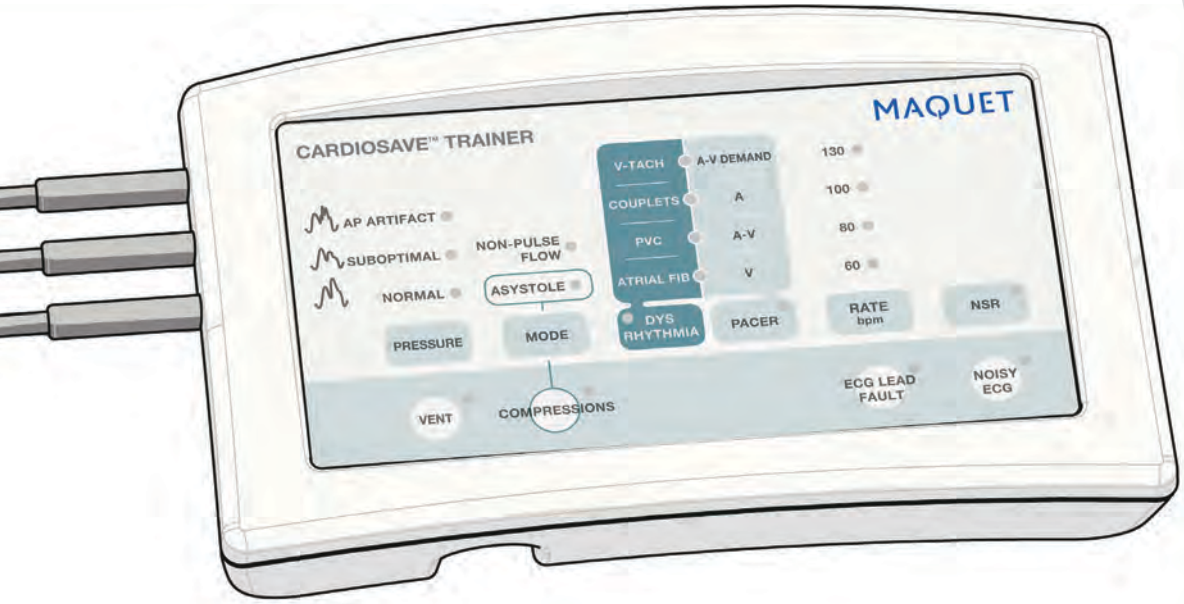
MAQUET
GETINGE GROUP

CARDIOVASCULAR

CARDIOSAVE™
INTRA-AORTIC BALLOON PUMP TRAINER
USER MANUAL



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INTRODUCTION

This manual provides instructions for the setup, usage, and training simulations with the **CARDIOSAVE Trainer**.

This section provides an introduction to the **CARDIOSAVE Trainer**. Chapter One of this manual covers the features, functionality and installation of the **CARDIOSAVE Trainer**. The second chapter covers the general use of the keypad, ECG and Pressure Signals, and specifications. The third chapter offers simulation procedures for training scenarios, and the final section covers the warranty for the Trainer.

DOCUMENT CONVENTIONS

Please read and adhere to all warnings, precautions and notes listed here and 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 **NOTE** is provided in the appropriate areas throughout the manual when additional general information is applicable.

WARNINGS

WARNING:

The **CARDIOSAVE Trainer** is intended only as a training device. It should never be connected to **CARDIOSAVE** when the pump is connected to a patient.

NOTES

Note:

In order to accurately evaluate alarm performance with the **CARDIOSAVE Trainer**, it is important to simulate real use conditions. Of particular importance is the backpressure seen by **CARDIOSAVE** during clinical use. This backpressure simulates patient blood pressure and its affects on the gas dynamics and thereby, the alarm detection process.

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1 GETTING ACQUAINTED WITH THE CARDIOSAVE TRAINER

1.1 CARDIOSAVE TRAINER GENERAL DESCRIPTION

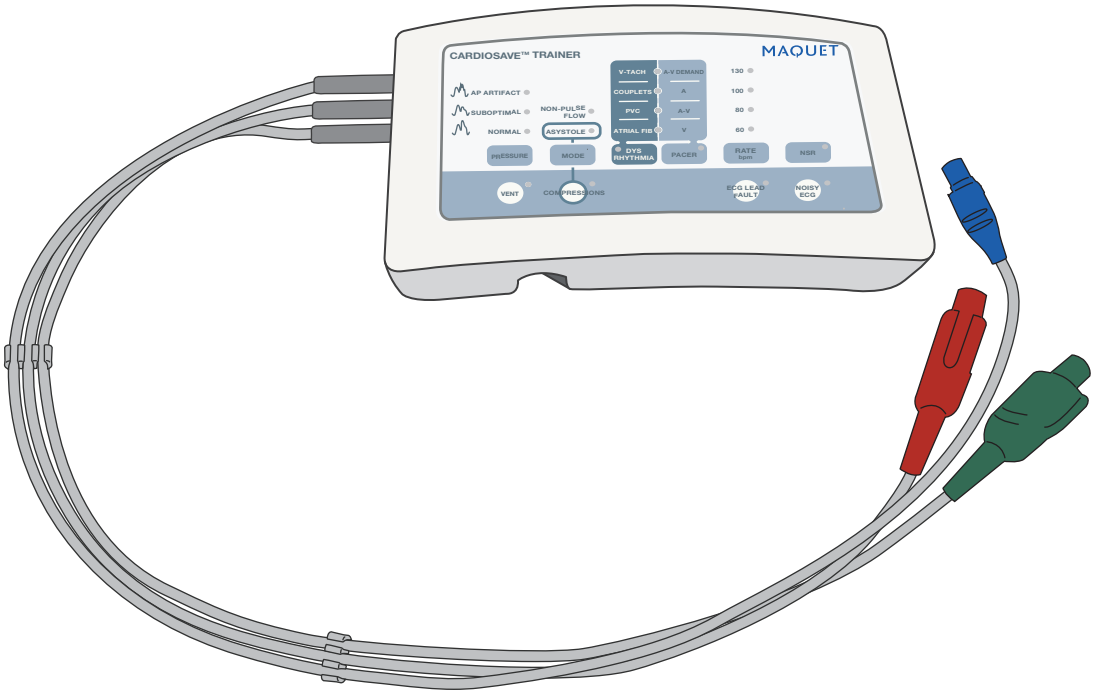

Figure 1-1: CARDIOSAVE Trainer

The **CARDIOSAVE Trainer** is not a medical device.

