the patient's augmented diastolic pressure.
3. To immediately reactivate Catheter Alarms, set CATHETER ALARMS to the CATHETER ALARMS ON position via the PUMP OPTIONS menu from within the PREFERENCES MENU.

Message Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: Catheter gas loss/gain, and restriction alarms are temporarily inactivated when PAUSE CATHETER ALARMS in the PUMP OPTIONS menu is selected.
System Response: Assist will not be suspended by any IAB Gas Loss/Gain or Catheter Restriction Alarms, and Catheter Alarms will not be displayed.
Reset: Automatically, when the 60 minute interval expires or, when the user activates CATHETER ALARMS ON.

Gas Loss Alarm Has Been Set To OFF

The user has set the Gas Loss Alarm to OFF, overriding the IABP's normal response to this alarm.

1. If appropriate, set the GAS LOSS ALARM to the ON position via the PUMP OPTIONS Menu.

Message Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: Gas Loss Alarm has been set to OFF by the user.
System Response: Assist will not be suspended by the Gas Loss Alarm. Alarm messages will still be posted for notification.
Reset: Message clears when the user sets the Gas Loss Alarm to ON.

Function Unavailable in External Pressure Source

No associated Help Screen.

Message Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: The user has attempted to Zero Pressure or Calibrate Pressure while an External Pressure Source is in use.
System Response: Unaffected-zeroing of the transducer or calibration of the Fiber-Optic Sensor is not attempted.
Reset: Message automatically clears after 5 seconds.

Function Unavailable in AUTO OPERATION MODE

No associated Help Screen.

Message Attributes:
Operation Mode: Auto
Trigger Source: ECG or Pressure
Detailed Cause: Displayed when the operator presses an unavailable key while in the Auto OPERATION MODE.
System Response: Unaffected. No action in response to pressing unavailable keys.
Reset: Message clears automatically after 5 seconds.

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Function Not Available

No associated Help Screen.

Message Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: The user has attempted to activate an unavailable IABP function.
System Response: Unaffected.
Reset: Message clears automatically after 5 seconds.

Battery in Use

The IABP is on battery power.

1. If available, switch to an AC power source.

Message Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: The IABP is being powered by battery.
System Response: Unaffected.
Reset: Automatic once AC power source is connected.

System Test OK

No associated Help Screen.

Message Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: The IABP has passed all power-up diagnostic tests.
System Response: Vent / IAB deflated.
Reset: Message automatically clears 10 seconds after the completion of tests.

Trainer in Use - NOT FOR CLINICAL USE!

No associated Help Screen.

Message Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: Displayed when any of the three Trainer cables are connected to the IABP.
System Response: Unaffected.
Reset: Message clears when all Trainer cables are removed.

Auto R-Wave Deflate

The patient's rhythm is too unpredictable to accurately anticipate the next beat. The System is now using R-Wave deflation to optimize timing during diastole.

1. DO NOT adjust the deflation setting. The System will readopt the prior deflation timing setting once the rhythm becomes predictable.
2. If you do not want the System to override the deflation setting, set R-TRAC to the OFF position by accessing the PUMP OPTIONS menu via the PREFERENCES menu.

Message Attributes:
Operation Mode: All
Trigger Source: ECG in Auto; ECG or Pacer A in Semi Auto.
Detailed Cause: The R-TRAC feature is ON and the patient's rhythm is too unpredictable to accurately anticipate the next beat. In response, the system has automatically selected R-Wave Deflation Mode.
System Response: Pumping Unaffected. The system is now using R-Wave deflation timing instead of the current deflation setting.
Reset: Status automatically clears when patient rhythm becomes predictable. Disable by setting R-TRAC to OFF via the PUMP OPTIONS menu.

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R-Wave Deflate

No associated Help Screen.

Message Attributes:
Operation Mode: All
Trigger Source: ECG in Auto; ECG or Pacer A in Semi Auto.
Detailed Cause: The operator has enabled R-Wave deflation timing by moving the deflate setting to the extreme right position.
System Response: Unaffected. Deflation occurs upon detection of the R-Wave.
Reset: Move deflation setting off of the extreme right position.

Initial Set Up

1. Ensure the Helium tank is open and verify Helium pressure.
2. Establish ECG and Pressure connections.
3. If using a Fiber-Optic IAB, ensure that the Fiber-Optic Sensor Connector is attached. Otherwise, zero the transducer:
   Vent the transducer to atmosphere.
   Press the ZERO PRESSURE key for 2 seconds.
   Close the transducer.
4. Confirm that the OPERATION MODE is AUTO.
5. Attach the IAB catheter and extender tubing to the Pneumatic Module.
6. To initiate pumping, press the START key. In response, the IABP will Autofill and then begin pumping. If desired, IAB DEFLATION timing can be fine-tuned using the IAB DEFLATION controls.
7. Verify the setting of the AUG. ALARM:
   After approximately 3 minutes, verify that the AUG. ALARM setting is approximately 10 mmHg less than the patient's augmented diastolic pressure.
   If needed, adjust the AUG. ALARM setting by pressing the AUG. ALARM key and using the ARROW keys to change the value.
8. Initial setup is now complete.

Message Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: Upon initial start up of the System detailed instruction shall be available.
System Response: Unaffected.
Reset: Initial Set Up Informational Message extinguished upon entering Assist mode; Initial Set Up Help Screen will remain displayed until closed by the user.

Unable to Charge Batteries

A component over temperature condition has suspended the IABP's ability to charge the batteries.

1. Switch to another MAQUET IABP if available.
2. If another MAQUET IABP is not available, ensure at least one charged battery is present in the battery bays.
3. If charged batteries are unavailable, ensure that the IABP is connected to an uninterruptible AC power source.
4. Contact MAQUET Service.

Message Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: An over temperature condition of the power management board has suspended the IABP's ability to charge batteries.
System Response: Patient therapy uninterrupted, ability to charge batteries is suspended.
Reset: Automatically once the power management temperature falls below the established over temperature threshold.

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Unusable Battery Detected in Bay #___

An unusable battery has been detected in the indicated battery bay.

1. Remove the unusable battery from the indicated bay.
2. Insert an alternate charged battery into the available battery bay.
3. Contact MAQUET Service.

Message Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: An unusable battery has been detected by the IABP.
System Response: Unaffected.
Reset: Automatically, once the unusable battery is removed from the battery bay.

No Backup Battery Detected

AC is the only power source available to the IABP.

1. Restore a backup source of power by inserting a functional battery into an available battery bay.

Message Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: The IABP is operating without a backup power source.
System Response: Unaffected.
Reset: Automatically, once a backup power source is added to the IABP.

Hold Power Button for 2 Seconds to Shutdown

No associated Help Screen.

Message Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: The Power Button was not held long enough to initiate a system shutdown.
System Response: Unaffected.
Reset: Automatically after 10 seconds.

Internal Transducer Calibration Out of Range

The system has detected that an internal transducer's calibration is out of range.

1. Switch to another MAQUET IABP if available and contact MAQUET Service.
2. If another MAQUET IABP is not available, a Fiber-Optic Sensor is in use and Arterial Pressure indices are required, disconnect the Fiber-Optic Sensor Connector. Provide an alternate A.P. source (i.e.: radial) by connecting and zeroing a standard transducer or by connecting an interface cable from the A.P. high level output of an external monitor to the IABP.

Message Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: See Probable Cause above.
System Response: Pumping is unaffected however Pressure indices are not displayed. Service is required.
Reset: When the internal transducers are recalibrated.

Fan Failure Detected

The IABP has detected a failure of one or more system fans.

1. Switch to another MAQUET IABP if available and contact MAQUET Service.

Message Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: A System fan in not functioning adequately or has failed.
System Response: Unaffected-may lead to a Over Temperature condition.
Reset: Message is cleared once corrective service is performed.

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IABP May Require Maintenance

IABP internal self-checks have detected a condition that may require service.

1. If available, switch to another MAQUET IABP and contact MAQUET Service for system diagnosis.
2. If another MAQUET IABP is not available, verify IABP functionality and continue use. Once IABP use is discontinued, contact MAQUET Service for system diagnosis.

Message Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: A pressure monitor self-check detected a pressure value that may have been temporarily out of tolerance at least twice within a 10 minute period.
System Response: Unaffected.
Reset: Message and audio remains until system shutdown.

IABP May Require Maintenance

IABP internal self-checks have detected a compressor condition that requires service.

1. If available, switch to another MAQUET IABP and contact MAQUET Service for system diagnosis.
2. If another MAQUET IABP is not available, verify IABP functionality and continue use. IABP use may be continued for up to 72 hours from the initial occurrence of this condition, while a replacement IABP is obtained.
3. NOTE: Once the IABP has powered down for a 15 minute period the IABP will display “Power-Up Test Fails Code #___” and will be unavailable for use. Note the code number displayed and contact MAQUET Service for system diagnosis.
4. Once IABP use is discontinued, contact MAQUET Service for system diagnosis.

Message Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: A compressor self-check has detected a pressure value that is out of tolerance.
System Response: The compressor speed has been adjusted to compensate for the condition. An Audio Double Beep is sounded for 30 seconds and repeats every 60 minutes while the message is posted. Once the IABP has powered down for a 15 minute period the IABP will display “Power-Up Test Fails Code #___” and will be unavailable for clinical use.
Reset: Message and audio remains until system shutdown.

Helium Transducer Not Calibrated

The Helium transducer has not been calibrated.

1. Using the Helium gauge on the Hospital Cart, verify the Helium supply is adequate.
2. If the Helium supply is adequate, continue use.
3. If the Helium supply is not adequate, replace the Helium tank.
4. Once IABP use is discontinued, contact MAQUET Service for Helium transducer calibration.

Message Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: The IABP is in Hospital configuration and the Helium transducer has not been calibrated.
System Response: Unaffected, however the Helium Tank Icon will not be displayed.
Reset: Message clears once a Helium transducer calibration has been performed.

Helium Transducer Not Calibrated

The Helium transducer has not been calibrated.

1. Switch to another MAQUET IABP if available contact MAQUET Service.

Message Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: The IABP is in Transport configuration and the Helium transducer has not been calibrated.
System Response: Unaffected, however the Helium Tank Icon will not be displayed.
Reset: Message clears once a Helium transducer calibration has been performed.

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Fiber-Optic Module Requires Maintenance
The IABP has detected that maintenance of the Fiber-Optic Module is required.
1 Switch to another MAQUET IABP if available and contact MAQUET Service for Fiber-Optic Sensor Module repair.
2 If another MAQUET IABP is not available, continue current use. Once IABP use is discontinued, contact MAQUET Service for Fiber-Optic Sensor Module repair.

Message Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: The IABP has detected that maintenance of the Fiber-Optic Module is required.
System Response: Unaffected, Fiber-Optic signal remains available.
Reset: Message clears once the Fiber-Optic Module is repaired.

Safety Disk Replacement is Due
The Safety Disk has reached its maintenance interval.
1 Continue normal IABP use.
2 Once IABP use is discontinued, contact MAQUET Service for Safety Disk replacement.

Message Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: The Safety Disk cycle count has reached 6,000,000 cycles or 4 years from the last replacement.
System Response: Unaffected.
Reset: Message will appear on each startup and clear after the first IABP assist cycle. The message is permanently cleared when the Safety Disk cycle count and date are reset.

2.4.6 SUDDEN SHUTDOWN ALARM

In the event that the IABP experiences an unexpected shutdown the IABP will sound the Sudden Shutdown Alarm (i.e. IABP is unplugged and backup batteries are not present) A repetitive audio tone will sound for up to 30 minutes or until the IABP is restarted, whichever occurs first. The Sudden Shutdown Alarm does not provide any visual alarm indicators. The audio alarm is self-powered via its own dedicated internal battery.

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2.5 CLINICAL CONSIDERATIONS

2.5.1 WATER CONDENSATION

During balloon pumping, a fine mist or small droplets of water may occasionally be observed within the IAB extension catheter. This mist is condensed water. The IABP utilizes a Condensation Removal System in order to remove water vapor from the system with each inflate/deflate cycle, without operator intervention.

Note:
If large water droplets remain in the extender catheter, it may be attached to suction to remove them. Be sure the extension catheter is disconnected from IAB and pneumatic module.

Note:
When transferring a patient from another IABP system without a condensate removal feature, ensure that all droplets of condensate are removed from the extension catheter tubing before connecting to the IABP.

CAUTION:
The operator is urged to routinely check the IAB catheter extender for the formation of condensate. If excessive condensation is allowed to accumulate it will affect system performance. Excessive condensate may indicate the need to service the Pneumatic Module.

2.5.2 CLINICAL CONSIDERATIONS DURING OPERATION

ECG:
There are several methods to correct conditions which alter or hamper the acquisition of a reliable ECG signal. Reposition or replace ECG electrodes and check that the patient cable is properly connected. In **Semi Auto** OPERATION MODE, choose an alternate lead selection. For proper electrode usage follow the techniques recommended in the ECG Acquisition Section of Chapter 2.

Pressure:
If an arterial pressure monitoring line is being used, maintain a continuous flush of the arterial line per standard hospital procedure. When monitoring via the inner lumen of the IAB, follow the special maintenance instructions provided with the IAB. Adequate flushing to maintain pressure line patency and alignment of stopcock in the proper position will prevent the majority of possible pressure trace problems.

Atrial Fibrillation:
Ensure that R-Trac is **On**. In **Auto** OPERATION MODE, there are no special pump considerations for handling atrial fibrillation. In **Semi Auto** OPERATION MODE, select **ECG** as the trigger source. This will allow the system to track random rhythm most consistently by automatically holding the IAB inflated until the detection of the next R-Wave. Pressure triggering is not recommended in atrial fibrillation.

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Triggering on Ectopics:

The IABP automatically deflates when the ectopic R-Wave is sensed and assists the ectopic beat. In **Semi Auto** OPERATION MODE, if the ectopic beat is of small amplitude, reliable triggering can be maximized if an ECG lead is selected which minimizes the amplitude difference between the normal QRS complex and that of the ectopic beat. No special adjustments are necessary.

Cardiac Arrest Ventricular Fibrillation:

When defibrillating the patient, the IABP has protection and is completely isolated from the patient and the defibrillator's electrodes. However, the operator should stand clear of the pump during defibrillation. This is particularly important when the IABP is operated while disconnected from an earth grounding point, such as the A.C. power receptacle.

Ventricular Standstill or Prolonged Cardiac Arrest:

If possible, use **ECG** or **Arterial Pressure** as the trigger source during CPR. This facilitates synchronization of the assist to the rate and rhythm of chest compressions.

In **Auto** OPERATION MODE, the ECG (R-Wave) or arterial pressure signal will automatically be selected as the trigger source. Choice is dependent upon relative signal quality.

If neither the ECG nor the arterial pressure signals produce adequate trigger reliability to allow for auto operation, the IABP may be triggered by its own internal clock. Select the **Semi Auto** OPERATION MODE and set the trigger source to **Internal**. The default internal rate is 80 bpm but can be varied between 40 and 120 bpm in the Trigger menu.

Prolonged Time in Standby and Thrombus on the IAB membrane:

If the IABP is placed in **Standby**, the time in **Standby** will be displayed on the Balloon Pressure Waveform on the Monitor Display. After 10 minutes, the informational message **Prolonged Time in Standby** will be displayed, and If the **Standby Advisory Tone** is **On** in the **Audio** preferences menu, an alarm will sound briefly. Verify whether it is appropriate to resume assist. If so, press the **Start** key to resume assist.

WARNING:

The patient balloon should not remain inactive in the patient (i.e., not inflating and deflating) for more than 30 minutes, due to the potential for thrombus formation.

Note:

The Standby Advisory Tone automatically defaults to the On position at start-up.

Patient Risk Currents:

Simultaneous connection of several medical devices to the patient may cause summation of leakage currents which can exceed the values allowed by the Safety Agency Standards. See Agency Compliance in section 7.15.

