

# Cardiosave Software Revisions

B.17 / C.06 - D.00 Software

# Cardiosave Version B.17 / C.06 to D.00 Software

## Background

- The following slides outline the changes that may be apparent during everyday use of Cardiosave.
- The revisions can result in the following:
  - Change in operation.
  - New messages on the monitor display.
  - Additional information in the Help Screens.
  - New key and additional information on the Touchscreen.

## Field Safety Corrective Actions Addressed

- Cardiosave Software Version D.00 Addresses three (3) open Field Safety Corrective Actions (FSCA).
  - Cybersecurity Vulnerabilities– Ripple20
  - Battery Usage, Charging, Maintenance and Storage Instructions  
(Part of this FSCA was completed at an earlier date as part of the release of the Cardiosave Li-Ion Battery Transport and Storage Case.)
  - Shutdown Upon Battery Removal

# Flat Arterial Pressure (A.P.) surveillance

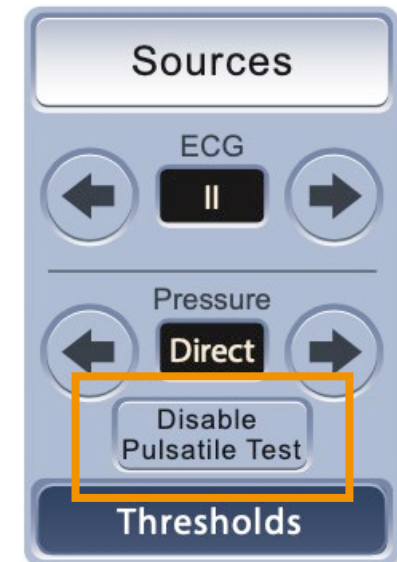
# Flat Arterial Pressure (A.P.) surveillance

## Reason for update

- This change was implemented to comply with new regulatory standards, which require detection and an alarm for a blood pressure monitoring fault.

## Description

- With this software change, the system performs a flat A.P. surveillance check of the arterial pressure source.
  - Monitors for sustained loss of pulsatility on the A.P. waveform when pulsatility is expected.
- If a sustained loss of pulsatility is detected, **No Pressure Source Available** - Medium Priority Alarm will occur.



# Flat Arterial Pressure (A.P.) surveillance

Newly added probable cause for existing Medium Priority Help Screen

## No Pressure Source Available

**The A.P. transducer has been vented to atmosphere for more than 10 seconds.**

1. Verify that the transducer is not vented to atmosphere.
2. If vented, reestablish A.P. pulsatility by closing the vent stopcock.

**The pressure monitoring tubing has become disconnected.**

1. Verify the integrity of the pressure monitoring lines and luer connectors.
2. Correct per hospital pressure monitoring procedures.

# Flat Arterial Pressure (A.P.) surveillance

Newly added probable cause for existing Medium Priority Help Screen

## No Pressure Source Available

**The pressure monitoring lumen of the IAB may have become restricted due to clot formation and is producing a flat A.P. waveform.**

1. Attempt to aspirate the inner lumen. If you met resistance during aspiration, consider the inner lumen to be occluded. Discontinue the use of the inner lumen by placing a luer cap on the female luer hub of the inner lumen. Provide an alternate A.P. source (i.e. radial) by connecting and zeroing a standard transducer. If an alternate A.P. source (i.e. radial pressure source) is not available, connect 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 in the SOURCES Menu.
2. If an alternate A.P. source is not available, override the alarm by pressing the DISABLE PULSATILE TEST button in the SOURCES menu.

# Flat Arterial Pressure (A.P.) surveillance

Newly added probable cause for existing Medium Priority Help Screen

## No Pressure Source Available

**A defective A.P. transducer or pressure transducer cable is producing a flat A.P. waveform.**

1. Check for damage to the pressure transducer cable.
2. Consider replacing the pressure transducer cable and pressure transducer.
3. If alarm persists, 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. Manually switch the IABP's pressure input to EXTERNAL using the PRESSURE ARROW keys in the SOURCES Menu.
4. If an alternate A.P. source is not available, override the alarm by pressing the DISABLE PULSATILE TEST button in the SOURCES menu.