The **CARDIOSAVE Trainer** is used by health care clinicians and clinical representatives as an educational tool to simulate patient waveforms on **CARDIOSAVE**, which aids in the education and training of the **CARDIOSAVE** Intra-Aortic Balloon Pump.

The **CARDIOSAVE Trainer** is also used by the MAQUET sales team and clinical representatives during sales demonstrations to simulate patient waveforms on **CARDIOSAVE** for potential customers who are interested in purchasing the **CARDIOSAVE** Intra-Aortic Balloon Pump.

This Trainer supports only the **CARDIOSAVE** Intra-Aortic Balloon Pump. It does not and is not expected to support earlier generation MAQUET/Datascope IABPs.

Note:
When a **CARDIOSAVE Trainer** is in use, **CARDIOSAVE** displays the **Trainer in Use - NOT FOR CLINICAL USE!** advisory message on the screen.

WARNING:

The CARDIOSAVE Trainer is intended only as a training device. It should never be connected to CARDIOSAVE when the pump is connected to a patient.

1.2 PRODUCT CONTROLS AND FUNCTIONALITY

1.2.1 PRESSURE KEY

The **PRESSURE** key controls various conditions that impact the appearance of the arterial pressure (AP) waveforms.

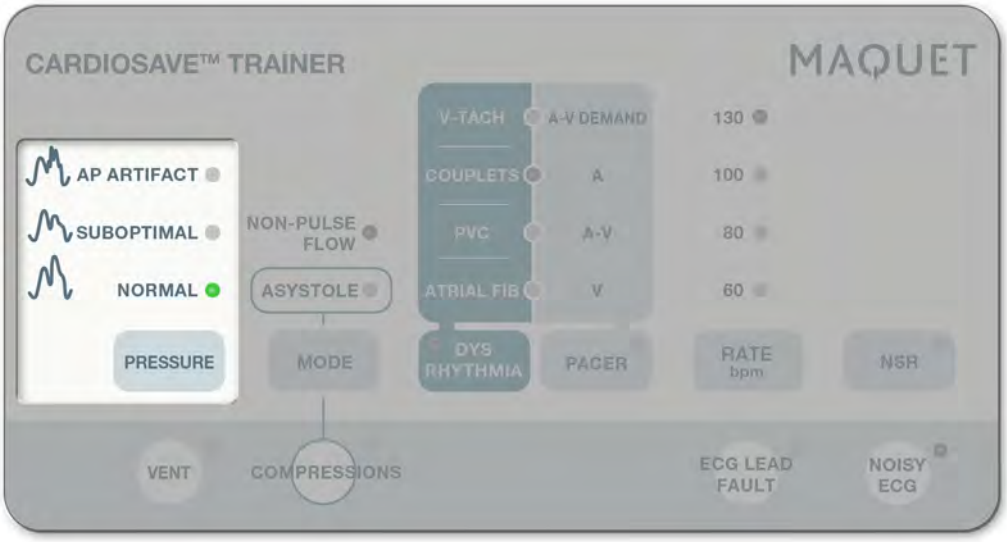

Figure 1-2: CARDIOSAVE Trainer Pressure Key Functions

Each time the **PRESSURE** key is pressed, it advances to the next pressure state in the group:

- Normal
- Suboptimal
- AP Artifact
  - Underdamped Waveform
  - Overdamped Waveform

Note:
When a pressure state is active, the LED light next to it is illuminated or blinking.

Key Presses	Pressure State	Result
First Press	Suboptimal	Produces an augmented waveform that is approximately 10 mmHg below the systolic peak pressure, with a steady LED.
Second Press	AP Artifact	Produces an underdamped AP waveform with a steady LED.
Third Press	AP Artifact	Produces an overdamped AP waveform and a blinking LED.
Fourth Press	Returns to Normal	Pressure returns to normal state, which simulates an optimal AP waveform.

1.2.2 MODE KEY

The **MODE** key simulates no or low states of Ventricular output.

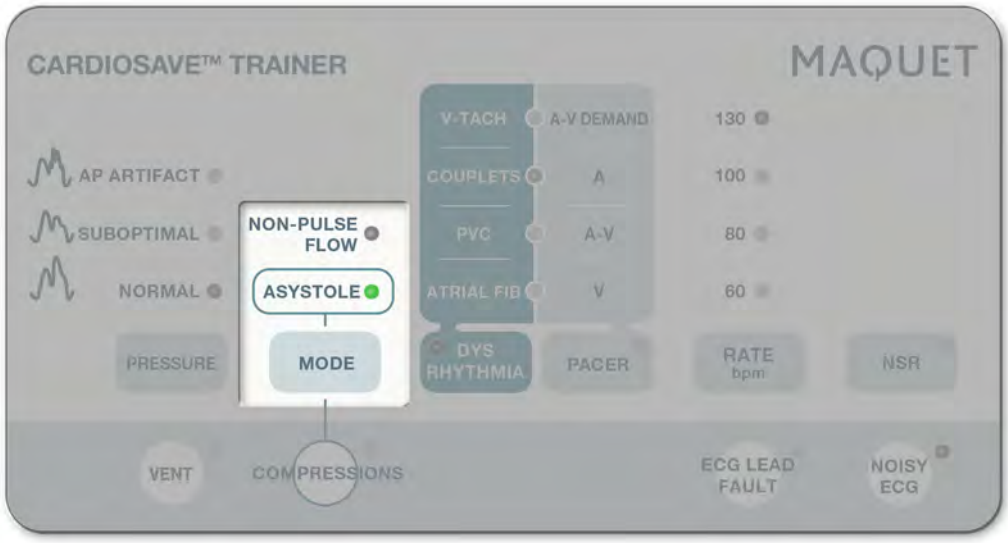

Figure 1-3: CARDIOSAVE Trainer Mode Key Functions

Each time the **MODE** key is pressed, it moves the Trainer to the next Mode in the group:

- Inactive
- Asystole
- Non-pulse flow

Note:
In relation to the Trainer, “inactive” means that asystole, and non-pulsatile flow is not active.

Key Presses	State	Result
Default Setting	Inactive	Trainer is in the inactive state with no LEDs illuminated.
First Press	Asystole	Produces a flatline ECG and an Asystolic AP waveform.
Second Press	Non-pulse Flow	Produces non-pulsatile AP waveform, typical when using a non-pulsatile Ventricular Assist Device.
Third Press	Returns to Inactive	LEDs are turned off and returns to the inactive state.