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2.5.3 USE IN ELECTRO-SURGICAL ENVIRONMENT

The IABP has built in electro-surgical interference suppression which minimizes electro-surgical unit (ESU) noise from disturbing system performance. While the system will suppress ESU noise, it cannot eliminate it all together. Sparking to tissue occurs when an ESU is operated. This generates noise that extends into the ECG and Pressure signal frequency range. Since the system must pass these frequencies, some ESU noise may interfere with the ECG signal, particularly with high ESU power settings. The Pressure signal is typically immune to ESU noise when acquired by rated 3rd party medical grade transducers and cabling. See section 7.15 for transducers rated for compliance with the CARDIOSAVE. The IABP has been designed for ESU suppression to protect against patient burns for both the ECG and Pressure system input connections when the recommended cabling and transducers are used.

Limiting the power of this noise energy is desirable. The magnitude of interference is directly related to the power setting of the ESU, which should be as low as possible for the intended effect. Successful ECG triggering in the presence of ESU noise depends, to a large extent, on proper patient preparation and ESU use.

Following the guidelines listed will minimize the amount of energy coupled from the ESU to the ECG and Pressure Inputs of the IABP, generally resulting in stable ECG and Pressure triggering. When the IABP is in **Auto** OPERATION MODE, it will automatically select **Pressure** as the trigger source when ESU interference is detected and return to **ECG** a short interval after interference ceases. If the clinician prefers to use **Pressure** as the trigger source during the operating room procedure, this can be accomplished by selecting **Semi Auto** OPERATION MODE. Then select **Pressure** from the Trigger menu. Return to **Auto** OPERATION MODE when appropriate.

In the presence of Electro-Surgical Interference the following alarms shall be suspended until the Electro-Surgical Interference has ceased:

- High Drive Pressure
- IAB Disconnected
- IAB Catheter Restriction
- Gas Gain in IAB Circuit
- Gas Loss in IAB Circuit

Once the Electro-Surgical Interference has ceased the suspended alarms shall be reactivated automatically. If any of the above alarm conditions still exist after Electro-Surgical Interference has ceased the active alarm will be displayed.

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When the IABP is used in an electro-surgical environment, the following techniques are recommended to minimize interference from electro-surgical devices:

- Always use supplied MAQUET/Datascope Corp. Operating Room ECG patient cable and lead wire option. See CARDIOSAVE ECG Operating Room Lead Wires in section 6.1.1.2 for more information. These cables are shielded and incorporate ESU suppression components.
- Keep the ECG and Pressure transducer cables at right angles to the electro-surgical cables to the greatest extent possible.
- Locate the ECG electrodes as far away from the surgical site as possible.
- Locate the ECG electrodes approximately equidistant from the surgical site to minimize any difference in potential between electrodes.
- Place all ECG electrodes on the same plane (either anterior or posterior) to minimize any difference in potential between electrodes.
- Keep all Pressure fluid lines away from the electro-surgical cables to the greatest extent possible.
- Use only Pressure transducers which meet the requirements for ANSI/AAMI BP22:1994/(R) 2006, Blood Pressure Transducers. See section 7.15 for transducers rated for compliance with the CARDIOSAVE. These type transducers mitigate against ESU interference and patient burns by providing galvanic isolation of the electrical connections. Use only transducer interface cables which provide shielding of signal conductors to reduce pick-up of ESU noise.
- Place the electro-surgical return plate directly under the surgical site.
- Use the minimum required electro-surgical setting.

WARNING:

External bedside monitors used to supply the ECG signal to the IABP in the operating room must be equipped with electro-surgical interference suppression.

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2.5.4 USE DURING CARDIOPULMONARY BYPASS

During full cardiopulmonary bypass, the IABP can be used to inflate and deflate an IAB by selecting **Semi Auto** OPERATION MODE and using the **Internal** as the trigger source. The internal rate can be adjusted in the Trigger menu. The Inflation and Deflation Timing Controls should be set to their default mid position.

If ECG activity is detected while **Internal** is the trigger source, the IAB will be immediately deflated to avoid asynchronous pumping and resultant interference with systole.

WARNING:

Do not remain in the internal trigger mode when the patient is generating a cardiac output.

When weaning a patient from cardiopulmonary bypass, the IABP can be used to assist cardiac function. If ECG is established it can be used as the trigger source. Verify whether a reliable ECG trigger is present by noting a flashing heart shaped icon in the Trigger Rate parameter area of the display. The icon should flash one time for each detected trigger event.

If the patient's ECG amplitude is insufficient to cause triggering, using **Pressure** as the trigger source is a viable alternative. The IABP will automatically adjust the pressure threshold as low as 7 mmHg and optionally users may manually control pressure threshold levels when in **Semi Auto** OPERATION MODE.

As bypass flow rate is decreased and the heart begins to generate a cardiac output, check that timing is correct. Frequent reassessment may be necessary as changes in patient condition may alter the relationships between electromechanical events.

If a MAQUET/Datascope Corp. Fiber-Optic IAB is being used to monitor arterial pressure, during or after bypass surgery, then the following caution may also apply.

CAUTION:

During or after any surgery that results in a 6°C or more change in patient core temperature in less than 2 hours, the Fiber-Optic IAB should be recalibrated by pressing and holding the Calibrate Pressure key for 2 seconds while assisting.

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2.6 PRINTING

2.6.1 PRINTER OPERATION

To initiate a printout, press the **Print Strip** key. To start a continuous printout, hold the **Print Strip** key for two (2) seconds. To stop the continuous printout, press the **Print Strip** key again. Printing will stop after the print trailer information has been printed.

If desired, printing can be initiated automatically due to an alarm event or at a fixed interval selected by the user. The initiation, format and length of the printout will adhere to the settings in the **Printer** preferences menu in the **Preferences** menu (see section 1.3.13.3).

The speed of printing (25 or 50 mm/sec) is controlled by the **Sweep Speed** setting in the **Display** preferences menu of the **Preferences** menu (see section 1.3.13.1).

2.6.2 PRINTER FORMATS

The dual trace chart recorder provides a hard copy record of patient waveforms. Printouts follow the format defined by the settings in the **Printer** preferences menu of the **Preferences** menu. Dual or single trace formats may be selected. Waveform choices are: **ECG & A.P.**, **ECG & Balloon**, **A.P. & Balloon**, **ECG Only**, **A.P. Only**, and **Balloon Only**.

Note:
For the dual waveform settings, two of the three single waveforms (ECG, Arterial Pressure and Balloon) are recorded simultaneously for the length specified in the Printer Tab. Waveforms will be printed as in the following examples.

ECG & A.P.:

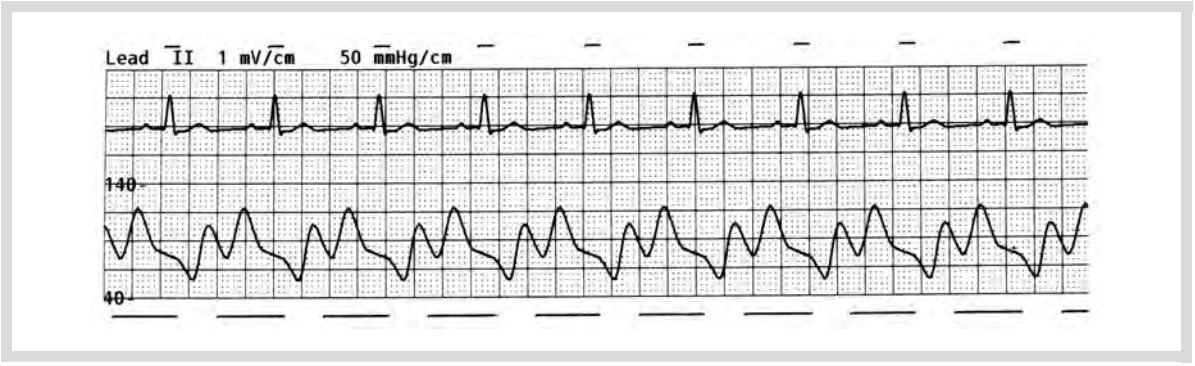


Figure 2-17: ECG and Arterial Pressure sample

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ECG & Balloon:

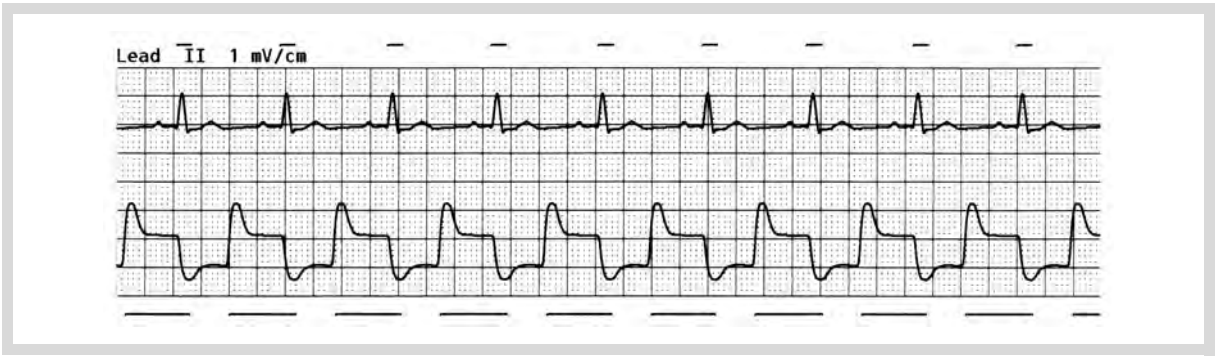


Figure 2-18: ECG and Balloon Waveform sample

A.P. & Balloon:

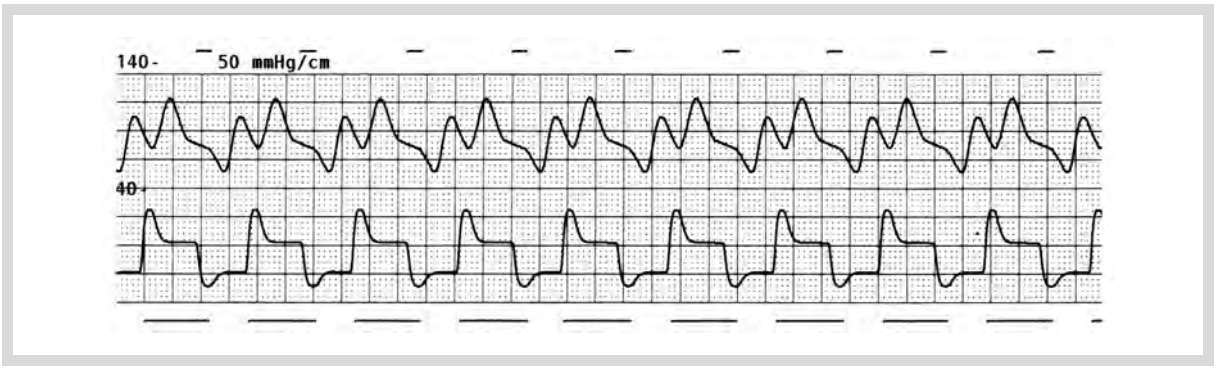


Figure 2-19: Arterial Pressure and Balloon Waveform sample

ECG Only: A delayed ECG waveform will be recorded for the length specified in the printer configuration menu. Numeric information for **Lead** selection and **Scale** is annotated at the beginning of the trace. If either are changed, the numeric information is reprinted.

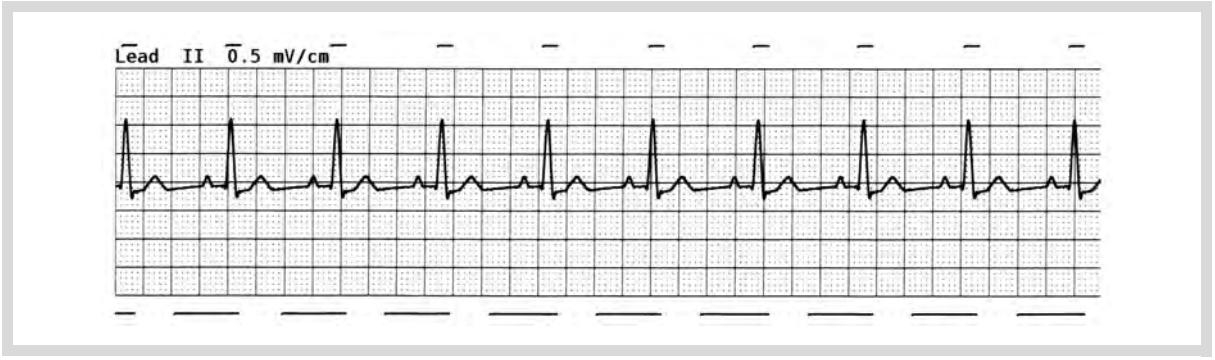


Figure 2-20: ECG Sample

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A.P. Only: A delayed invasive arterial pressure waveform will be recorded for the length specified in the printer configuration menu. Scale information is annotated at the beginning of the trace. If the pressure scale changes, the annotation is automatically repeated.

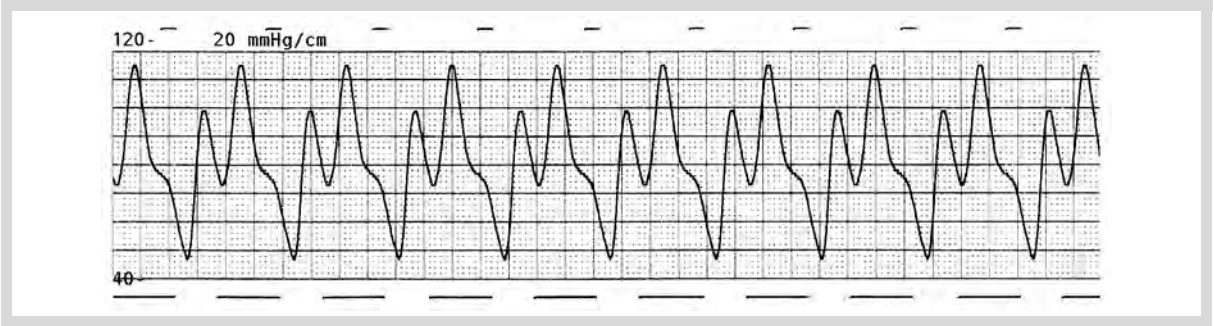


Figure 2-21: Arterial Pressure Sample

Balloon Only: A delayed balloon pressure waveform will be recorded for the length specified in the printer configuration menu.

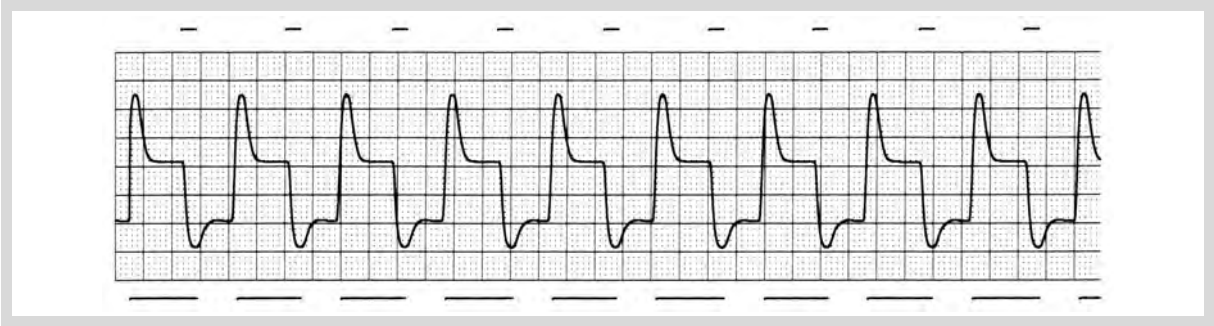


Figure 2-22: Balloon Waveform Sample

Note:
There is no scale information printed for the balloon pressure waveform.