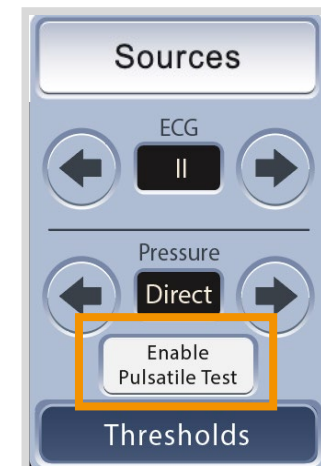
# Flat Arterial Pressure (A.P.) surveillance

## Clinical considerations

- The **Disable Pulsatile Test** key allows the user to suspend the Flat Arterial Pressure (A.P.) Surveillance checks.
  - Disabling the pulsatility check can accommodate the following:
    - The absence of pulsatility, which can exist when IAB support is temporarily paused while the patient is concurrently being supported with a non-pulsatile mechanical circulatory support device.
    - When persistent conditions persist, such as a clotted A.P. lumen.
      - If the pressure monitoring lumen of the IAB is clotted, provide an alternate A.P. source.

## Clinical considerations

- The flat A.P. surveillance can be resumed by pressing the **Enable Pulsatile Test** key.
- The pump will also automatically resume the flat A.P. surveillance check after detecting 30 continuous seconds of pulsatility on the waveform





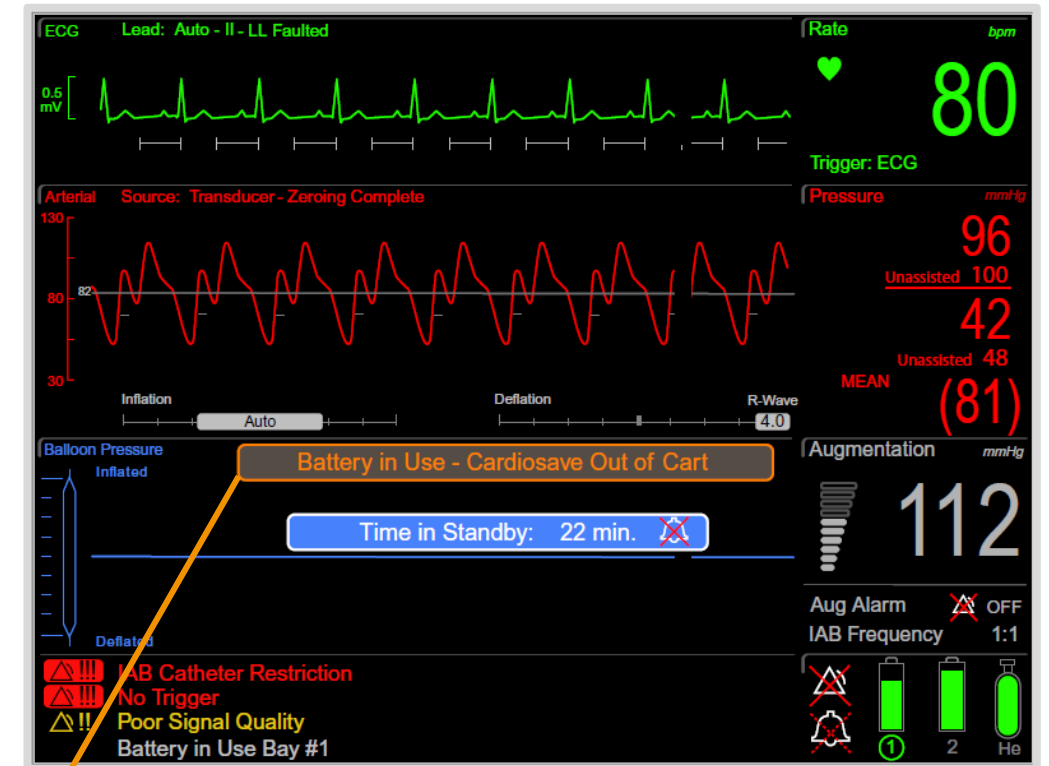
# Docking Status Banner on Monitor Display

# Docking Status Banner on Monitor Display

## Newly added Status Indicators

### Description

- The following changes were made to the **Monitor Display**:
  - The **Time in Standby** banner was relocated slightly lower.
  - The new banner, **Battery in Use – Cardiosave Out of Cart**, will be displayed whenever the Cardiosave IABP Console is not securely docked into the hospital cart and running on battery power.