1.2.3 DYSRHYTHMIA KEY

The **DYSRHYTHMIA** key simulates various cardiac rhythms used to demonstrate the pump's behavior during common dysrhythmias.

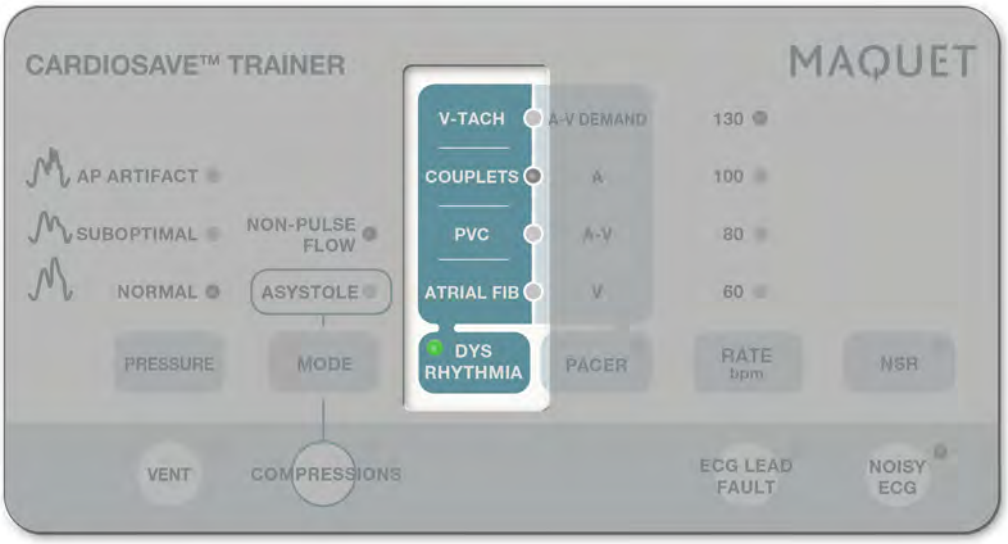

Figure 1-4: CARDIOSAVE Trainer Dysrhythmia Key Functions

Each time the **DYSRHYTHMIA** key is pressed, it moves the Trainer to the next Dysrhythmia selection in the group (Atrial Fib, PVC, Couplets and V-Tach). The Dysrhythmia LED remains lit as well when the user cycles through each state of Dysrhythmia.

Note:
When PVC, Couplets, or V-Tach is illuminated, the most recently selected heart rate is enabled.

Key Presses	State	Result
First Press	Atrial Fib	Dysrhythmia and the Atrial Fib LEDs are illuminated. Turns off NSR LED, if lit.
Second Press	PVC	Dysrhythmia and the PVC LEDs are illuminated.
Third Press	Couplets	Dysrhythmia and the Couplets LEDs are illuminated.
Fourth Press	V-Tach	Dysrhythmia and the V-Tach LEDs are illuminated.
Fifth Press	Deactivates Dysrhythmia state	Dysrhythmia LEDs are turned off, and the NSR LED is illuminated. The system goes into a normal sinus rhythm.
Press NSR key	Deactivates Dysrhythmia state	Dysrhythmia LEDs are turned off, and the NSR LED is illuminated. The system goes into a normal sinus rhythm.

1.2.4 PACER KEY

The **PACER** key simulates various pacemaker patterns. It is used to demonstrate the pump's management of common pacing conditions.

Figure 1-5: CARDIOSAVE Trainer Pacer Key Functions

Each time the **PACER** key is pressed, the Trainer cycles to the next state in the series: Ventricular (V), Atrio-Ventricular (A-V), Atrial (A) and Atrio-Ventricular Demand (A-V DEMAND). The pacer is simulated at a fixed rate of 80 BPM.

Key Presses	State	Result
Default	Inactive	Pacer LED is off.
First Press	Ventricular (V)	Pacer and the V LEDs are illuminated. Turns off NSR LED, if lit.
Second Press	Atrio-Ventricular (A-V)	Pacer and the A-V LEDs are illuminated.
Third Press	Atrial (A)	Pacer and the A LEDs are illuminated.
Fourth Press	A-V Demand	Pacer and the A-V Demand LEDs are illuminated.
Fifth Press	Deactivates Pacer state	Pacer LEDs are turned off, and the NSR LED is illuminated. System goes into a normal sinus rhythm.
Press NSR key	Deactivates Pacer state	Pacer LEDs are turned off, and the NSR LED is illuminated. System goes into a normal sinus rhythm.

1.2.5 RATE BPM KEY

The **RATE BPM** key allows the user to simulate and make changes to the base heart rate.

Figure 1-6: CARDIOSAVE Trainer Rate Key Functions

When the Trainer is either in the normal sinus rhythm mode or generating a ventricular rhythm (PVC, Couplets, or V-Tach), press the **RATE** key to change the rate at which the simulated waveforms are generated. The presence of ventricular rhythms can cause the instantaneous rate to be higher than the indicated average rate due to the short R-R interval preceding a ventricular beat.

Note:
This key is not accessible during paced rhythms or atrial fibrillation.

Key Presses	State	Result
Default	80 BPM	80 LED is illuminated.
First Press	100 BPM	100 LED is illuminated.
Second Press	130 BPM	130 LED is illuminated.
Third Press	60 BPM	60 LED is illuminated.
Fourth Press	80 BPM	80 LED is illuminated.

Note:
Pressing the **RATE** key enacts a continuous loop of heart rate selections (60, 80, 100, 130). Pressing the **NSR** key when 60, 100, or 130 is selected, the system reverts back to a heart rate of 80.

Note:
For normal sinus rhythm mode, the rates are +/- 2 bpm.

1.2.6 NSR KEY

The **NSR** key conveniently returns the system back to a normal sinus rhythm from other Trainer modes.