Trigger and Inflation Markers: Along the top edge of the print strip a small horizontal marks in which the leading edge indicates the point at which the trigger event has been detected. Along the bottom edge of the print strip are horizontal marks indicating the approximate Inflation Interval (see item 12, section 1.2.3).

ECG & A.P.:

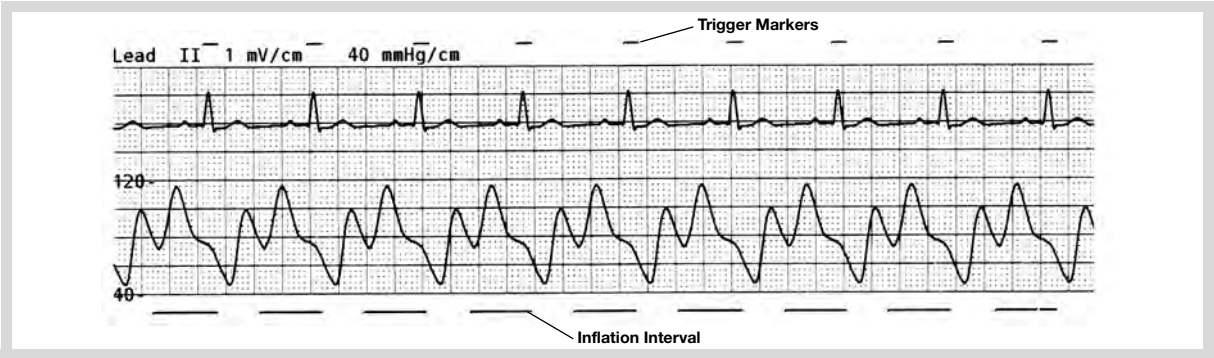


Figure 2-23: ECG and Arterial Pressure sample

Copyright Datascope Corp.

Print Data Marker: When the waveform traces are frozen and a print strip is initiated, a vertical bar may be dis-played on the print strip to identify the end of the frozen waveform data and the start of current waveform data.

ECG & A.P.:

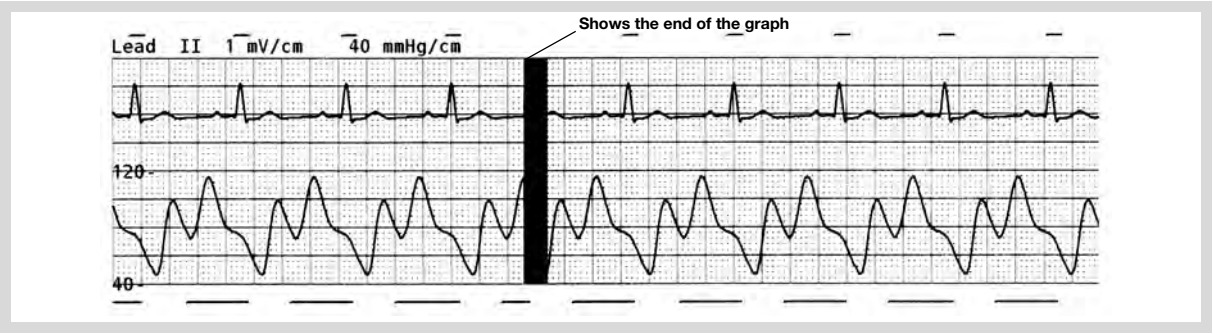


Figure 2-24: ECG and Arterial Pressure sample

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2.6.3 TRAILER ANNOTATIONS

At the completion of the recording, an annotated trailer is appended to the print. The annotation describes patient and system status. The format of the annotation depends upon the IAB **Assist Frequency** selection. Specifically, it determines how the systolic and diastolic pressures are presented. When **1:2** or **1:3** is selected as the IAB frequency, the recorder will print both assisted and unassisted systolic and diastolic pressure information.

See Trailer Formats for samples of these trailer formats. The date and time of the recording is automatically printed by the IABP. The Patient I.D. is left blank and can be filled in manually by hand, if desired.

2.6.3.1 SAMPLE PRINTER FORMATS FOR WAVEFORMS

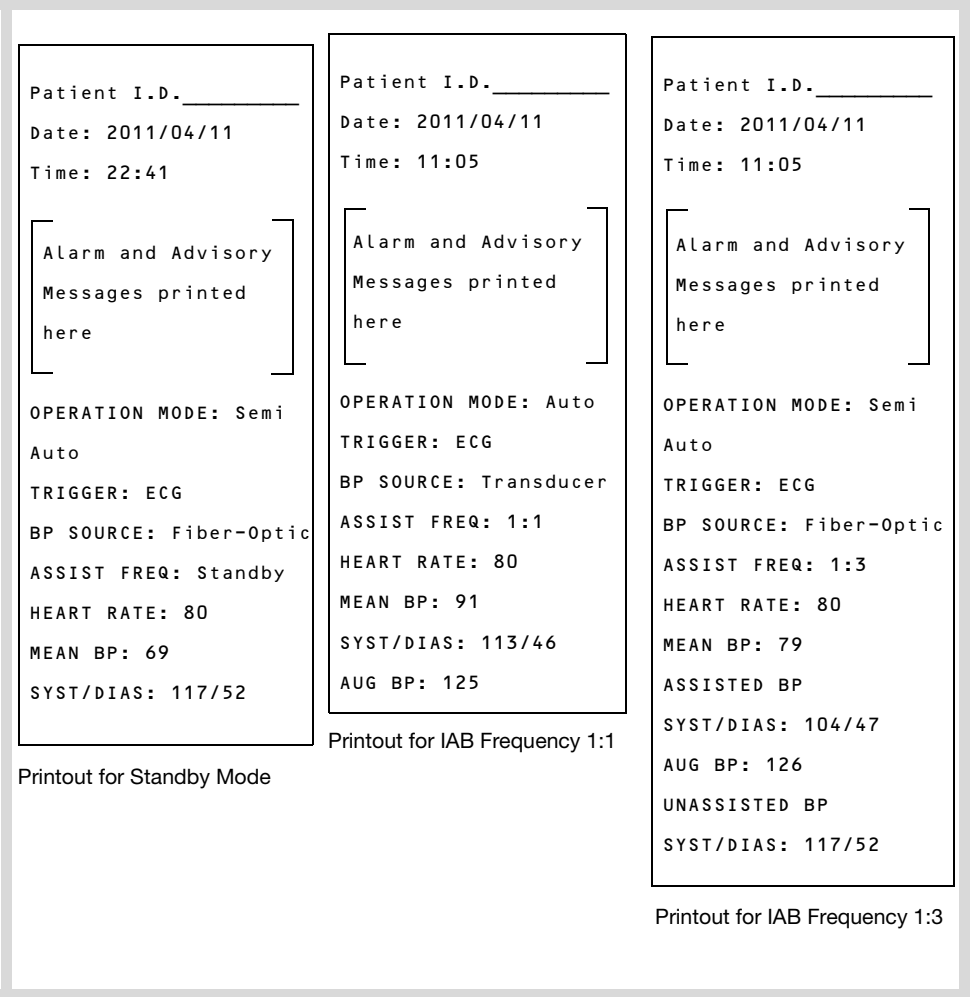


Figure 2-25: Trailer Formats

Note:
The same trailer format is used for both 1:2 and 1:3 assist frequencies.

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Copyright Datascope Corp.

3 PORTABLE/TRANSPORT OPERATION

CARDIOSAVE Rescue is optimized for portability during patient transport situations, and has the ability to use exchangeable, rechargeable batteries to power the unit if AC power is not available. **CARDIOSAVE Rescue** is specifically designed for air and vehicular transport, and features:

- A lightweight, portable design.
- Extendable wheels. This allows for better stability and ease of movement over rough, uneven surfaces.
- A retractable handle, used for pulling the IABP while in transport.
- Handles to ease lifting into vehicles, helicopters or fixed wing aircraft.

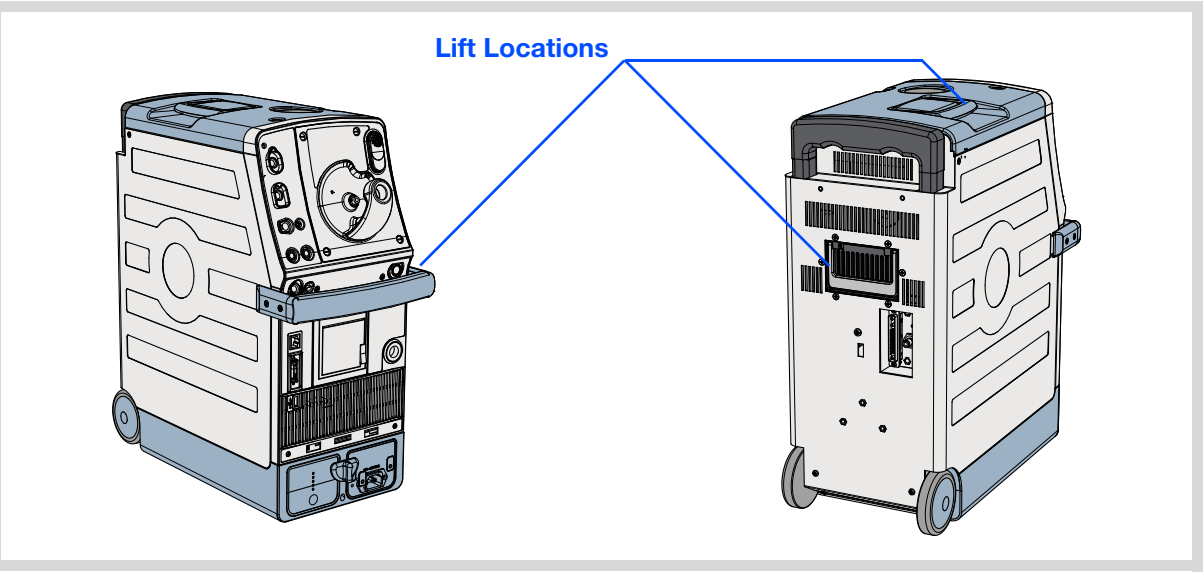


Figure 3-1: Transport System Lift Locations

CAUTION:

The pull up handle must not be used to lift the Transport System. Use only designated lift points and handles.

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3.1 PORTABLE OPERATION

Datascope Corp. recommends the following:

1. Ensure that the batteries are fully charged prior to starting transport.
2. Ensure sufficient additional charged batteries are available.
3. Ensure that the Internal Helium Reservoir is full.
4. The use of a MAQUET/Datascope Corp. Fiber-Optic IAB will eliminate the pressure waveform artifact that commonly occurs when moving patients using conventional fluid-filled pressure monitoring catheters. Altitude changes are compensated for automatically by the IABP.
5. The system must be properly secured when used in an ambulance, helicopter, or fixed wing aircraft.

WARNING:

The user should continually rely on visual alarm messages during high noise transport situations.

CAUTION:

Secure the system during transport to prevent impact injuries.

Note:

For information on outfitting an aircraft for IABP transport contact your local sales representative.

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3.2 INTERNAL HELIUM RESERVOIR

The Internal Helium Reservoir provides the IABP with fresh helium for IAB fill. This reservoir is filled using the Helium Refilling Station. With a full charge, the Helium Reservoir can provide Helium for 3 days of continuous use.

The Internal Helium Reservoir contains sufficient helium to provide approximately 36 fills (equivalent to approximately 72 hours of run time) at full capacity. Every time a fill occurs, helium will be depleted in the following approximate amounts:

- 6 fills (equivalent to approximately 12 hours of run time) - every time the balloon is connected, reconnected and IAB fill performed to restart therapy.
- 6 fills (equivalent to approximately 12 hours of run time) - every time the pump is powered down, powered up and IAB fill performed to restart therapy.
- 1 fill (equivalent to approximately 2 hours of run time) - auto fill every 2 hours.
- 1 fill (equivalent to approximately 2 hours of run time) - for every 25mmHg decrease in atmospheric pressure or approximately 1000 feet (305 meters) in altitude increase during ascent.
- 1 fill (equivalent to approximately 2 hours of run time) - for every 50mmHg increase in atmospheric pressure or approximately 2000 feet (610 meters) in altitude decrease during descent.

3.2.1 HELIUM REFILLING STATION

CAUTION:

The Helium Refilling Station is not intended for use in transport. The Helium Refilling Station is intended to be used in office buildings, aircraft hangars, or similar environments, and should not be within the vicinity of a patient.

The Helium Refilling Station is used to refill the IABP's Internal Helium Reservoir. It connects to the helium fill port on the Pump Console and provides fresh helium for filling the IAB. The Helium Refilling Station is designed to accept Datascope Corp. 90 Liter Refillable, 99 Liter Refillable, and 140 Disposable Helium Tanks. For instructions on using the Helium Refilling Station, and replacing the helium tank, refer to "Filling the Internal Helium Tank" in section 4.2.

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3.3 BATTERY OPERATION

The IABP has two Battery Bays which accommodate exchangeable rechargeable batteries. The system automatically switches to battery power if AC power is not available (intentionally or due to power loss).

Prior to portable operation, the battery should be fully charged. The current state of charge of each installed battery is depicted in the Battery Icon Display Area on the Monitor Display (item 25 section 1.2.8). The percentage of charge on the battery pack can be observed by depressing the charge status button located on the back of each battery pack. Five LED's are provided to indicate the state of charge. Each LED indicates approximately 20% charge.

Installed batteries can only be charged from a Transport Power Supply when the Transport Power Supply is plugged into an AC receptacle, and the IABP is powered off.

WARNING:

Sufficient additional charged batteries should be on hand during transport to prevent IABP shutdown due to inadequate battery capacity.

WARNING:

Removing both batteries or removing the energized battery, when AC power is not connected, will stop the therapy, (i.e., power down the pump).

CAUTION:

System batteries must be properly maintained and periodically tested. See the Battery Section of the User Maintenance Chapter.

3.3.1 BATTERY IN USE

- The **Battery in Use** Informational Message is displayed in the Message Display Area (section 1.2.7) and the Battery Icon in the Battery Icon Display Area (item 25 section 1.2.8). Verify that the Battery Icons display the charge level for each of the installed batteries.

- As the charge level of the battery decreases, the battery icon will reflect this by incrementally decreasing the colored level inside the battery icon. Similarly, as the charge level of the battery decreases, the battery icon’s colored level will transition from green to yellow to red. When a battery is depleted, and no longer available for use, the battery icon will appear grayed out.

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- When the battery has approximately 30 minutes of operating time remaining, the following occurs:
  - The **Low Battery** Medium Priority Alarm message is displayed continuously in the Message Display Area.
  - The Battery Icon Display Area will display the approximate time remaining in 5 minute intervals starting at <30 min.

A reduction in run time will occur over a battery's life due to age, storage temperature and discharge cycles. Batteries which are continually subjected to complete discharge cycles without the recommended immediate recharging, can incur permanent damage. See the Battery Section of the User Maintenance Chapter for additional information.

3.3.2 BATTERY CHARGING STATION

CAUTION:

The Battery Charging Station is not intended for use in transport. The Battery Charging Station is intended to be used in office buildings, aircraft hangars, or similar environments, and should not be within the vicinity of a patient.

The Battery Charging Station is used to charge the IABP's exchangeable rechargeable lithium ion batteries. It connects to an AC receptacle and is capable of charging two batteries sequentially. When the first inserted battery is fully charged, the second battery will automatically begin charging. Charging status is illustrated by a status LED. A flashing green LED indicates that the battery in that bay is currently charging. This LED will change to a solid green LED once the battery has completed charging. A solid lit yellow LED indicates that the battery in that bay is currently waiting to charge, and will begin charging once the first battery has completed. Lastly, a flashing red LED indicates that an error has been detected with the battery and as a result, will not charge.

Note:

Detecting a bad battery will take approximately 3 minutes.