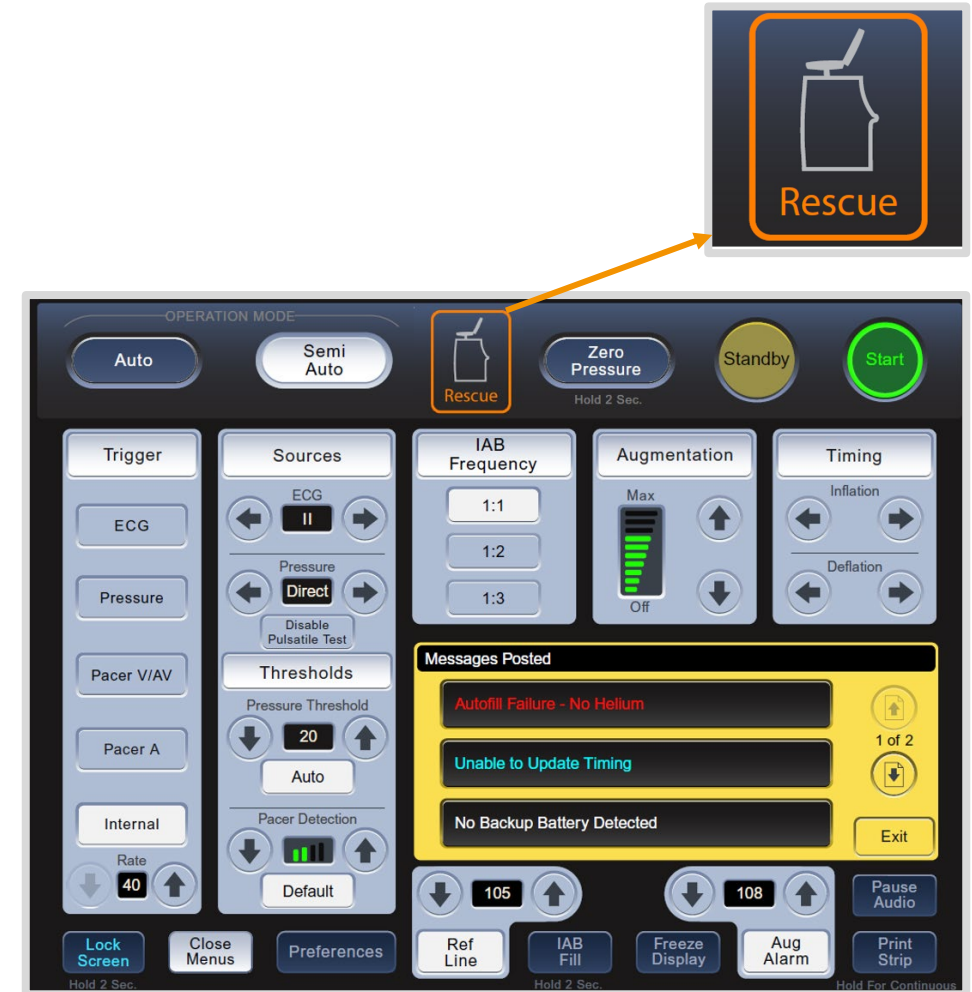
Battery in Use - Cardiosave Out of Cart

# Docking Status Banner on Monitor Display

## Newly added Status Indicators

### Description

- The following changes were made to the **Touchscreen** :
  - An orange border has been added around the Rescue icon when the IABP Console is not securely docked in the Hospital Cart.
  - When the IABP is in Rescue Mode, the orange border will continuously flash between dark orange and light orange.
- If the IABP is set up in the Hybrid Mode and the Rescue icon is displayed on the Touchscreen, ensure that the IABP Console is securely docked in the Hospital Cart.