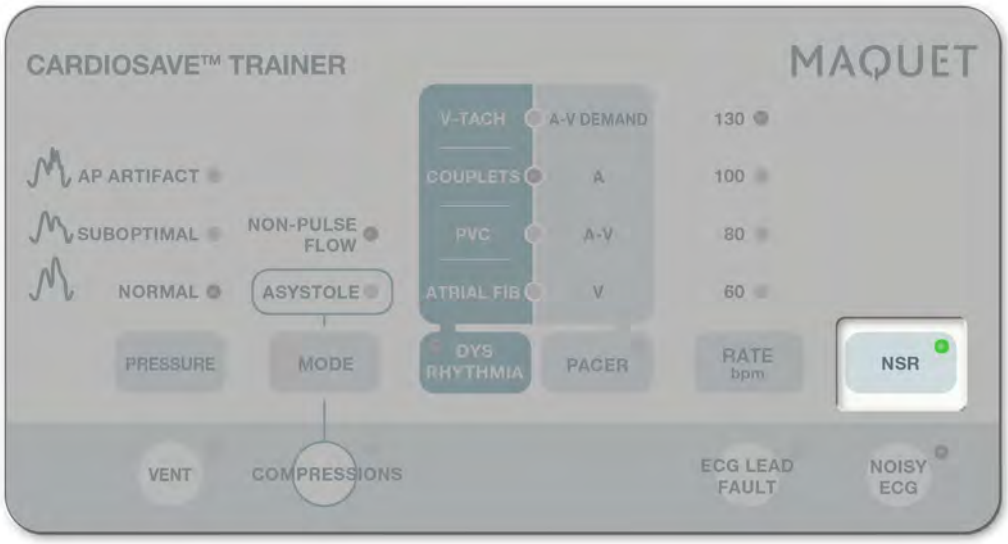

Figure 1-7: CARDIOSAVE Trainer NSR Key

Each time the **NSR** key is pressed (if not already illuminated), the Trainer returns to a normal sinus rhythm with a heart rate of 80.

Key Presses	State	Result
Any Press	Returns to normal sinus rhythm (if NSR key is not already illuminated).	NSR LED is illuminated. Any asystole, dysrhythmia, and pacer modes are terminated.
Any Press	Resets RATE	NSR LED is illuminated, or remains illuminated. Resets RATE to 80 BPM.

1.2.7 VENT KEY

The **VENT** key simulates the arterial pressure transducer being vented to atmospheric pressure.

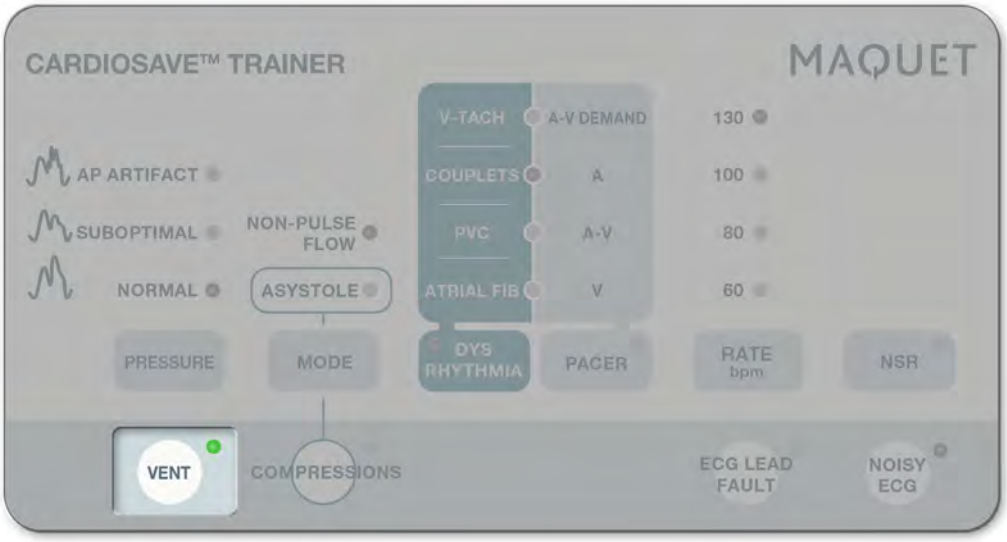

Figure 1-8: CARDIOSAVE Trainer Vent Key

Each time the **VENT** key is pressed, the Trainer simulates a flat lined 0(+/-10) mmHg output.

Key Presses	State	Result
Default Setting	Inactive	VENT LED is not illuminated. AP waveform is output as normal.
First Press	Active	VENT LED is illuminated. Overrides the output of the AP waveform and simulates a flatlined 0(+/-10) mmHg output.
Second Press	Returns to inactive	VENT LED is turned off and returns to the default state of a normal AP waveform output.

1.2.8 COMPRESSIONS KEY

The **COMPRESSIONS** key simulates the arterial pulses that can be generated by the chest compressions associated with CPR (Cardiopulmonary Resuscitation).

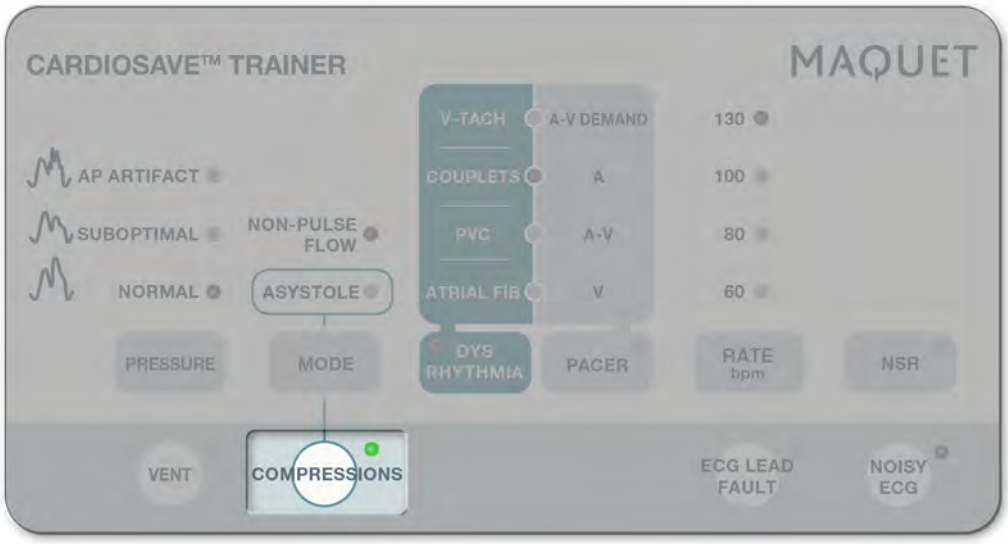

Figure 1-9: CARDIOSAVE Trainer Compressions Key

If the Trainer is outputting in Asystole mode when the **COMPRESSIONS** key is pressed, the Trainer simulates chest compressions. The AP waveform shows increases in pressure that correspond to a heart rate of 100 BPM. If the pump is assisting, the AP waveform shows the effects of augmentation on the compression pulses.