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3.4 TRANSPORT POWER SUPPLY

The Transport Power Supply provides the IABP with the ability to use AC power. Installed batteries will only be charged from a Transport Power Supply when the Transport Power Supply is plugged into an AC receptacle, and the IABP is powered off.

When a Transport Power Supply is installed and in a Battery Bay and plugged into an AC receptacle, the Transport Power Supply icon with AC plug is displayed in the Battery Icon Display Area (item 25 section 1.2.8), informing the user that the Transport Power Supply is installed, and the IABP is currently running on AC power. When the Transport Power Supply is not plugged into an AC power receptacle, the AC plug icon is not displayed on the Transport Power Supply icon.

CAUTION:

When AC power operation is intended, insure that the system is plugged into a live AC receptacle and that the “Battery in Use” informational message is NOT displayed.

3.5 OPERATION FROM A DC-TO-AC INVERTER

The IABP can be powered from a DC-to-AC inverter if the DC source and the inverter meet the specifications defined below. The DC source and inverter should be checked for proper operation by qualified maintenance personnel prior to emergency use.

CAUTION:

Prior to emergency use, when the System is to be powered from an AC inverter, the inverter should be checked for proper operation with the System by qualified maintenance personnel. The message “Battery in Use” will not be displayed during proper AC inverter operation.

CAUTION:

When AC power operation is intended, insure that the system is plugged into a live AC receptacle and that the “Battery in Use” informational message is NOT displayed.

3.5.1 SPECIFICATIONS FOR DC SOURCE AND INVERTER

Voltage Output:	100-120/220-240 VAC ±10%
Frequency:	50 Hz ±2 Hz, 60 Hz ±2 Hz
Overshoots:	Does not continuously generate overshoots greater than 375 Volts peak with widths greater than 10 mSec when powering the system.
Waveform:	Sine wave or modified sine wave
Output Capability:	Minimum of 500 watts continuous power; 1000 watts surge power
Safety Compliance:	Meets or exceeds safety standards per IEC 60601-1.

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3.6 PLASTIC WEATHER COVER

The Plastic Weather Cover is an accessory designed to protect the CARDIOSAVE in transport configuration from ingress of liquids during a transport situation. The cover is designed to fit over the Pump Console and Display while still allowing access to the pull handle, and maintaining visibility of the Monitor and Touchscreen. The Plastic Weather Cover is to be used any time the Pump Console is used outside during, or when there is the possibility of, wet weather.

3.7 OPERATION DURING AIR TRANSPORTATION

Note:
Before using the system in air transportation, check for sufficient supply of helium since the balloon will be filled several times.

For proper operation during air transport, the IABP balloon pressure must adapt to local atmospheric pressure. The system will automatically purge and fill the IAB when local atmospheric pressure decreases or increases by 25 or 50 mmHg, respectively. These pressure changes occur approximately every 1,000 feet of rise or 2,000 feet of drop in altitude.

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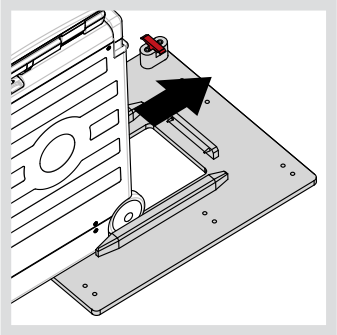
3.8 USING THE TRANSPORT MOUNTING PLATE

Before Mounting **CARDIOSAVE** to the Transport Mounting Plate, ensure that the Transport Mounting Plate is configured and secured properly to the transport vehicle with the plate properly affixed in the rails and both red levers are locked in place.

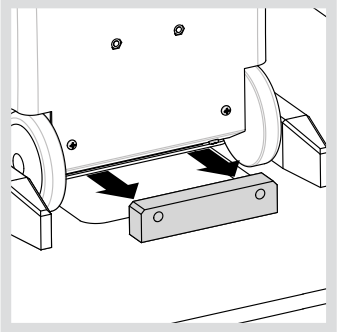
CAUTION:

Beware of pinch points. Keep hands clear when rolling CARDIOSAVE into position on the Transport Mounting Plate.

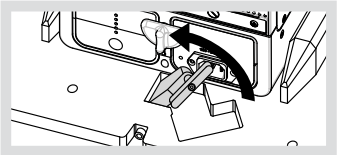
1. Center **CARDIOSAVE** on the open end of the Transport Mounting Plate and ensure that the pump has its wheels fully retracted before attempting to roll into position on the plate.

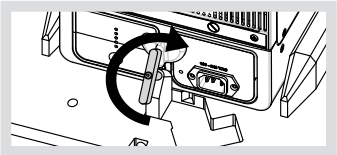


2. Roll **CARDIOSAVE** into the Transport Mounting Plate between the guide tracks until it is seated on the guide pins and firmly braced against the rear track.



3. Lift the swing bolt into the upright position, then turn the bolt clockwise until fully tightened, and ensure **CARDIOSAVE** is firmly locked in place.





Note:

If utilizing a Transport Power Supply in Battery Bay 2, lift the Pump Console slightly to allow the swing bolt to move into the upright position.

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4 USER MAINTENANCE

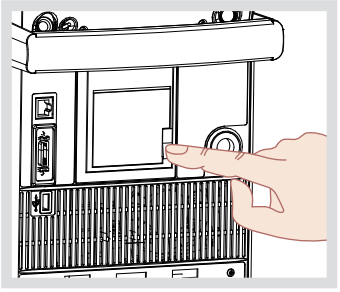
This section of the manual outlines routine maintenance which should be performed by the user or MAQUET Factory Trained and Certified Service Personnel. Guidelines for correcting certain problems are also provided. Some system problems may require the user to contact the local MAQUET Office or a MAQUET Authorized Service Representative.

4.1 CHART PAPER LOADING

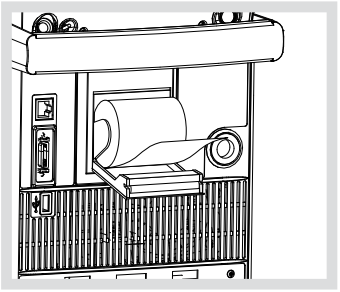
Instructions are provided below for the periodic replacement of chart paper. In order to obtain satisfactory recordings it is important that the correct type of paper be used (P/N 0683-00-0422-02).

Paper can be replaced as follows:

1. Open the paper compartment by pressing the release bar.
2. Remove the depleted paper spindle.



3. Place the new paper inside the paper compartment, leaving enough paper exposed to exit the door.
4. Close the paper compartment.
5. Press the **Print Strip** key to confirm correct paper roll insertion.



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4.2 FILLING THE INTERNAL HELIUM TANK

WARNING:

Only personnel familiar with the handling of high pressure gas tanks should install or replace the helium tank.

CAUTION:

Use medical grade helium only.

CAUTION:

The Helium Refilling Station is not intended for use in transport. The Helium Refilling Station is intended to be used in office buildings, aircraft hangars, or similar environments, and should not be within the vicinity of a patient.

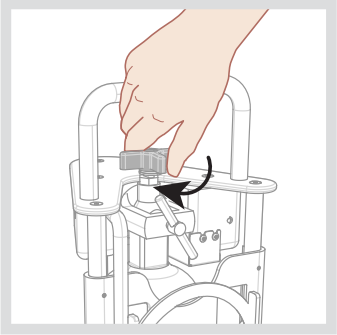
CAUTION:

Follow hospital protocol regarding biohazards to prevent contact with pathogens when refilling IABP with helium.

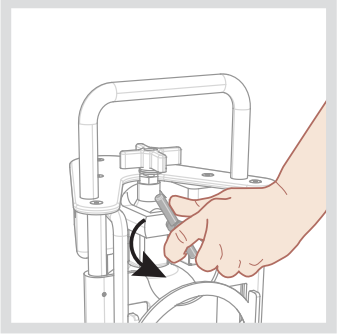
The helium tank should be filled when pressure drops below a preset level. This is indicated when the **Low Helium** informational message is displayed during operation. There is no need to interrupt IABP therapy. However, the internal helium tank should be filled as soon as possible to avoid a potential autofill failure which can delay pumping.

4.2.1 INSTALLATION AND REPLACEMENT OF THE HELIUM TANK

1. Attach the helium tank knob to the top of the helium tank. Close the helium tank by turning the knob fully clockwise.

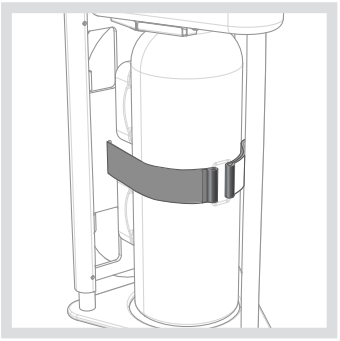


2. Slowly loosen the yoke T-handle counter-clockwise (some helium may escape). Ensure that the yoke T-handle is loosened enough to allow the helium tank to clear the guide pins.

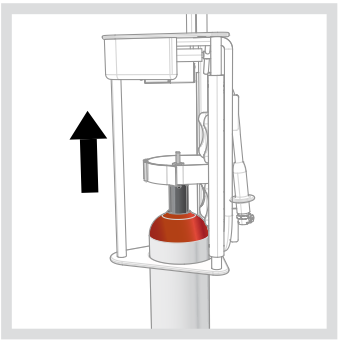


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3. Loosen the hook-and-loop strap holding the helium tank in place.

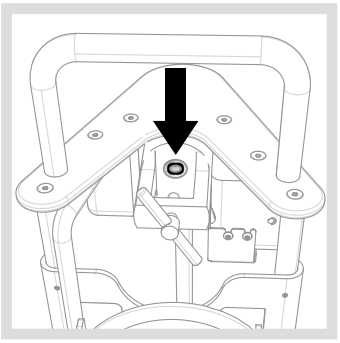


4. Remove the helium tank from the Helium Refilling Station by first disengaging the helium tank from the guide pins on the pressure regulator, then sliding the Helium Refilling Station over the tank.

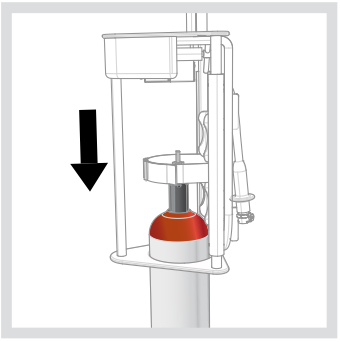


Note:
Disposal of used helium tanks should be in accordance with prevailing local statutes and in conformance with recycling requirements.

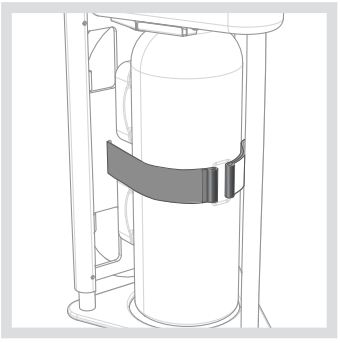
5. Check that the washer is present and in good condition on the yoke, and replace with a fresh washer if necessary.



6. Install a fresh helium tank in the Helium Refilling Station by first sliding the Helium Refilling Station over the helium tank (ensuring that the helium tank is properly oriented to line up with the guide pins), Then engage the tank on the guide pins on the pressure regulator.

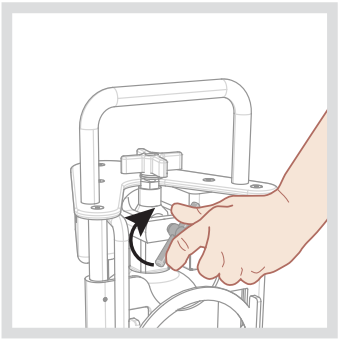


7. Tighten the hook-and-loop strap around the helium tank to hold it in place.



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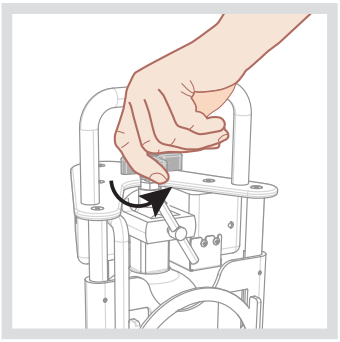
8. Fully tighten the yoke T-handle clockwise.



9. Attach the helium tank knob to the top of the new helium tank, and slowly open the tank by rotating the knob counter-clockwise (listen for any escaping helium). Using the mechanical gauge, verify helium pressure.

CAUTION:

Close helium tank valve when not in use.

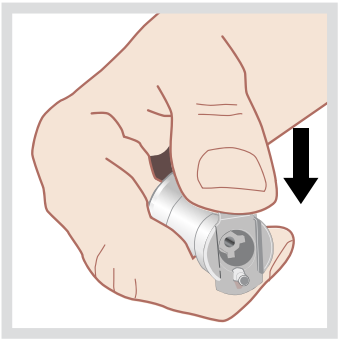


4.2.2 FILLING THE INTERNAL HELIUM RESERVOIR

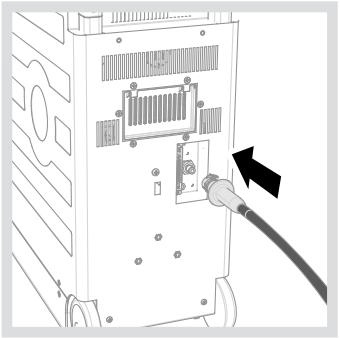
1. Open the locking connector on the Helium Refilling Station hose by pressing down on the thumb lock until the connector is open.

WARNING:

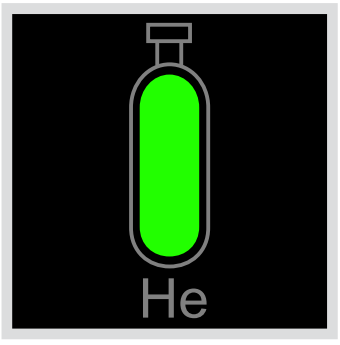
Route hose and position Helium Refilling Station safely. Keep walkways clear to reduce risk of injury



2. While holding the Pump Console in place, connect the Helium Refilling Station hose to the helium fill port on the Pump Console by pressing until the connector locks in place.



3. Leave Helium Refilling Station hose connected for a minimum of 30 seconds. Using the Helium Indicator on the Monitor Display, verify helium pressure is within acceptable limits. Once pressure is within acceptable limits, remove the hose from the Pump Console.



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4.3 HELIUM TANK REFILLING INFORMATION

Operation of the system with helium as the shuttle gas requires using one of three custom size medical gas tanks available only through MAQUET (see Helium Tanks in section 6.1.3). These tanks incorporate a standard post-style valve and may be refilled by suppliers who normally refill D size tanks. Tanks filled by any medical gas supply company may be used if they meet DOT, CGA, and USP requirements. Additional local requirements may apply depending on specific locale. Datascope Corp. recommends using only medical grade USP helium with the system.

If your usual medical supplier cannot refill tanks with medical grade helium, consult the following suggested sources. Any phone or fax numbers that have been provided may have changed. Please check your local directory for current phone numbers. Also, the Customer Service Representative at the Regional Sales Office nearest your location can supply the name of a local distributor who can provide this product.

Puritan Bennett Gas - U.S.

Phone:	(800) 234-5456

Use the following extensions to reach the Regional Sales Office:

Atlanta:	46
Baltimore:	47
Boston:	48
Chicago:	21
Kansas City:	20
Miami:	50
Ontario, CA:	74
San Francisco:	70
St. Louis:	30

BOC Gases - Domestic and International

Phone:	(800) 262-4273 or (908) 464-8100
Fax:	(888) 262-3298
Website:	www.boc.com

Praxair, Inc. - Domestic and International

Phone:	(800) 772-9247 or (716) 879-4077
Fax:	(716) 879-2015
Website:	www.praxair.com

4.4 DISPOSAL OF THE HELIUM REFILLING STATION

The Helium Refilling Station is a reusable device. However, if disposal is necessary, do so in accordance with local and national regulations.