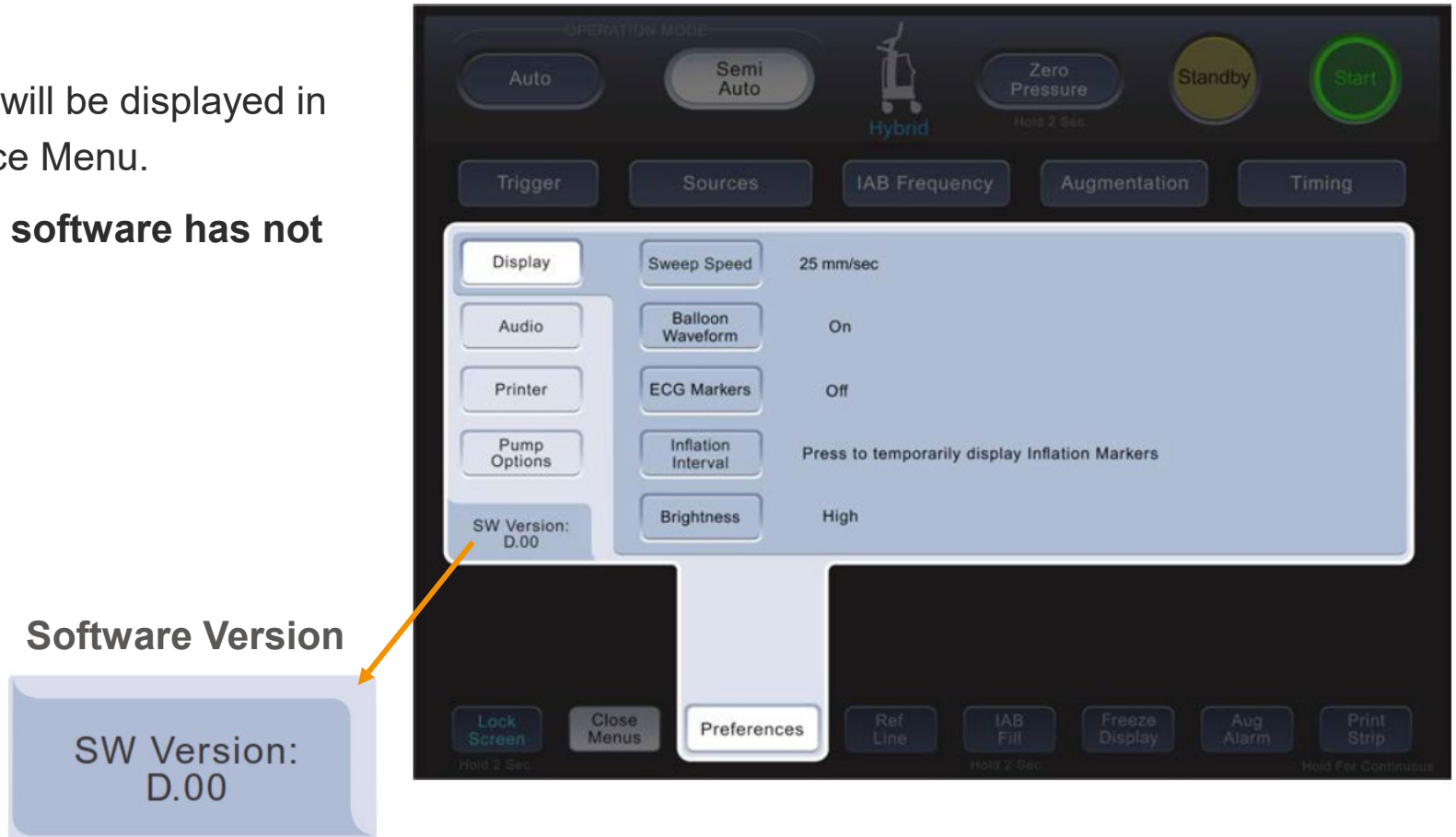
# Software Version added to Preferences Menu

# Software Version in Preferences Menu

## Description

The installed software (SW) version will be displayed in the lower-left corner of the Preference Menu.

- If this information is absent, the software has not been updated to D.00 SW.