Note:
The **COMPRESSIONS** key is only enabled when in Asystole mode. When active this key also disables the **RATE** key.

Key Presses	State	Result
Default	Inactive	COMPRESSIONS LED is off.
First Press	Active, if in Asystole mode.	COMPRESSIONS LED is illuminated and chest compressions are simulated.
Second Press	Returns to inactive, if in Asystole mode.	Deactivates compressions, and LED is turned off.

1.2.9 ECG LEAD FAULT KEY

The **ECG LEAD FAULT** key simulates the disconnection of multiple ECG skin electrodes.

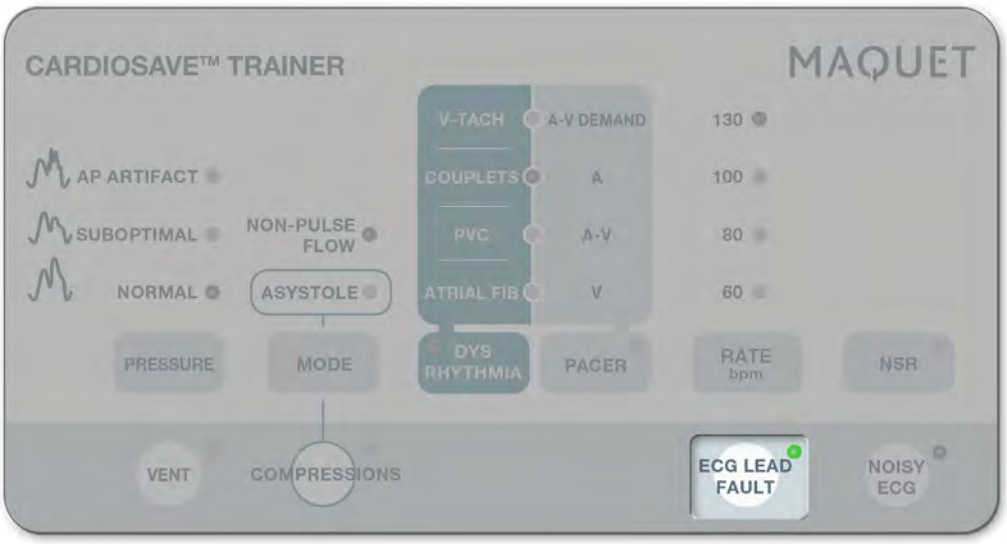

Figure 1-10: CARDIOSAVE Trainer ECG LEAD FAULT Key

Each time the **ECG LEAD FAULT** key is pressed, the Trainer simulates an ECG signal that has faulted, resulting in a flatlined ECG.

Key Presses	State	Result
Default Setting	Inactive	ECG Lead Fault is not illuminated.
First Press	Active	ECG Lead Fault is illuminated. Simulates an ECG signal that is faulted and flatlined.
Second Press	Returns to inactive	LED is turned off and ECG signal is restored.

1.2.10 NOISY ECG KEY

The **NOISY ECG** key simulates a poor quality ECG signal used to demonstrate the pump's management of patient signal selection.

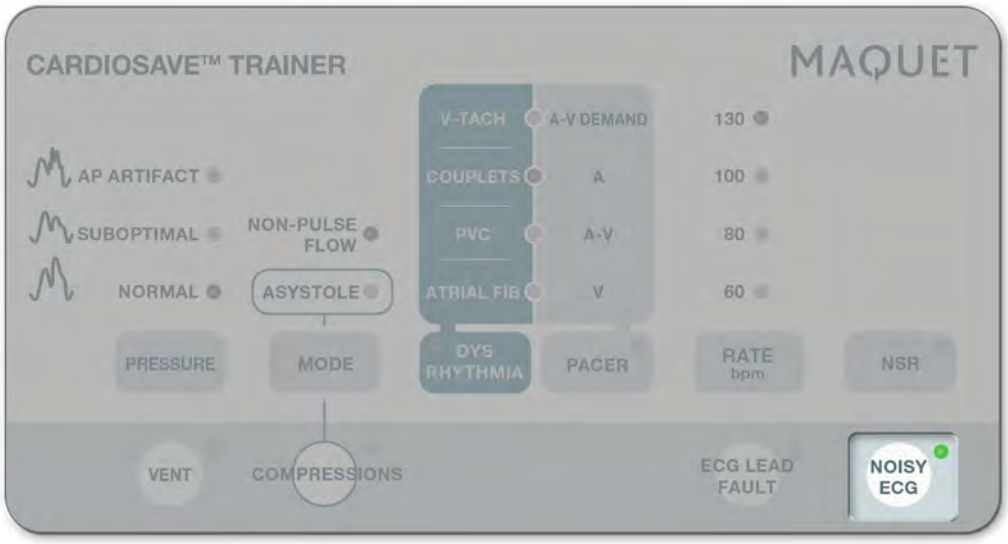

Figure 1-11: CARDIOSAVE Trainer NOISY ECG Key

When the **NOISY ECG** key is pressed and the LED is illuminated, the Trainer simulates a noisy ECG signal.

Key Presses	State	Result
Default Setting	Inactive	Noisy ECG LED is not illuminated, and the ECG signal is normal.
First Press	Active	Noisy ECG LED is illuminated, and noise is simulated on the ECG signal.
Second Press	Returns to inactive	LED is turned off, and the ECG signal returns to normal.

1.3 CONNECTORS AND CABLES

The Trainer plugs into the Direct ECG and Pressure Inputs on the back panel of **CARDIOSAVE**. The Trainer Connector plugs into the Trainer Input, also on the back of the pump. **CARDIOSAVE** must be powered on in order for the Trainer to function.