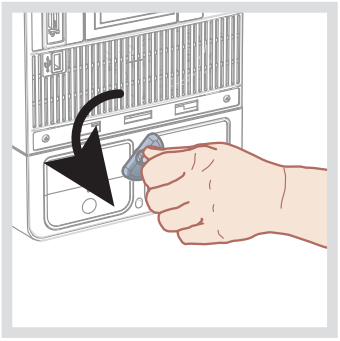
Copyright Datascope Corp.

4.5 INSTALLATION AND REPLACEMENT OF BATTERIES

The IABP is capable of running from DC battery power supplied by lithium-ion rechargeable batteries which can be installed in the two (2) Battery Bays on the Pump Console. To avoid interruption of therapy, discharged batteries should be replaced with new charged batteries as necessary. For more information on battery maintenance, see “Battery Maintenance” in section 4.7.

To replace the batteries:

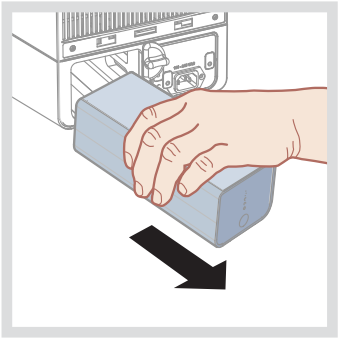
1. Turn the knob to unlock, and remove the battery from the Battery Bay (counter-clockwise for Battery Bay 1, or clockwise for Battery Bay 2).



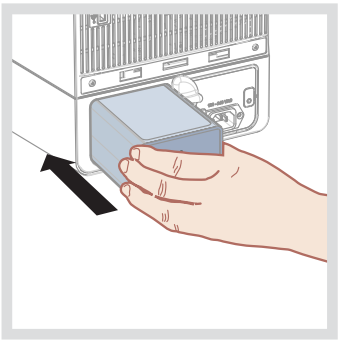
WARNING:

Removing both batteries or removing the energized battery, when AC power is not connected, will stop the therapy, (i.e., power down the pump).

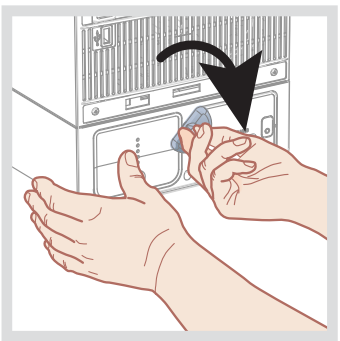
2. Slide the battery out of the Battery Bay.



3. Slide a charged battery into the Battery Bay.



4. While holding the battery in the Battery Bay, turn the knob to lock the battery in the Battery Bay.



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4.6 USING THE BATTERY CHARGING STATION

WARNING:

Internal Shock Hazard - This instrument does not contain any user-serviceable parts. DO NOT remove the instrument covers. Refer servicing to MAQUET Factory Trained and Certified Service Personnel.

WARNING:

Route Battery Charging Station AC power cord safely. Keep walkways clear to reduce risk of injury

WARNING:

Do not stack the Battery Charging Station with or on other equipment.

WARNING:

Use only Datascope Crop. batteries REF 0146-00-0097.

CAUTION:

Do not use a damaged or broken unit or accessory.

CAUTION:

The Battery Charging Station is not intended for use in transport. The Battery Charging Station is intended to be used in office buildings, aircraft hangars, or similar environments, and should not be within the vicinity of a patient.

The Battery Charging Station is used to charge the IABP's exchangeable rechargeable lithium ion batteries when they are not being used to operate the IABP. Batteries should be maintained at full charge when being used to operate the IABP. Battery charge time is 5 hours per pack to 90% or greater capacity. For more information on battery maintenance, see "Battery Maintenance" in section 4.7.

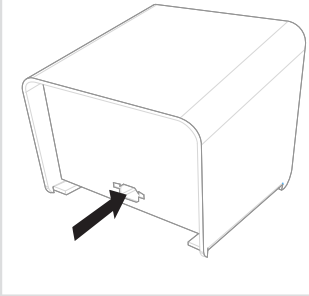
4.6.1 CLEANING THE BATTERY CHARGING STATION

For clean instructions, see "Cleaning the System and Accessories" in section 4.8.1.1.

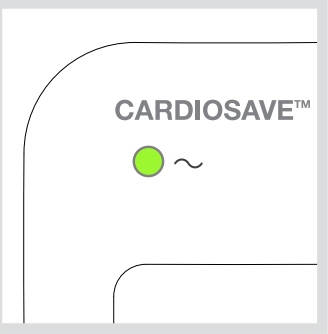
Copyright Datascope Corp.

4.6.2 CHARGING A SINGLE BATTERY

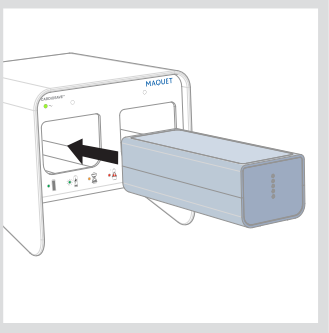
1. Attach the power cord, appropriate for the country of use securely into the back of the Battery Charging Station, and plug the power cord into a compatible grounded AC receptacle. Do not use an adapter to eliminate the plug's connection to ground.



2. Ensure the green power LED is illuminated.

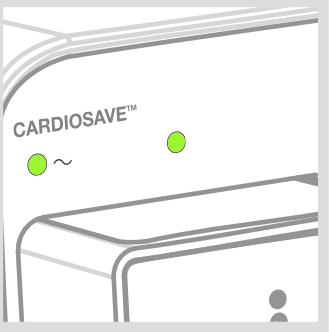


3. Insert a battery into the battery slot, ensuring that the battery connector is facing the battery slot. Press gently on the battery to ensure it is fully seated in the charging slot.



Note:
Both slots can be used for single battery charging.

4. The status LED over the battery slot will begin to flash green indicating that the battery is currently being assessed, and if necessary will begin to charge. Battery charging is indicated by the sequential flashing of the 5 battery status LEDs on the rear of the battery pack. Once the battery is charged, the status LED will be illuminated solid green. The battery is now fully charged and ready for use.



5. If the status LED over the battery slot is flashing red, an error has been detected with the battery and as a result, will not charge.



Note:
Detecting a bad battery will take approximately 3 minutes.

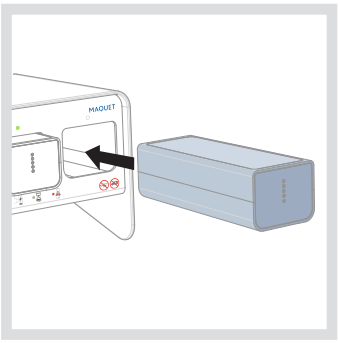
Copyright Datascope Corp.

4.6.3 CHARGING MULTIPLE BATTERIES

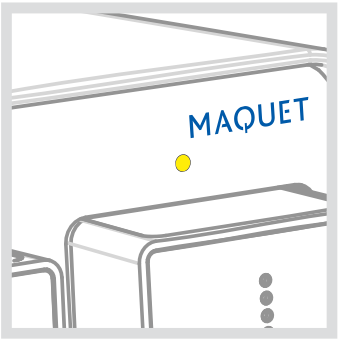
See Section 4.6.2 “Charging a Single Battery” before reading this section.

If a battery is already charging in the Battery Charging Station, a second battery can also be inserted. When the first inserted battery is fully charged, the second battery will automatically begin charging.

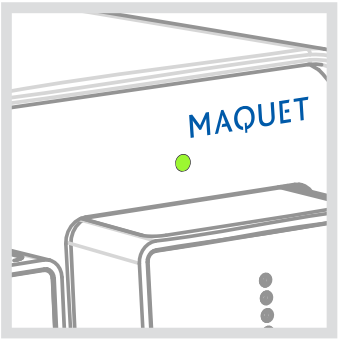
1. Insert a battery into the second battery slot, ensuring that the battery connector is facing the battery slot. Press gently on the battery to ensure it is fully seated in the charging slot.



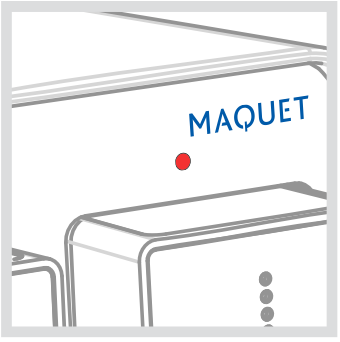
2. If the battery in the first battery slot is still charging, the status LED over the second battery slot will be illuminated solid amber indicating that the battery in that slot is currently waiting to charge, and will begin charging once the first battery has completed.



3. Once the battery is ready to charge, the status LED over the battery slot will begin to flash green indicating that the battery is currently being assessed, and if necessary will begin to charge. Battery charging is indicated by the sequential flashing of the 5 battery status LEDs on the rear of the battery pack. Once the battery is charged, the status LED will be illuminated solid green. The battery is now fully charged and ready for use.



4. If the status LED over the battery slot is flashing red, an error has been detected with the battery and as a result, will not charge.



Note:
Detecting a bad battery will take approximately 3 minutes.

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4.7 BATTERY MAINTENANCE

The IABP comes standard with 2 batteries shipped with the system.

Replace batteries as required. Batteries should be replaced after 200 full discharge cycles, at no more than four (4) year intervals, or if run time is less than 60 minutes minimum, at 120 BPM.

Disposal of batteries should be conducted in accordance with local statutes and the labeling shown on the battery pack.

To obtain optimum battery performance and expected battery life the following guidelines should be observed:

- The batteries should be maintained at full charge when the IABP is not in use. It is required that the IABP be plugged into an AC outlet when the system in not in use. If the unit must be stored for an extended time period (2 months or longer) and AC power is not available to maintain the batteries, or if the unit is stored in an ambient exceeding the maximum operating temperature, disconnect the batteries from the Pump Console. Due to battery self-discharge the disconnected batteries must be fully recharged at least every six (6) months.
- Excessive heat is very detrimental to battery life. Do not operate the system in ambient above the maximum operating temperature.
- Back up batteries should be checked before each use, and maintained in accordance with other guidelines in this section.
- When a **Low Battery** message is displayed after any system operation, the battery should be recharged within 24 hours to prevent battery damage.
- Do not attempt to repair the batteries. If the case is cracked or the connector is broken, replace the battery.
- Do not disassemble the batteries. Batteries contain a strong colorless electrolyte which man cause permanent loss of eyesight and injury when in direct contact with the eyes or skin. Immediately flush with clean water when in contact with leaked electrolyte and consult a physician.
- Do not short circuit the battery or battery terminals.
- Avoid carrying the batteries in a pocket that may contain conductive materials.
- Stop using the battery if it is leaking, deformed, damaged, or different from its normal condition.

WARNING:

Batteries have the risk of fire, explosion or severe burn hazards. Do not disassemble, crush, heat above 60° C (140° F), or incinerate. Replace only with Datascope Corp. REF 0146-00-0097.

WARNING:

Compressed gasses (helium tanks) and Lithium ion batteries are considered Dangerous Goods/ Hazardous Materials per I.A.T.A. and D.O.T. regulations.

It is a violation of U.S. federal and international law to offer any package or over pack of dangerous goods for transportation without the package being appropriately identified, packed, marked, classified, labeled and documented according to D.O.T. and I.A.T.A. regulations. Please refer to the applicable I.A.T.A. Dangerous Goods Regulations and/or the Code of Federal Regulations 49 (Transportation, Parts 171-180) for further information.

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4.8 USER MAINTENANCE BETWEEN PUMPING PROCEDURES

4.8.1 CLEANING

4.8.1.1 CLEANING THE SYSTEM AND ACCESSORIES

Clean the unit with a damp sponge and a mild soap solution or ammoniated cleaner. DO NOT USE organic solvents or abrasive cleansers. Avoid getting the cleaner in the vents, battery slots, or on the connector openings. Patient contact parts, such as ECG leads and blood pressure transducers, should be kept clean and disinfected. Standard hospital operating procedures regarding cleaning and infection control should always be observed. If appropriate, contact the pressure transducer manufacturer for the recommended sterilization procedures.

4.8.1.2 CLEANING THE MONITOR DISPLAY AND TOUCHSCREEN

Clean the Monitor Display and Touchscreen carefully to prevent scratches. Dust and dirt particles can be blown off or brushed off using a soft cloth. Fingerprints and stains may be removed by using a screen cleaning spray or solution applied to a lint free or microfiber cleaning cloth. DO NOT USE alcohol or solvents containing chlorinated hydrocarbon. DO NOT apply cleaner directly to the screen. Recommended cleaner: Getinge Group Tec-Surf II, Catalog number 61301600047, multi-purpose, broad spectrum disinfectant/cleaner.

4.8.2 LOW HELIUM

Prior to transport, test the Helium Indicator.

Note:
This test should be performed when the system is not in use. It may be necessary to fill the IAB more that once before the **Low Helium** informational message is displayed.

1. Turn on the **CARDIOSAVE Rescue**.
2. Check the Helium Indicator to determine the helium level in the internal helium reservoir.
3. Connect and IAB Catheter and Catheter Extender to the Pneumatic Module.
4. Initiate Autofill cycles by pressing the IAB Fill key for 2 seconds. When Autofill is complete, remove the Catheter Extender from the Pneumatic Module, and then re-connect.
5. Continue filling and disconnecting to deplete helium.
6. The **Low Helium** message will be displayed.

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4.9 CALIBRATING THE TOUCHSCREEN

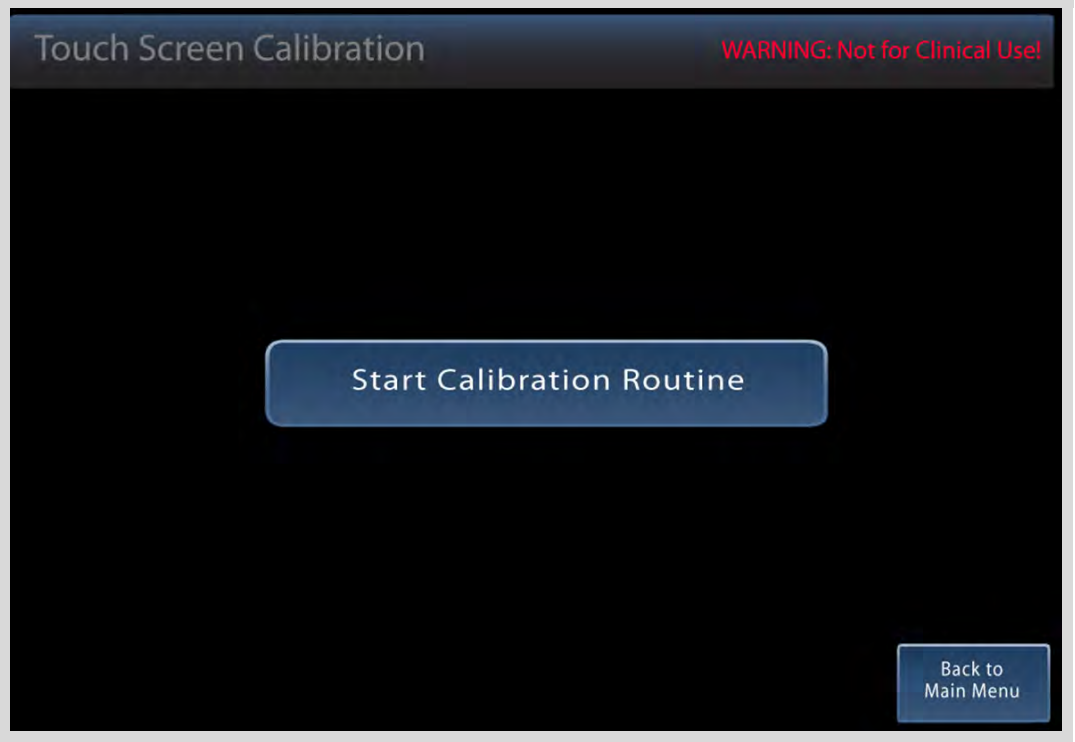


Figure 4-1: Example Touchscreen Calibration

The user can perform a Touchscreen calibration only when the IABP is in the alternate power-up mode. To enter the alternate power-up mode, start with the IABP turned off. While pressing and holding the **Low Level BP Output – Vent Button** (item 3, section 1.5.1), press and release the green **IABP Power Button** on the back panel (item 13, section 1.5.1) while continuing to hold the **Low Level BP Output – Vent Button** until the **Special Activation Main Menu** is displayed. Once the **Special Activation Main Menu** is displayed, release the **Low Level BP Output – Vent Button**.