# System power down/power up

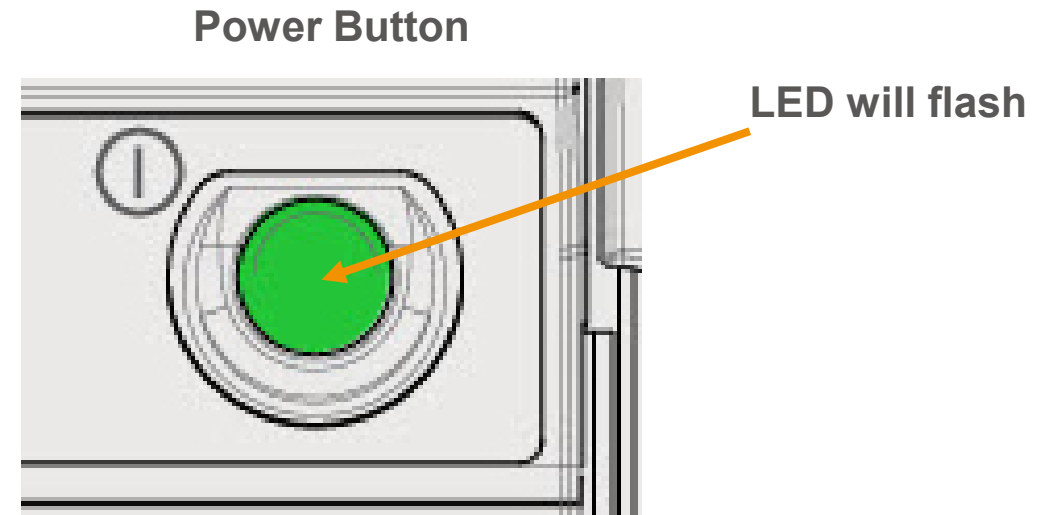
# System power down/power up

## Reason for update

- Due to characteristics of electronic components, rapidly powering down and then powering up the system can have undesirable effects on operation.
- There are no known issues with the previous B.17 or C.06 software, but this will ensure safer power down/power up sequences.
- This update will prevent the user from restarting the unit within 10 seconds of a previous shutdown.

## Description

- Whenever the Cardiosave system is powered down, the user will be unable to restart the unit for 10 seconds.
- The power button LED will flash during this 10 second period.



# Unexpected Shutdown Upon Battery Removal



# Unexpected Shutdown Upon Battery Removal

## Reason for update

- Previously Datascope/Getinge initiated a voluntary Medical Device Correction for the Cardiosave Hybrid Intra-Aortic Balloon Pump (IABP) due to unexpected shutdown upon battery removal.
- Prior to D.00 software, during a very specific set of conditions, the Cardiosave Hybrid IABP could unexpectedly shut down when the device was running on AC power, only one battery installed in the IABP, and the battery was physically removed while the battery was being charged.

## Description

- The system will now recognize the charging battery's removal, disconnect the battery charging system and also switch to AC power without interruption of therapy.



*Cardiosave Hybrid*

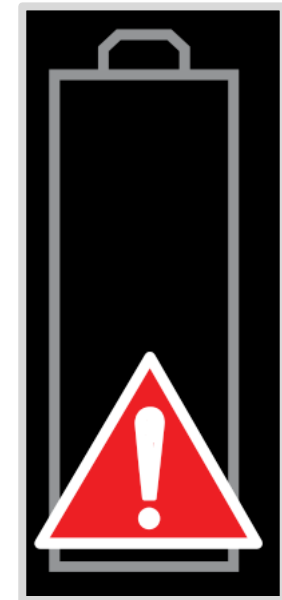
# Battery Charge Level Unavailable Bay #\_\_\_\_

# Battery Charge Level Unavailable Bay #\_\_\_\_

Newly added High Priority Alarm

## Note

- With this revision, it is possible to have a functioning battery but not have current battery information on the screen.
- A High Priority Alarm and Help Screen has been added to the system.



*Battery icon*

# Battery Charge Level Unavailable Bay #\_\_\_\_

Newly added High Priority Alarm

## Alarm event

- The indicated battery is unable to communicate its charge level to the IABP.

## IABP response

- *Cardiosave will continue to deliver active IABP therapy.*
- The High Priority Alarm Icon - red flashing alarm icon with three (3) exclamation points will be visible on the Monitor Display.
- The uniform audio tone for High Priority Alarms will be played in the following sequence:
  - five notes - short pause - five notes - long pause; the cycle repeats.

## Alarm reset event

- When the battery is replaced.



*High priority alarm icon*

# Battery Charge Level Unavailable Bay #\_\_\_\_

Newly added High Priority Help Screen

## Battery Charge Level Unavailable Bay #\_\_\_\_

**The battery in the identified bay or bays is unable to communicate the battery charge level.**

1. Immediate battery replacement is required.
2. Replace the battery that is currently in use. If a fully charged battery is not available, connect to an AC power source as soon as possible.
3. If battery operation on the indicated battery is required, monitor the system closely for a system shutdown, the Low Battery Alarm will not be displayed.
4. Contact MAQUET Service to obtain a new battery.

# Battery Maintenance Required Bay #\_\_\_\_

# Battery Maintenance Required Bay #\_\_\_\_

Newly added Informational Message

## Alarm event

- Previous Maintenance date is past due.

## IABP response

- An informational message will be posted on startup and remain displayed for 5 minutes or until the Cardiosave IABP starts assisting.
- The Informational audio tone shall sound for 60 seconds or until the pump begins assisting.