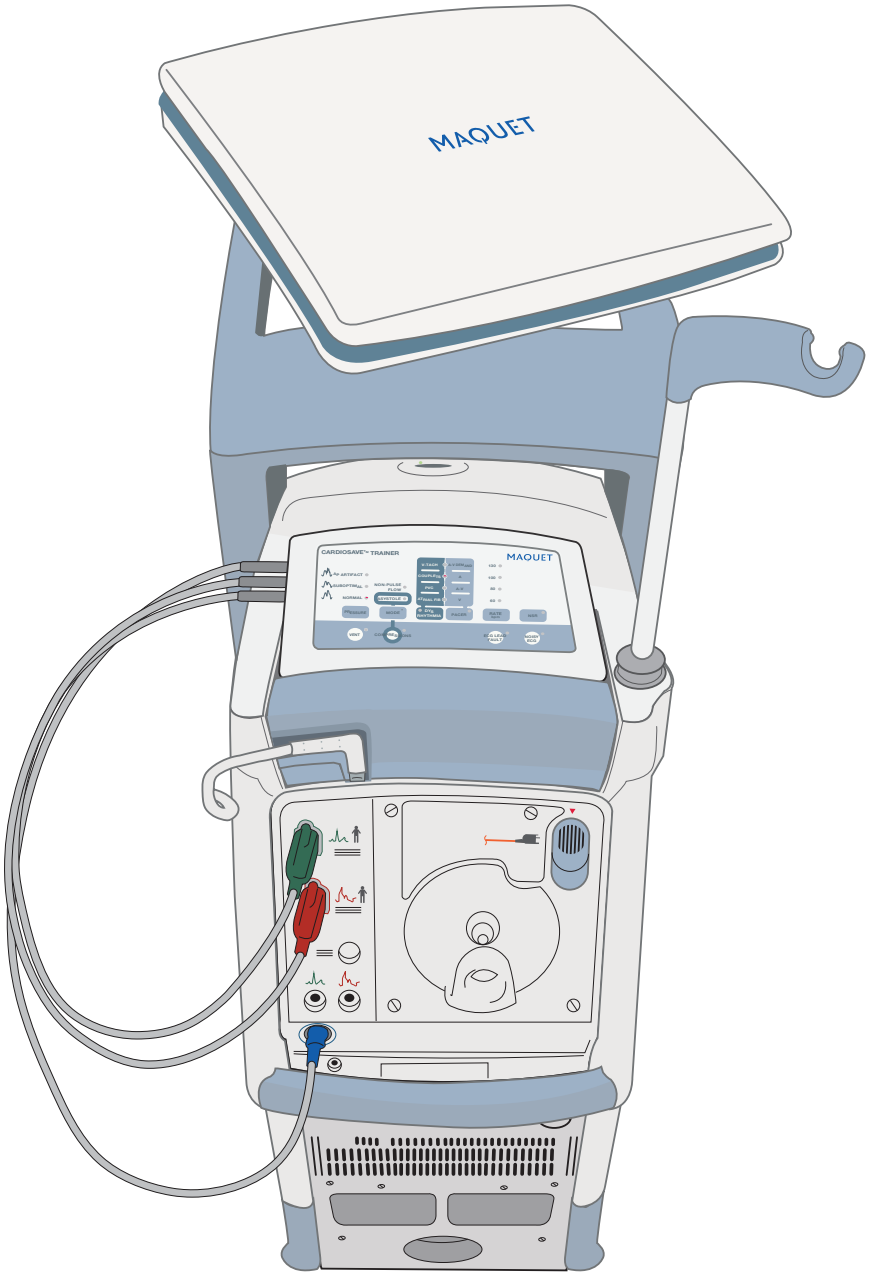

Figure 1-12: CARDIOSAVE IABP with the Trainer mounted and connected

WARNING:

The CARDIOSAVE Trainer is intended only as a training device. It should never be connected to CARDIOSAVE when the pump is connected to a patient.

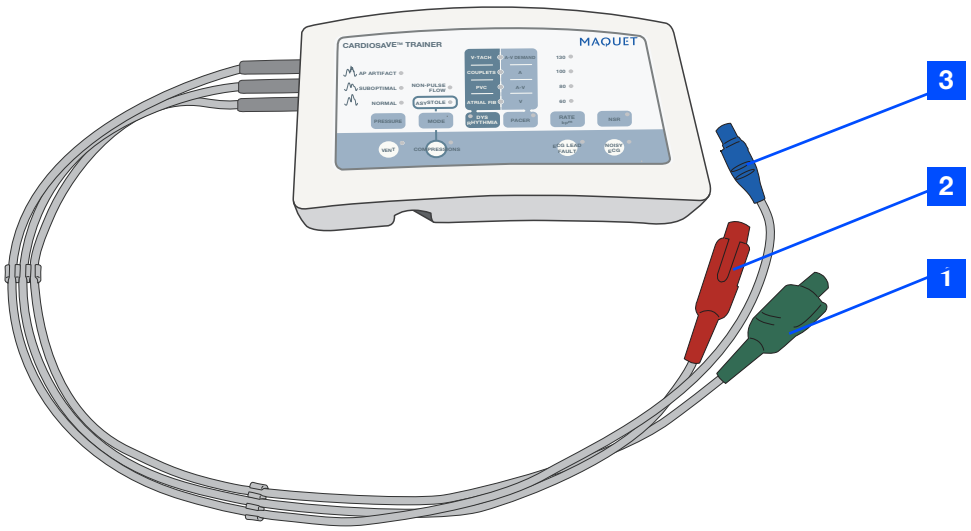

Figure 1-13: CARDIOSAVE Trainer with connector and cable callouts

1. ECG Connector

A 12-pin male connector (green) that mates with the pump console's ECG input.

2. Blood Pressure (BP) Connector

A 12-pin male connector (red) that mates with the pump console's pressure input connector.

3. Trainer Connector

A 12-pin connector (blue) that mates with the pump console's Trainer input. The Trainer Input Cable must be connected in order to display patient waveforms.

1.4 INSTALLATION

The **CARDIOSAVE Trainer** plugs directly into the ECG, Pressure and Trainer inputs on the back pannel of the **CARDIOSAVE** IABP.

- The GREEN ECG connector from the Trainer plugs into location 1.
- The RED BP connector from the Trainer plugs into location 2.
- The BLUE Trainer Connector from the Trainer plugs into location 3.