To Calibrate the Touchscreen:

1. From the **Special Activation Main Menu**, select **Calibrate Touch Screen**.
2. Press the **Start Calibration Routine** key. This will begin the calibration procedure.

Note:
Insure an upright viewing angle and the use of a soft tip stylus is recommended.

3. The user will be prompted to press four targets ⊕ to complete Touchscreen calibration. The targets are displayed in each corner of the Touchscreen in the following order: Upper Left, Upper Right, Lower Right, and Lower Left. Accurately press and release the center of each target as it appears.
4. After all four targets have been pressed the user will be prompted to touch two additional targets to verify the calibration. Accurately press and release the center of each target as it appears.

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5. If the Touchscreen calibration was successful, the message **Calibration and Verification was Successful** is displayed. Touchscreen calibration is now complete, and the user may exit the **Touchscreen Calibration Screen** by pressing the **Back to Main Menu** key in the lower right corner.

   If the Touchscreen calibration was unsuccessful, the message **Verification of Calibration Failed** is displayed. The user is prompted to press anywhere on the Touchscreen to restart calibration procedure. Once this is done, repeat steps **3**-**5** to begin the calibration procedure.

After three consecutive unsuccessful Touchscreen calibration attempts, the message **Touch Screen Calibration has Failed** is displayed. The system has failed to calibrate and verify the Touchscreen. The user will be will be unable to attempt another Touchscreen calibration without power cycling the IABP in alternate power-up mode, and should contact MAQUET Service.

When the IABP is started in the alternate power-up mode with an uncalbrated Touchscreen, the message **The Touch Screen is uncalibrated** is displayed at power-up, and the user is prompted to press anywhere on the Touchscreen to start the calibration procedure. Once this is done, repeat steps **3**-**5** to begin the calibration procedure.

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4.10 PREVENTIVE MAINTENANCE SCHEDULES

Two preventive maintenance schedules have been provided.

Schedule A indicates which actions should be taken by either the Clinical User or by a MAQUET Trained/Certified Biomedical Technician (BMET). These steps do not require the use of tools and may be performed in a clinical setting.

Schedule B indicates the actions which should be performed only by a MAQUET Trained/Certified BMET. Special tools are required and, in some cases, the instrument covers must be removed.

WARNING:

Preventive Maintenance should never be performed when the IABP is attached to a patient.

WARNING:

Internal Shock Hazard - This instrument does not contain any user-serviceable parts. DO NOT remove the instrument covers. Refer servicing to MAQUET Factory Trained and Certified Service Personnel.

CAUTION:

This product requires scheduled preventative maintenance in order to maintain its specified performance. Note that maintenance includes periodic cleaning to assure that proper cooling airflow of the system's electronics is maintained.

4.10.1 SCHEDULE A

To be performed by the clinical user or the MAQUET factory trained and certified technician,

	Required Action	Before or After Each Use	Every Month	Every 12 Months
1	Clean system if necessary. Check Patient cables*, Pneumatic Module Luer fitting for cracks, and power cord for damage.	■		
2	Perform Pneumatic Module Leak Test (See section 2.2)	■		
3	Check battery system (See section 4.7)	■		
4	Check Autofill operation and helium supply.		■	
5	Check lead fault, transducer operation, and Low Helium Advisory.		■	
6	Perform a Touch Screen Calibration in Alternate Power-Up Mode. (See section 4.9)			■
7	Check battery run time. Replace batteries when operating time is outside of specifications. (Less than 60 minutes per battery at 120 BPM.)			■

* *Patient contact parts, such as ECG leads and blood pressure transducers, should be kept clean and disinfected. Standard hospital operating procedures regarding cleaning and infection control should always be observed.*

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4.10.2 SCHEDULE B

To be performed by the MAQUET factory trained and certified technician.

	Required Actions (Refer to Service Manual)	Every 12 Months or 2500 Hours	6,000,000 Inflate, Deflate Cycles or 4 Years.*	12,000,000 Inflate, Deflate Cycles or 4 Years.*	Every 5000 Hours
1	Perform visual inspection check list.	■			
2	Remove main and back covers, vacuum inside of console, covers and fan intake areas.	■			
3	Vacuum the compressor fan, and area of the pneumatics. Inspect hoses and pump shock mounts.	■			
4	Replace the Safety Disk in the Pneumatic Module.		■		
5	Replace Tidal Disk in the Pneumatic Module.			■	
6	Replace the muffler/filter on the vacuum regulator input and pressure reservoir input.				■
7	Replace the compressor assembly.				■
8	Test Critical Alarm board. Replace 9 Volt battery if test fails, or after 2 years of use.	■			
9	Confirm operation of the main fan behind the back panel, and the fan mounted above the compressor. Confirm operation of the fan in the Transport Power Supply if so equipped.	■			
10	Check system batteries for rated voltage and check battery run time. Replace batteries when operating time is less than 60 minutes per battery at 120 BPM, or after four (4) years.**	■			
11	Perform Fiber Optic Test. Clean Fiber Optic components if necessary, and retest	■			
12	Calibrate system and perform functional tests.	■			

* *Whichever comes first.*
** *This does not imply a four (4) year warranty.*

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4.11 EMPTYING INTERNAL HELIUM SUPPLY

CAUTION

The internal helium tank contains 200 PSI of helium. This tank **MUS**T be emptied prior to shipping the system via commercial shipping.

Note

Make sure the Hospital Cart Helium Tank is not connected prior to performing the Empty Internal Helium Tank.

EMPTY INTERNAL HELIUM EMPTY INTERNAL TANK (Using Special Activation Main Menu)

1. From the Special Activation Main Menu, select Empty Internal Helium Tank.
2. Verify that the Helium Refilling Station has been disconnected.
3. From within the Empty Internal Helium Tank screen press the Empty Internal Helium Tank button located in the center of the screen.
4. Wait until the Status field displays Empty Complete.
5. Emptying of the internal Helium tank is now complete.

MANUAL RELEASE OF PRESSURE FROM HELIUM RESERVOIR (Only performed if the system is not functional in Special Activation Main Menu to empty the internal cylinder.)

1. If **CARDIOSAVE Rescue** is being shipped, ensure that the Helium Refilling Station is disconnected from the unit.
2. Looking at the back of the Transport module, a pneumatic plug is located in the second air vent to the right of the recessed handle, approximately half way up the vent.
3. Insert a 1/16” allen wrench into the plug and rotate it 1 turn counter-clockwise.
4. Remove the allen wrench.
5. The unit is now ready for shipping.

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4.12 WARRANTY

Datascope warrants that its products will be free from defects in workmanship and materials for a period of 12 months from the date of shipment except that (1) disposable or one-use products are warranted to be free from defects in workmanship and materials up to a date one year from the date of purchase or the date of first use, whichever is sooner (2) pneumatic filters, and tubing are consumed during the course of normal use and are not warranted.

The Lithium-Ion batteries that are initially shipped with the IABP are warranted to be free from defects in materials and workmanship for a period of 12 months from the date of shipment

The Safety Disk initially shipped with the IABP is warranted for 12 months from the date of shipment.

Recommended preventive maintenance is the responsibility of the user, for which parts and labor are not included under this warranty.

Datascope shall not be liable for any incidental, special, or consequential loss, damage or expense directly or indirectly arising from the use of its products, liability under this warranty and the buyer's exclusive remedy under this warranty is limited to servicing or replacing at Datascope's option at the factory or at an authorized Datascope distributor, any product which shall under normal use and service appear to the Company to have been defective in material or workmanship.

No agent, employee, or representative of Datascope has any authority to bind Datascope to any affirmation, representation, or warranty concerning its products, and any affirmation, representation, or warranty made by any agent, employee, or representative shall not be enforceable by the buyer.

This warranty is expressly in lieu of any other express or implied warranties, including any implied warranty of merchantability or fitness, and of any other obligation on the part of the seller.

Damage to any product or parts through misuse, neglect, lack of preventive maintenance, accident or by affixing any non-Datascope supplied accessories and IAB's or by any customer modification voids this warranty. Datascope makes no warranty whatever in regard to trade accessories, such being subject to the warranty of their respective manufacturers.

A condition of this warranty is that this equipment or any accessories which are claimed to be defective be returned when authorized by Datascope, freight prepaid to Datascope, Mahwah, New Jersey. Datascope shall not have any responsibility in the event of loss or damage in transit.

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4.13 DATASCOPE'S RESPONSIBILITY

Datascope Corp is responsible for the effects on safety, reliability and performance of the equipment only if:

1. Assembly operations, extensions, readjustments, modifications or repairs are carried out by persons authorized by Datascope; and

2. The electrical installation of the relevant room complies with IEC requirements (VDE 0107); and

3. The equipment is used in accordance with the Instructions for Use.

4.14 EXTENDED WARRANTY

Datascope warrants that components within the Intra Aortic Balloon Pump units will be free from defects in workmanship and materials for the number of years shown on the Datascope invoice. Under this extended warranty, Datascope will repair any defective component other than consumables, at no charge for labor and/or materials. Consumable items are identified as, but not limited to batteries, all external cables, displays, lead wires, interface cables, safety disks, and tidal volume disks.

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5 EXTERNAL INTERFACES

5.1 EXTERNAL MONITOR INTERFACING

The IABP can acquire patient ECG and arterial pressure signals supplied as a high-level output from a compatible external monitor. It can also provide a low-level arterial pressure output signal. This signal is derived from either the IAB Fiber-Optic Sensor, or from the pump's Arterial Pressure Transducer and made available to the physiologic pressure transducer input on the patient's bedside monitor. Its low level output emulates that of a typical Arterial Pressure Transducer, allowing direct connection to the patient inputs of the bedside monitor. The signal provides a standard sensitivity of 5µV/V/mmHg excitation and is fully isolated and defibrillation proof for safe use with any monitor. The connectors for external monitor signals are on the IABP back panel as described in Section 1.5.1 Back Panel.

WARNING:

External bedside monitors used to supply the ECG signal to the IABP in the operating room must be equipped with electro-surgical interference suppression.

Note:
External monitors must be IEC 60601-1 compliant.

5.1.1 EXTERNAL MONITOR ECG REQUIREMENTS

- **Bandwidth* (-3 dB referenced to 10 Hz):**
  0.5 Hz maximum to 100 Hz minimum (Set monitor to Diagnostic Quality bandwidth)
- **Propagation Delay* (Delay of QRS complex):**
  25 mSec maximum
- **Scale Factor* (referenced to 10 Hz):**
  1 V/mV ±10%
- **Pacer Enhancement:**
  Enable (if this feature is available on the monitor) to enhance pacer identification and blanking.

** Required for proper IABP triggering.*

Note:
Due to the bandwidth limitation of external monitor outputs, direct patient leads are preferred for optimal Pacer identification and blanking.

Note:
Proper pacer detection may require that the external monitor re-inserts pacer events into its ECG signal.

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5.1.2 EXTERNAL MONITOR ARTERIAL BLOOD PRESSURE REQUIREMENTS

- **Bandwidth* (-3 dB referenced to DC):**
  DC to 15 Hz minimum
- **Propagation Delay*:**
  25 mSec maximum (Delay, measured at the 50% maximum height point, using a 1 Hz sine wave applied to the external monitor's input)
- **Scale Factor*:**
  1 V/100 mmHg ±2%

**Required for proper IABP triggering and pressure accuracy.*

MAQUET supplies interface cables which can be custom wired for compatibility with any monitor which meets these minimum requirements. Wiring instructions for both ECG and Arterial Pressure interface cables are provided.

5.1.3 ECG INPUT FROM MONITOR

External Signal Cable (Standard Accessory P/N 0012-00-0323)

1. The cable is supplied with a stereo phone plug to be connected to the ECG Monitor Input jack on the back panel of the IABP.
2. The other end should be terminated with the appropriate connector for the external monitor.
3. The following connections should be made to the external monitor connector:



Figure 5-1: External ECG Signal Cable

5.1.4 PRESSURE INPUT FROM MONITOR

External Signal Cable (Standard Accessory P/N 0012-00-0323)

1. The cable is supplied with a stereo phone plug to be connected to the Pressure Monitor Input jack on the back panel of the IABP.
2. The other end should be terminated with the appropriate connector for the external monitor.
3. The following connection should be made to the external monitor connector.



Figure 5-2: External Pressure Interface Cable

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5.1.5 LOW LEVEL PRESSURE OUTPUT TO MONITOR

Low Level Interface Cable (P/N 0012-00-1589-01)

1. The cable is supplied with a 9-pin circular plug to be connected to the IABP Low Level BP Output - to Bedside Monitor: jack on the back panel of the IABP.
2. The other end should be connected to the external monitor's low level blood pressure transducer input connector.
3. Once the appropriate connection is made, follow these steps to zero the bedside monitor:
   - Press and release the vent button on the back of the pump.
   - Within 15 seconds, zero the pressure channel on the bedside monitor.
   - The bedside monitor does not need to be zeroed again unless the connection is interrupted.

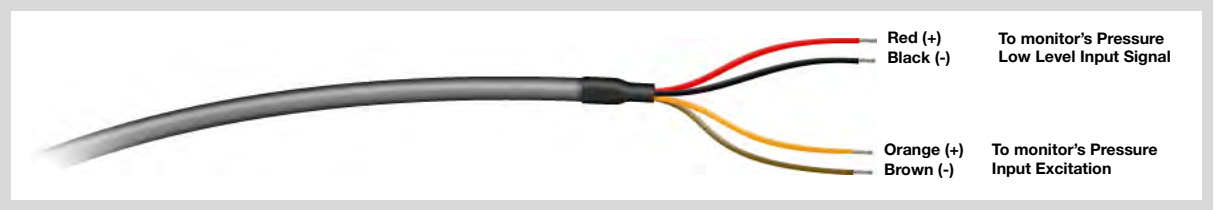


Figure 5-3: Low Level Pressure Output Interface Cable

For assistance in interfacing the IABP with external monitors, contact the MAQUET Technical Support Department.

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5.2 EXTERNAL CARDIOSAVE IABP DATA COMMUNICATIONS

5.2.1 OVERVIEW

CARDIOSAVE provides for external data communications for electronic medical records (HIS/CIS).

All external data communications are via the Ethernet Port on the back of the **CARDIOSAVE** Pump Console. Connect one end of an appropriate length ethernet cable to the RJ-45 Ethernet Port as shown in Figure: 5-4. Connect the other end to the hospital network ethernet port in the patient's room.

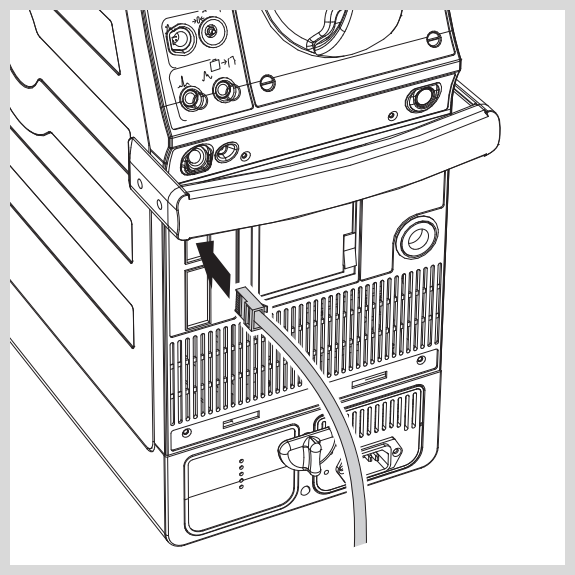


Figure 5-4: Connecting the ethernet cable

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5.2.2 HIS/CIS

HIS/CIS is a **CARDIOSAVE** communication feature that may be used by the hospital to create an electronic medical record. It cannot affect operator settings or alter patient parameters. The **CARDIOSAVE** IABP must be connected to a network that has access to data conversion/storage devices in order for this data to be effectively used.