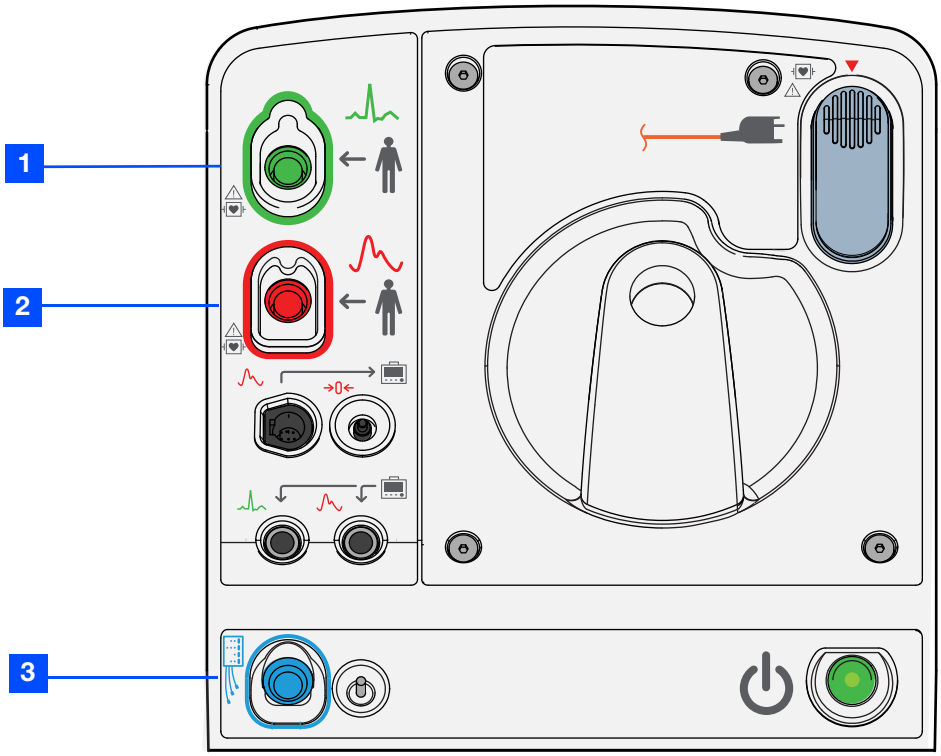

Figure 1-14: CARDIOSAVE IABP Back Panel

Note:
The CARDIOSAVE IABP console must be turned on in order to use the Trainer.

2 GENERAL USE AND STARTUP

2.1 STARTUP STEPS FOR USING THE TRAINER

1. Turn on **CARDIOSAVE**.
2. Attach the **CARDIOSAVE Trainer** as described in “Installation” on page 1-14. The message **Trainer in Use - NOT FOR CLINICAL USE!** is displayed on the Monitor Display.
3. Attach an IAB with a helium extender tubing to the system. If attaching a MAQUET/Datascope Fiber-Optic IAB, the sensor connector should also be connected.

Note:
The default Operation Mode is AUTO and the frequency is 1:1.

4. If using a conventional IAB, press the **VENT** key to simulate venting a transducer to atmosphere. Zero the IABP by pressing and holding the **Zero Pressure** key on the Touchscreen for 2 seconds. Once zeroed, the message **Zeroing Complete** appears above the arterial pressure waveform on the Monitor Display and zeros are displayed to the right of the arterial pressure waveform.

Note:
If using a MAQUET/Datascope Fiber-Optic IAB, there is no need to zero. Once the **Start** key is pressed, the IABP automatically performs a calibration.

5. Press the **START** key. The IAB initiates an Autofill (and calibration if a MAQUET/Datascope Fiber-Optic IAB is being used). Once complete, pumping begins at MAX augmentation.

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3 USING THE CARDIOSAVE TRAINER

3.1 CONDITIONS AND SIMULATIONS ON THE CARDIOSAVE TRAINER

This chapter covers some of the possible simulations and conditions that can be generated with the **CARDIOSAVE Trainer**. Not all simulations and alarms are listed.

WARNING:

The CARDIOSAVE Trainer is intended only as a training device. It should never be connected to CARDIOSAVE when the pump is connected to a patient.

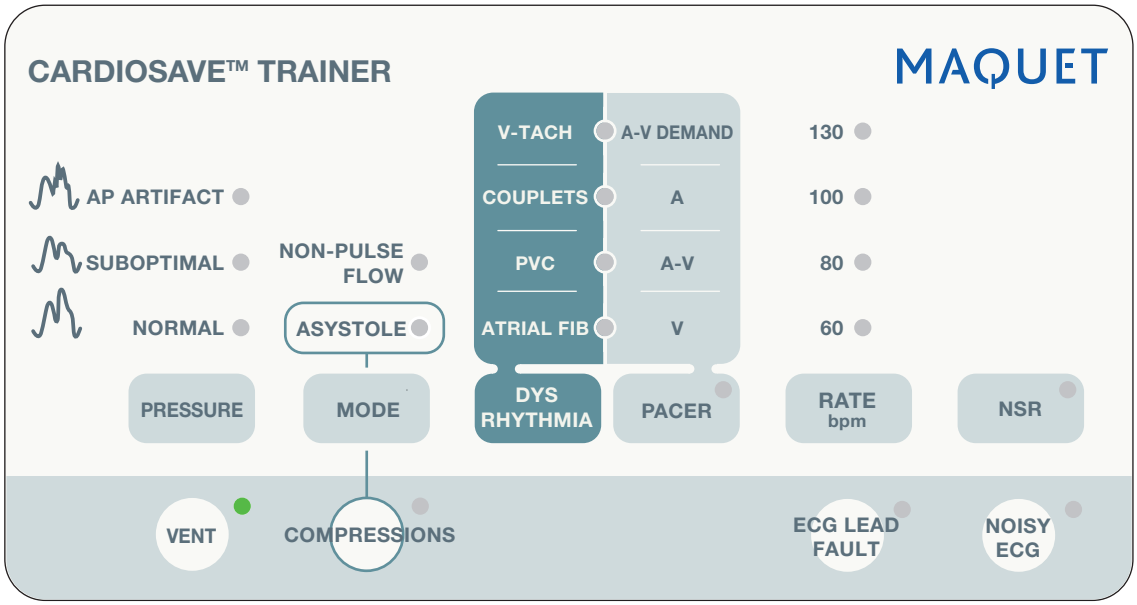

Figure 3-1: CARDIOSAVE Trainer Keypad

3.1.1 ZEROING (CONVENTIONAL IAB)

1. Press the **VENT** key on the Trainer keypad, then press **Zero Pressure** key on Touchscreen for 2 seconds. Once zeroed, the message **Zeroing Complete** appears above the arterial pressure waveform on the Monitor Display and zeros will be displayed to the right of the arterial pressure waveform.
2. Press the **VENT** key again and the arterial pressure indices are now displayed on the Monitor Display.

Note:

If a MAQUET/Datascope Fiber-Optic IAB pump is connected, zeroing is not necessary because the IABP will automatically perform a calibration on startup when the **Start** key is pressed. To manually initiate a calibration, press the **Calibrate Pressure** key for two seconds, while pumping.