To activate the HIS/CIS communication:

1. Ensure that a proper ethernet cable is connected between the Ethernet Port on **CARDIOSAVE** and the hospital network Ethernet Port.
2. Press the **Preferences** key on the **CARDIOSAVE** Touchscreen, then press the **Pump Options** key.



Figure 5-5: Example Pump Options menu

3. Press the **Network Connections** key, then press the **HIS/CIS** key.

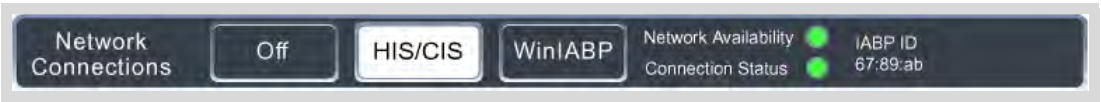


Figure 5-6: Example Network Connections menu

4. Verify that the status indicators are green next to **Network Availability** and **Connection Status**. A red status indicator indicates that a proper connection has not been made between the hospital network and the IABP.

Please refer to the CARDIOSAVE HIS/CIS Communication Protocol specification P/N: 0070-00-0701 for details on the data supplied via this communication. The hospital needs to develop or separately purchase any data equipment or software to convert the **CARDIOSAVE** HIS/CIS data to their individual usage.

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6 ACCESSORIES

This section of the manual lists accessories used with the IABP. Please refer to the appropriate sections of this manual for detailed instructions on how the accessories are used in conjunction with the system.

6.1 ACCESSORIES SHIPPED WITH CARDIOSAVE RESCUE

Description	Part Number	Quantity
CARDIOSAVE Accessory Kit	0020-00-0480-XX	1
CARDIOSAVE Battery Pack	0146-00-0097	2
CARDIOSAVE Helium Refilling Station	0998-00-0801	1
CARDIOSAVE Mounting Plate	0436-00-0223	1
CARDIOSAVE AC Transport Power Supply	0014-00-0085	1
AC Line Cord	0012-00-1823-XX*	1
Helium Tank(s)	See Helium Tanks in section 6.1.3	1

* *-01 110V - NA (Type B plug)*
-02 220V - EU (Type E/F plug)
-03 220V - CH (Type I plug)
-04 220V - UK (Type G plug)

6.1.1 CARDIOSAVE ACCESSORY KIT COMPONENTS

Description	Part Number	Quantity
CARDIOSAVE Blood Pressure Transducer Adapter Cable	0012-00-1815	1
CARDIOSAVE ECG Trunk Cable - 5 lead	0012-00-1812-XX	1
CARDIOSAVE ESIS Lead Wires 50" - 5 Lead (OP Rm)	0012-00-1814-XX	1
CARDIOSAVE Operators Manual - disc	0070-CD-0638	1
External Signal Cable	0012-00-0323	1
Thermal Recorder Chart Paper Starter Pack (pack of 4)	0683-00-0422-04	1
Helium Cylinder Washer	0348-00-0185	5
CARDIOSAVE Non-locking Male Luer Plug	0103-00-0717	5
Fiber Optic Cleaning Swabs (pack of 5)	0683-00-0519-02	1
Fiber Optic Connector Cleaner	0683-00-0521-01	1
CARDIOSAVE Plastic Weather Cover	0198-00-0087	1
1/16” Hex Key	0003-00-0060	1

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6.1.1.1 CARDIOSAVE BLOOD PRESSURE TRANSDUCER ADAPTER CABLE

The blood pressure transducer adapter cable is a 12-pin to 6-pin reusable adapter cable which allows **CARDIOSAVE Rescue** to interface with a blood pressure transducer and its transducer interface cable equipped with a 6-pin connector used by previous MAQUET/Datascope Corp. IABPs. The transducer signal pin connections for the 6-pin Cannon-style male plug are as follows: **Pin 1** = BP Excitation +, **Pin 2** = BP Signal +, **Pin 3** = BP Signal -, **Pin 4** = BP Excitation -, **Pin 5** = Shield and **Pin 6** = No connection.

Use only blood pressure transducers and transducer interface cables from third party suppliers which comply with ANSI/AAMI BP22:1994/(R) 2006, Blood Pressure Transducers. See section 7.15 for transducers specified as compliant with the CARDIOSAVE.

CAUTION:

Blood pressure transducers used with the IABP shall meet the standard for interchangeability and performance as defined by ANSI/AAMI BP22:1994/(R) 2006, Blood Pressure Transducers.

6.1.1.2 CARDIOSAVE ECG OPERATING ROOM LEAD WIRES

High performance (low noise), fully shielded ESIS (Electro-Surgical Interference Suppression) ECG patient lead wires are recommended for operating room use. The fully shielded ESIS lead wire set contains RF chokes to minimize the pick-up of interference and the risk of ESU-induced patient burns at electrode sites.

Note:

It is recommended to replace ECG lead wire sets when 10 or more sterilizations or cleanings have occurred.

6.1.1.3 EXTERNAL SIGNAL CABLE

The external signal cable is an unterminated stereo phone plug which can be custom wired for use with a compatible monitor which meets the minimum requirements described in Section 5.1.1 External Monitor ECG Requirements, and can be used for both high-level external ECG or Pressure Input.

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6.1.2 CARDIOSAVE BATTERY PACK

Battery Packs are a standard accessory with the IABP, but are shipped separately from the standard accessory kit.

Two (2) **CARDIOSAVE** Battery Packs are supplied with the IABP.

6.1.3 HELIUM TANKS

Helium tanks are a standard accessory with the IABP, but are shipped separately from the standard accessory kit.

Four different helium tanks are available. When either of the 90 liter refillable tanks or 99 liter refillable tanks are ordered, a quantity of three (3) is shipped. When the 140 liter disposable tank is ordered, a quantity of one (1) is shipped.

Description	Part Number
90 Liter Refillable Helium Tank (Qty. 3)	0075-02-0001-03 or 0075-02-0002-03*
99 Liter Refillable Helium Tank (Qty. 3)	0075-00-0024-03
140 Liter Disposable Helium Tank (Qty. 1)	0202-00-0104
99 Liter Empty Helium Tank (Qty. 3)	0075-00-0034-03

* *P/N 0075-02-0001-XX is BSI and APPAVE approved. P/N 0075-02-0002-XX is TUV approved.*

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7 SPECIFICATIONS

7.1 TRIGGERING

ECG/Pacer A: (R-Wave Detection Modes)	Trigger threshold is dynamically adjusted by the system for improved sensitivity and selectivity of R-Wave detection. Minimum threshold is 80 ±20µV reference to input (r.t.i.).
Pacer Blanking: (R-Wave Detection Modes)	ECG trigger: 44 mS Pacer A trigger: 100 mS
Tall T-Wave Rejection: (R-Wave Detection Modes)	Rejects all T-Waves 180 mS in duration, where the Q-T interval is ≤350 mS and the amplitude is ≤120% of QRS amplitude.
Pacer Rejection: (R-Wave Detection Modes)	Rejects all pacer pulses of amplitude ±2.0 mV to ±700 mV and durations between 0.1 mS to 2.0 mS with: **1** No tail (overshoot) **2** 4-100 mS time constant tails ≤2 mV (Tail amplitude not to exceed 25% of pacer pulse height)
Pressure:	Auto Threshold mode (default): Automatically adjusted to approximately 3/8 of the systolic pulse height, 7mmHg minimum. Manual Threshold mode: User adjustable between 7 and 30 mmHg, (±3 mmHg).
Pacer V / A-V:	V Pacer: fixed rate up to 180 bpm (no demand pacing). A-V Pacer: fixed rate up to 180 bpm when A-V intervals are appropriately shortened with increasing heart rate. (no demand pacing)
Internal Trigger:	80 ±1 bpm default setting. Adjustable from 40 - 120 bpm.
Electro-Surgical Interference Suppression (ESIS):	The operation of an Electro-Surgical Unit in the proximity of the IABP does not cause any unrecoverable malfunction or require user intervention.

Note:
Pacer tail peak amplitudes shall not exceed 25% of the pacer pulse amplitude per AAMI EC13-2002 paragraph 4.1.4.2.

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7.2 ECG CHANNEL

7.2.1 PATIENT LEAD ECG INPUT

Leads:	Auto OPERATION MODE: I, II, III, External Semi Auto OPERATION MODE: I, II, III, aVR, aVL, aVF, V, or External
Input Linear DC Offset Range:	±300 mV minimum
Linear Input Range:	±5.0 mV minimum
Input Impedance:	2.5 M Ohm minimum (single ended measurement for 0.67-40Hz)
Defibrillator Overload Protection:	Withstands up to 360 Joules when tested per IEC 60601-2-27:2005 Paragraph 17h)
Defibrillator Recovery Time:	Differential and Common Mode Test: 5 sec. maximum when tested per IEC 60601-2-27:2005 Paragraph 17h) 101.2 and 101.3 Electrode Polarization Test: 10 sec. maximum when tested per IEC 60601-2-27:2005 Paragraph 17h) 101.4
Lead Fault Detection:	Guaranteed Lead fault detection when any active electrode wire becomes open. Guarantee no lead fault with electrode impedance ≤ 51 K Ohms and with DC offsets ranging from -300 mV to +300 mV.
Noise:	< 30 µV p-p referred to input (r.t.i) with 51 K Ohm in parallel with 47 nF on each leg over ECG bandwidth.
Common Mode Rejection Ratio:	90 dB min. (with respect to non-isolated ground) at 50/60 Hz with an imbalance of up to 51 K Ohm in parallel with 47 nF and up to ±300 mV DC offset.

7.2.2 ECG WAVEFORM DISPLAY

Autoscaling of waveform amplitude:	Accommodates amplitudes up to ± 5 mV (minimum) without clipping. Inhibited from adapting to transient artifacts such as caused by: Electro-Surgical Unit, lead fault/change of lead, pacemaker pulse heights; A/D over-ranging caused by changes in electrode offset potentials, large ectopic beats, or defibrillator discharges. Does not re-scale when ECG base to peak amplitudes are less than 40 µV base to peak (r.t.i.)

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7.3 PRESSURE CHANNEL

7.3.1 IAB ARTERIAL PRESSURE TRANSDUCER INPUT

Input Sensitivity:	5.0 µV/V/mmHg (nominal)
Transducer Excitation:	+5 VDC ±5% (capable of supplying up to 25 mA)

7.3.2 ARTERIAL PRESSURE WAVEFORM DISPLAY

Autoscaling:	The Waveform is automatically scaled and displayed in the Arterial Pressure Waveform display window. Its associated pressure scale is annotated with numeric values at the lowest, middle and highest grid lines covering the vertical span of the scaled waveform.
Reference Line Range:	0-300 mmHg minimum (constrained to range of A.P. auto-scaling window)

7.3.3 DIGITAL ARTERIAL PRESSURE DISPLAYS

Resolution:	1 mmHg
Accuracy:	4 mmHg or 4%, whichever is greater. (Including BP22:2006 compliant transducer) 4 mmHg or 4%, whichever is greater. (Fiber-Optic IAB)
Range:	0 to 300 mmHg
Update Rate:	2 seconds (nominal)

(Assisted and Unassisted Systolic and Diastolic Pressures, Mean and Augmented Diastolic Pressures)

7.3.4 HYDRAULIC ARTERIAL PRESSURE ZERO

Zero Accuracy:	Waveform Display = ± 2 pixels (± 0.5mm) deviation from zero baseline at all pressure display scales. Display Indices = ± 0mmHg
Zero Range:	±120 mmHg minimum (waveform must be non-pulsatile)
Auto-Zero Time:	<3 Seconds

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7.3.5 LOW LEVEL OUTPUT SIGNAL CHARACTERISTICS

Pressure Range:	0 to +300 mmHg (minimum)
Accuracy:	4 mmHg or 4%, whichever is greater
Scale:	5.0 µV/V/mmHg ±4%
Frequency Response:	DC to 42 Hz ±15% (+0 to -3dB) for physiologic transducer. DC to 26 Hz ±15% (+0 to -3dB) for Fiber Optic Sensor IAB's
Output Impedance:	< 3 K Ohms DC to 5 kHz bandwidth
Noise:	0.5 mmHg p-p max. (0 to 1 KHz bandwidth) for physiologic transducer. 0.2 mmHg rms (0 to 26 Hz bandwidth) for Fiber Optic Sensor IAB's
Dielectric Withstand Voltage:	Minimum of 1500 V(rms) at 60 Hz for one minute with respect to chassis
Input Excitation Amplitude Range:	4 to 8 Volts DC minimum

7.4 AUDIBLE ALARM LEVEL

Alarm Sound Pressure Level:	Audible alarms are adjustable from less than 60 dBA to higher than 75 dBA.

7.5 HEART RATE METER

Usable Range:	15-214 bpm (ECG Trigger Source)
Resolution (Display):	1 bpm
Accuracy (Display):	±3 bpm or ±3%, whichever is greater.
Step Change Response Time:	10 Seconds max. (including 2 Sec. max. digital display update) to indicate new rate, to within 15 bpm, for a 40 bpm step change in rate tested from 80 to 120 bpm and from 80 to 40 bpm. Tested to IEC 60601-2-27 (ED. 2.0) Section 6.8.2.bb.

7.6 MONITOR AND TOUCHSCREEN DISPLAY CHARACTERISTICS

Type:	Color Liquid Crystal Display (LCD)
Resolution:	1024 Horizontal x 768 Vertical
Display Panel Size:	24.58 cm x 18.43 cm (9.68" x 7.26") 31 cm (12.1") diagonal
Viewing Angle (Typical):	Top 60°, Bottom 60°, Right 70°, Left 70°
Touchscreen:	8-Wire Resistive Touch

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7.7 PRINTER

Print Mechanism:	Thermal Array
Chart Paper Width:	50 mm
Chart Speeds:	25 mm/sec or 50 mm/sec (both ±5%)
Print Resolution:	600 dots per 25mm

7.8 POWER

7.8.1 POWER REQUIREMENTS

Power Consumption (AC Mains):	180 VA Nominal (150 Watts IABP @90 bpm, battery charged, not printing) 420 VA Maximum (350Watts IABP @150 bpm, printing, battery high rate charge)
Mains Voltage:	100 - 240 VAC ± 10% (automatic range switching)
Mains Frequency:	50/60 Hz ±3 Hz

7.8.2 BATTERY PACK

(P/N 0146-00-0097)

Type:	15 VDC (nominal), sealed, Lithium Ion, maintenance free
Run Time: (per pack, with full charge)	60 Minutes Minimum, 120 bpm, 22 +/- 5 degrees C 90 Minutes Typical - new battery, 90 bpm, 22 +/- 5 degrees C
Recharge Time:	5 hours per pack to 90% or greater capacity

Note:
A reduction in run time can occur over a battery's life for reasons such as age, storage temperature and discharge depth.

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7.9 HELIUM TANKS

7.9.1 90 LITER REFILLABLE HELIUM TANK

(P/N 0075-02-0001 (BSI, APPAVE approved))
(P/N 0075-02-0002 (TUV approved))

Capacity:	0.5 liters (30.5 in^3) @ 2900 psi (equivalent to approx. 90 std. liters @ 1 Bar (14.7 psi).
Weight (Full):	1.02 kg (2.25 lbs) nominal.
Endurance (Nominal):	2.7 months (filling every 2 hours. pumping continuously 24 hours. per day).
Approvals:	BSI, APPAVE, TUV, EEC per 84/526/EEC, BAM (Valve)
Container Specification:	7.06 cm x 23.19 cm (2.78" x 9.13") Overall Height 31.55 cm (12.42") aluminum cylinder pin-indexed yoke-type Medical Valve connection per ISO 407:1991 (E) para. 7.2.7/CGAV-1-1994 connection No. 930.

7.9.2 99 LITER REFILLABLE HELIUM TANK

(P/N 0075-00-0024-01) 1 pk.
(P/N 0075-00-0024-03) 3 pk.

Capacity:	0.69 liters (46.2 in^3) @ 2200 psi (equivalent to approx. 99 std. liters @ 1 Bar (14.7 psi)
Weight (Full):	1.13 kg (2.49 lbs) nominal
Endurance (Nominal):	3.0 months (filling every 2 hours. pumping continuously 24 hours. per day).
Compliance/Approvals:	U.S. DOT 3AL, Post Type Medical Valve U.S. CGA S-1.1-1994 U.S. CGA V-1-1994 U.S. CGA V-9-1991
Container Specification:	8.23 cm x 23.01 cm (3.24" x 9.06") Overall Height 31.39 cm (12.36") Service pressure of 153 Bar (2216 PSIG) aluminum cylinder pin-indexed yoke-type Medical Valve connection per ISO 407: 1991 (E) para. 7.2.7/CGAV-1-1994 connection NO. 930.

7.9.3 140 LITER DISPOSABLE HELIUM TANK

(P/N 0202-00-0104)

Capacity:	0.95 liters (58 in^3) @ 2200 psi (equivalent to approx. 140 std. liters @ 1 Bar (14.7 psi).
Weight (Full):	1.82 kg (4 lbs) nominal.
Endurance (Nominal):	4.25 months (filling every 2 hours. pumping continuously 24 hours. per day).
Compliance/Approvals:	U.S. DOT E8990, Post Type Medical Valve U.S. CGA S-1.1-1994.
Container Specification:	8.26 cm x 23.88 cm (3.25" x 9.40") Overall Height 31.37 cm (12.35"). Service pressure of 152 Bar (2200 psig) aluminum cylinder pin-indexed yoke-type Medical Valve connection per ISO 407: 1991 (E) para. 7.2.7/CGAV-1-1994 connection NO. 930.

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7.9.4 EMPTY 99 LITER HELIUM TANK, REFILLABLE

(P/N 0075-00-0034-03) 3 pk.

Volume:	42.6 cubic inches (698 cc) nominal.
Service Pressure:	153 Bar (2216 PSIG) nominal.
Weight:	2.49 lbs. (when full).
Endurance:	3.0 months when full (filling every 2 hours pumping continuously 24 hours per day.
Compliance/Approvals:	CGA V-9, Standard for Compressed Gas Cylinder Valve. CGA S-1.1, Pressure Relief Device Standard. CGA V-1, Standard for Compressed Gas Cylinder Valve Outlet and Inlet Connections.
Container Specification:	8.23 cm x 23.01 cm (3.24" x 9.06") Overall height 31.5 cm (12.4") aluminum cylinder pin-indexed yoke-type Medical Valve connection per ISO 407: 1991 (E) para. 7.2.7 / CGAV-1-1994 connection No. 930.

7.10 BATTERY CHARGING STATION

(P/N 0998-00-0802)

Voltage:	100 - 240 VAC
Frequency:	50/60 Hz
Current:	0.7 - 1.7 A

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7.11 PHYSICAL CHARACTERISTICS

7.11.1 WEIGHT*

	kg	lbs
■ Monitor:	3.6	8
■ Battery Pack (0146-00-0097):	1.4	3
■ Helium Tank (99 liter, full):	1.1	2.5
■ Pump Console	17.7	39
Transport Configuration: (including transport, and monitor with 2 batteries)	24.1	53

** All weights ±5%*

7.11.2 DIMENSIONS*

Transport and Display	
Display Closed:	57.2 cm H x 40.6 cm D x 33.0 cm W 22.5" H x 16" D x 13" W
Display Open 90°:	78.0 cm H 30.7" H

** All dimensions ± 5%. Dimensions include the Pneumatic Module.*

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7.12 ENVIRONMENTAL REQUIREMENTS

CAUTION:

After being stored at low temperature, allow CARDIOSAVE Rescue to be exposed to room temperature for at least 30 minutes before operating on battery power.

7.12.1 OPERATING AMBIENT

Operating Temperature:	10 °C to 40 °C (50 °F to 104 °F)
Operating Humidity:	15% to 85% Relative Humidity (non-condensing)
Operating Altitude:	-1250 feet to 12,000 feet (795 mmHg to 483 mmHg) (1060 hPa to 644 hPa)

Note:

In nature, the range of humidity specified is not found for all specified temperatures. Performance shall be verified at discrete temperature and humidity combinations per "ECRI -PB- 296 892" guidelines.

7.12.2 STORAGE AMBIENT (IABP OFF AND NOT CONNECTED TO AC POWER SOURCE)

Storage Temperature:	-20 °C to 60 °C (-4 °F to 140 °F)
Storage Humidity:	15% to 95% Relative Humidity (non-condensing)
Storage Altitude:	-1250 feet to 12,000 feet (795 mmHg to 483 mmHg) (1060 hPa to 644 hPa)

Note:

In nature, the range of humidity specified is not found for all specified temperatures. Performance shall be verified at discrete temperature and humidity combinations per “ECRI -PB- 296 892" guidelines.

7.12.3 SHIPPING

International Safe Transit Association (ISTA) Pre-shipment Test Procedure, Procedure 2B, 2008.

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7.12.4 VIBRATION/SHOCK

Sinusoidal Vibration:	EN 60068-2-6:2008 - Environmental Testing, Part 2 Test Fc: Vibration (sinusoidal) EN13718-1:2008 (E) section 4.6.2 which cites ISO 7137:1995. Test method is defined per RTCA/DO-160F par 8.5.1 Cat S, fuselage zone M.
Random Vibration:	FDA "Reviewer Guidance for Pre-Market Notification Submissions" section n.4 (iii) specified random vibration test per IEC 68-2-34, frequency range 20 to 500 Hz, ASD 0.02g^2/Hz, duration 9 min. Nonoperational. NOTE: IEC 68-2-34 has been superseded by IEC 60068-2-64:2008. For ground applications: EN 1789:2007 "Medical vehicles and their equipment - Road ambulances". For aircraft transport: RTCA/DO-160F "Environmental Conditions and Test Procedures for Airborne Equipment".
Bump Test:	EN 1789:2007 - Medical Vehicles and their equipment - Road ambulances: Functional shock test per IEC 60068-2-29, Test Eb, 15g, duration 6 ms, 1000 times in normal operating position.
Rough Handling Test:	Rough Handling Test - IEC 60601-1 (1988), sub-clause 21.6, with Amendment 1 (1991) and Amendment 2 (1995)
Shock - Operational:	RTCA/DO-160F Shock, Category B Operational standard test for fixed wing and helicopter: 6g, duration 11ms, saw-tooth, 3 times in each orientation
Shock - Non-Operational:	EN60068-2-27:2008, Environmental Testing, Part 2 Test Ea and guidance: Shock per Table 1: 20g, duration 11 ms, saw-tooth, one in each orientation (6 total, can use dummy load)
Crash Test:	EN 1789:2007 - Medical Vehicles and their equipment. RTCA/DO-160F - Environmental Conditions and Test Procedures for Airborne Equipment: Crash safety test for fixed wing and helicopter, 20g, duration 6ms, saw-tooth, one in each orientation (6 total, can use dummy load) Test also satisfies EN 1789:2007 - Medical Vehicles and their equipment, section 6.3.5.
Elevator Threshold Test:	ECRI PB-296892*, Section AIII.3.1
Barrier Impact Test:	ECRI PB-296892*, Section AIII.3.2.2
Drop Test:	ECRI* AIII.3.3 for Class 2 Device (Test 1 - steel ball drop / device on floor)
Tip-over Test:	IEC 60601-1, 1988 (plus Amendment 1:1991, Amendment 2: 1995, and Corrigendum, June 1995) Section 4, Clause 24, Page 119

** U.S. Department of Commerce, National Technical Information Service, PB-296 892 "Development of Environmental Test Methods for Non-Implantable Devices" by Emergency Care Research Institute (ECRI), Prepared for Food and Drug Administration, Apr.1979.*

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7.13 CARDIOSAVE RESCUE ELECTRO-MAGNETIC COMPATIBILITY

CARDIOSAVE Rescue meets the requirements of EN 60601-1-2:2007.

CARDIOSAVE Rescue must be put into service according to following special EMC cautions.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS

CARDIOSAVE Rescue is intended for use in the electromagnetic environment specified as follows. The customer or the user of **CARDIOSAVE Rescue** should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	**CARDIOSAVE Rescue** uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	**CARDIOSAVE Rescue** is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

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GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

CARDIOSAVE Rescue is intended for use in the electromagnetic environment specified below. The customer or the user of **CARDIOSAVE Rescue** should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of **CARDIOSAVE Rescue** requires continued operation during power mains interruptions, it is recommended that **CARDIOSAVE Rescue** be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

U_T is the a.c. mains voltage prior to application of the test level.

ESSENTIAL PERFORMANCE

All **CARDIOSAVE Rescue** IABP functions are consider essential performance.

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GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

CARDIOSAVE Rescue is intended for use in the electromagnetic environment specified below. The customer or the user of **CARDIOSAVE Rescue** should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of **CARDIOSAVE Rescue**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 KHz to 80 MHz	10 V	$d = 0.35 \times \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m	$d = 0.35 \times \sqrt{P}$ 80 MHz to 800 MHz $d = 0.7 \times \sqrt{P}$ 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 1 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which **CARDIOSAVE Rescue** is used exceeds the applicable RF compliance level above, **CARDIOSAVE Rescue** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating **CARDIOSAVE Rescue**.

[b] Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 10V(rms)

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RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE CARDIOSAVE RESCUE

CARDIOSAVE Rescue is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of **CARDIOSAVE Rescue** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and **CARDIOSAVE Rescue** as recommended below, according to the maximum output power of the communications equipment.

	Separation distance according to frequency of transmitter m (meters)		
Rated maximum output power of transmitter W (watts)	**150 KHz to 80 MHz** $d = 0.35 \times \sqrt{P}$	**80 MHz to 800 MHz** $d = 0.35 \times \sqrt{P}$	**800 MHz to 2.5 GHz** $d = 0.7 \times \sqrt{P}$
0.01	0.035	0.035	0.07
0.1	0.11	0.11	0.22
1	0.35	0.35	0.7
10	1.1	1.1	2.2
100	3.5	3.5	7

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

CARDIOSAVE Rescue meets the following requirements of RTCA/DO-160F.		
Radiated Emissions:	RTCA/DO-160F, Sec.21, Category B	100 MHz - 6 GHz
Radiated Susceptibility:	RTCA/DO-160F, Sec.20, Category T	100 MHz to 8 GHz 5V/m, >90% AM at 1 KHz
Emission of Radio Frequency Energy:	EUROCAE ED-14F, Sec. 21, Category B	100MHz-6GHz
Radio Frequency Susceptibility:	EUROCAE ED-14F, Sec. 20, Category I	100MHz-8GHz >90% AM at 1 KHz

7.13.1 ESU REJECTION

Performance During:	The operation of an Electro-Surgical Unit in the proximity of **CARDIOSAVE Rescue** does not cause any unrecoverable malfunction or require user intervention.

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7.14 BATTERY CHARGING STATION ELECTRO-MAGNETIC COMPATIBILITY

The **Battery Charging Station** meets the requirements of EN 60601-1-2:2007.

The **Battery Charging Station** must be put into service according to following special EMC cautions.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS

The **Battery Charging Station** is intended for use in the electromagnetic environment specified as follows. The customer or the user of the **Battery Charging Station** should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The **Battery Charging Station** uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The **Battery Charging Station** is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

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GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

The **Battery Charging Station** is intended for use in the electromagnetic environment specified below. The customer or the user of The **Battery Charging Station** should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the **Battery Charging Station** requires continued operation during power mains interruptions, it is recommended that the **Battery Charging Station** be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

U_T is the a.c. mains voltage prior to application of the test level.

ESSENTIAL PERFORMANCE

All the **Battery Charging Station** IABP functions are consider essential performance.

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GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

The **Battery Charging Station** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Battery Charging Station** should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the **Battery Charging Station**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 KHz to 80 MHz	3 V	$d = 0.35 \times \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 0.35 \times \sqrt{P}$ 80 MHz to 800 MHz $d = 0.7 \times \sqrt{P}$ 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 1 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **Battery Charging Station** is used exceeds the applicable RF compliance level above, the **Battery Charging Station** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the **Battery Charging Station**.

[b] Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 10V(rms)

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RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE CARDIOSAVE RESCUE

The **Battery Charging Station** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **Battery Charging Station** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **Battery Charging Station** as recommended below, according to the maximum output power of the communications equipment.

	Separation distance according to frequency of transmitter m (meters)		
Rated maximum output power of transmitter W (watts)	**150 KHz to 80 MHz** $d = 0.35 \times \sqrt{P}$	**80 MHz to 800 MHz** $d = 0.35 \times \sqrt{P}$	**800 MHz to 2.5 GHz** $d = 0.7 \times \sqrt{P}$
0.01	0.035	0.035	0.07
0.1	0.11	0.11	0.22
1	0.35	0.35	0.7
10	1.1	1.1	2.2
100	3.5	3.5	7

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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7.15 AGENCY COMPLIANCE

CARDIOSAVE Rescue is designed to comply with the following agency standards:

- EN60601-1:1990
- EN60601-1-2:2007
- EN60601-1-8:2007
- EN60601-2-34:2000[1, 2]
- UL 60601-1:2003
- CSA C22.2 - No. 601.1 - M90
- CSA C22.2 - No. 601.1S1 - 94
- EC Medical Device Directive 93/42/EEC
- WEEE Compliance: this system is in compliance with European Community Directive, 2002/96/EC with regard to waste management.
- RoHS II Directive (2011/65/EU): **CARDIOSAVE Rescue** Intra-Aortic Balloon Pumps imported into the European Union as of July 22, 2014 are compliant to the RoHS II Directive. The RoHS compliant pumps have serial number prefix “CH.”

1 When tested with Baxter, Model PX 600 or Abbott®, Model 42582-05 disposable pressure transducers.

2 The technology and auto calibration feature associated with the fiber-optic sensor necessitates deviations from test requirements of sections 51.102.1 (Sensitivity, repeatability, non-linearity, drift and hysteresis) and 51.102 2 (Accuracy of systolic and diastolic pressure) of the IEC 60601-2-34:2000 standard. The test requirements of these two sections were fulfilled via equivalent test methodologies developed by Datascope Corp.

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7.16 SAFETY DESIGNATIONS

7.16.1 SAFETY DESIGNATIONS PER IEC 60601-1 STANDARD

Type of protection against electric shock:	Class I and Internal Electric Power Source. Where the integrity of the external protective earth conductor arrangement is in doubt, operate equipment from its internal electric power source.
Degree of protection against electric shock:	ECG, Balloon, Pressure Transducer, and IAB sensor: Type CF defibrillator proof.
Supply Connection:	AC Operation: 100 - 240 VAC (nominal) 4.2 - 2.1 A; 50/60 Hz Internal Battery Operation: 15 VDC Internal Battery
Mode of Operation:	Continuous
Protection Against Hazards of Explosion:	Not protected (Ordinary)
Protection Against Ingress of Liquids:	IPX0
Degree of Electrical Connection Between Equipment and Patient:	Equipment designed for direct electrical and non-electrical connection to the patient.
Degree of Mobility:	Mobile
Degree of Safety of Application in the Presence of a Flammable Anesthetic:	Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.

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EC REP

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