3.1.2 SUBOPTIMAL DIASTOLIC AUGMENTATION

1. Press the **PRESSURE** key until the SUBOPTIMAL LED is illuminated. This typically triggers the **Augmentation Below Limit Set** alarm.
2. To return to super-systolic diastolic augmentation, press the **PRESSURE** key until the NORMAL LED is illuminated.

3.1.3 ARTERIAL PRESSURE WAVEFORM ARTIFACT

1. Press the **PRESSURE** key until the AP ARTIFACT LED is illuminated with a solid LED. This simulates an underdamped arterial pressure waveform.
2. Press the **PRESSURE** key again and the LED will blink next to AP ARTIFACT. This simulates an overdamped arterial pressure waveform.
3. To restore a crisp, clean arterial pressure waveform, press the **PRESSURE** key until the NORMAL LED is illuminated.

3.1.4 LOSS OF ARTERIAL PRESSURE WAVEFORM

1. For a conventional IAB, disconnect the Trainer pressure cable from **CARDIOSAVE**. After reconnecting, zeroing is necessary.
2. For a MAQUET/Datascope Fiber-Optic IAB, disconnect the Trainer pressure cable and the Fiber-Optic Sensor from the rear panel of **CARDIOSAVE**. Once both are reconnected, a calibration automatically occurs after 20 seconds, or a manual calibration can be invoked rather than waiting.

Note:
This simulation causes the **No Pressure Source Available** alarm to sound.

3.1.5 CARDIAC ARREST

1. Press the **MODE** key until the ASYSTOLE LED is illuminated. This creates a flatlined ECG and arterial pressure waveform. The **No Trigger** alarm sounds.
2. To simulate chest compressions while in ASYSTOLE mode, press the **COMPRESSIONS** key. Pumping automatically resumes in Pressure trigger (if in Auto Operation Mode) at a heart rate of 100 BPM.
3. To return to a normal sinus rhythm (NSR) and blood pressure, press the **NSR** key.

3.1.6 NON-PULSATILE FLOW

1. Press the **MODE** key until the NON-PULSE FLOW LED is illuminated. While the pump is in Standby mode, this simulates a low pulsatility arterial pressure waveform. While **CARDIOSAVE** is assisting, this simulates an example of how the arterial pressure waveform may appear with counterpulsation therapy.
2. To resume a normal arterial pressure waveform, press the **MODE** key once.

3.1.7 ATRIAL FIBRILLATION

1. Press the **DYSRHYTHMIA** key until the ATRIAL FIB LED is illuminated. After a short time period, the pump enacts Auto R-Wave Deflate.
2. To return to a normal sinus rhythm, press the **NSR** key. After a short time period, the Auto R-Wave Deflate will be inactivated.

3.1.8 VENTRICULAR ARRHYTHMIAS

1. To simulate PVCs, Couplets and runs of Ventricular Tachycardia, press the **DYSRHYTHMIA** key until the desired arrhythmia LED is illuminated.
2. To return to a normal sinus rhythm, press the **NSR** key.

3.1.9 VARIOUS PACER SETTINGS

1. To simulate A (Atrial), V (Ventricular), and A-V (Atrio-Ventricular) paced rhythms, press the **PACER** key until the desired paced rhythm LED is illuminated.
2. To return to a normal sinus rhythm, press the **NSR** key.

3.1.10 HEART RATE CHANGES

To simulate heart rates of 60, 80, 100, and 130, press the **RATE** key until the desired heart rate LED is illuminated.

3.1.11 NORMAL SINUS RHYTHM

Whenever a normal sinus rhythm is desired, press the **NSR** key.

3.1.12 ECG LEAD FAULT

1. While in Auto Operation Mode, press the **ECG LEAD FAULT** key and a green LED illuminates. A flatlined ECG appears and the pump switches to Pressure trigger.
2. Press the **ECG LEAD FAULT** key a second time and a ECG waveform reappears and the pump switches back to ECG trigger after a short time period.

3.1.13 ECG ARTIFACT

1. While in Auto Operation Mode, press the **NOISY ECG** key. The pump cycles through all available leads, then switches to Pressure trigger.
2. Press the **NOISY ECG** key a second time and the artifact disappears. The pump switches back to ECG trigger after an appropriate amount of time, resulting in a clean signal.

4 SPECIFICATIONS

4.1 IABP TRAINER SPECIFICATIONS

Feature	Specification
Heart Rate	60, 80, 100, 130, (±2%)
QRS Complex	
■ Amplitude	0.7 mV in lead II, (±0.05) mV peak to peak between 75 μV and 100 μV in AVL
■ Duration	92 (±10%) msec
■ Impedance: between C and RL	<100 Ω
Arterial Pressure	
■ Sensitivity	25 μV/mmHg nominal
■ Amplitude	101/52 (±3) mmHg, @ 80 BPM
■ Impedance	<100 Ω
■ Delay	40 (±10%) msec
Pacers	
■ Atrial	172 (±16) msec, prior to the “Q” wave
■ Ventricular	40 (±4) msec prior to the “Q” wave
■ A-V	172 (±16) msec and 40 (±4) msec respectively, prior to the “Q” wave
■ Normal Amplitude	> 3 mV in Lead II
■ Normal Duration	0.9 - 2.0 msec
■ Unenhanced Amplitude	0.90 (±0.10) mV
■ Unenhanced Duration	16 (±4) msec measured from start of pulse to 50% point on decaying waveform
■ Tail	No Tails
■ Power Consumption	100 mA maximum @ 5V nominal
Mechanical	
■ Size	7.6"(L) x 4.5" (W) x 2.0" (H)
■ Weight	16 oz

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A APPENDIX

A.1 WARRANTY

Datascope Corp. warrants that its products will be free from defects in workmanship and materials for a period of one year from the date of purchase except that 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.

Datascope Corp. 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 Corp's option, at the factory or at an authorized Datascope Distributor, any product which shall, under normal use, appear to Datascope Corp. to have been defective in material or workmanship.

No agent, employee, or representative of Datascope Corp. has any authority to bind *Datascope Corp.* 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 buyer.

This warranty is expressly in lieu of any other expressed 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, accident or by affixing any nonstandard accessory attachments, or by any customer modification, voids this warranty. Datascope Corp. 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 Corp., Mahwah, New Jersey. Datascope Corp. shall not have any responsibility in the event of loss or damage in transit.

A.2 DATASCOPE CORP.'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 MAQUET; 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.

To reorder the IABP Trainer User Manual, use part number 0070-00-0700.

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