## Informational message reset event(s)

- When battery maintenance has been performed, the battery requiring maintenance has been replaced, or the START key is pressed, initiating IABP assistance.

# Battery Maintenance Required Information

Newly added Informational Message Help Screen

## Battery Maintenance Required Bay #\_\_\_\_

**The battery in the identified bay requires maintenance.**

1. Continue operation on AC power.
2. If battery operation is required, the battery run time may be reduced. Monitor the system closely for a Low Battery alarm.
3. If a Low Battery alarm occurs, immediately connect the system to AC power or install a fully charged battery.
4. As soon as possible, execute the Battery Maintenance process as follows:
5. Connect the IABP to an AC power source.



# Battery Replacement Required Bay #\_\_\_\_

# Battery Replacement Required Bay #\_\_\_\_

Newly added Informational Message Help Screen

## Battery Replacement Required Bay #\_\_\_\_

**The battery in the identified bay or bays has become unreliable and requires replacement.**

1. Battery replacement is required.
2. Continue operation on AC power.
3. If battery operation on the indicated battery is required, the battery run time will be reduced.  
Monitor the system for a Low Battery alarm
4. If a Low Battery alarm occurs, immediately replace the battery or return to AC power.
5. Contact MAQUET Service to obtain a new battery.

**Battery in Use Bay #\_\_\_\_**

# Battery in Use Bay #\_\_\_\_

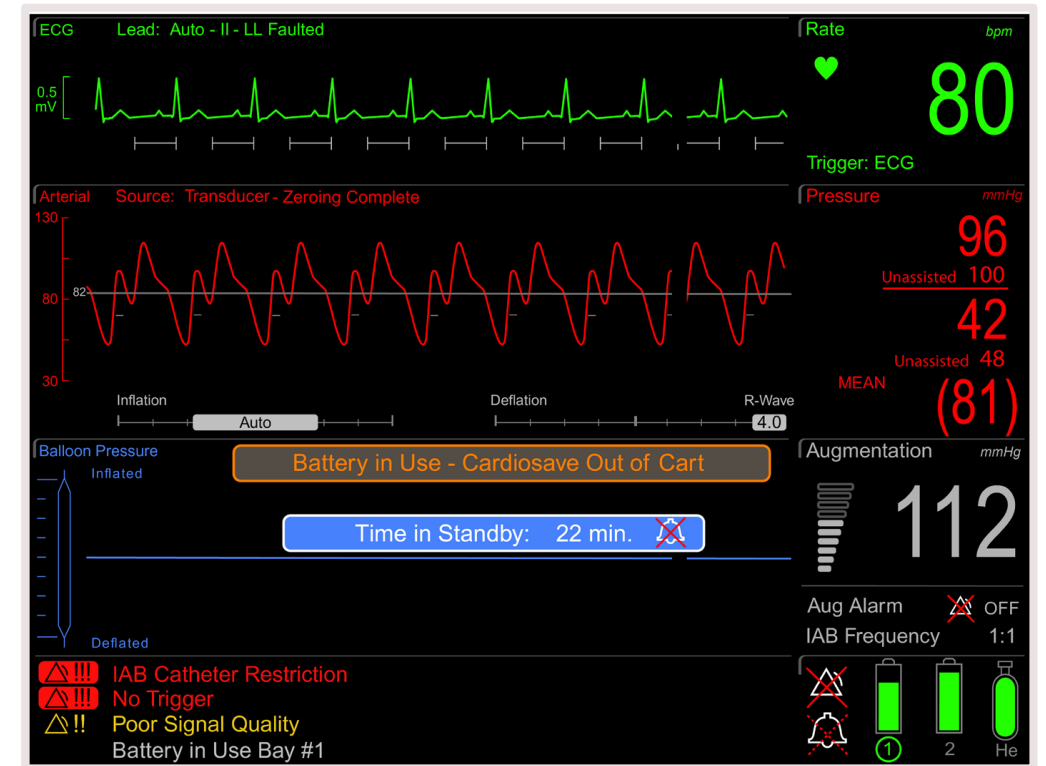
Newly added Bay Indicator on current Informational Message

## Reason for update

- To inform the user which of the two batteries is currently in use.

## Description

- A battery bay indicator was added to the current **Battery in Use** Informational Message on the Monitor Display to indicate which of the two batteries is currently in use.



Battery in Use Bay #1

# Low Battery Alarm

# Low Battery Alarm

## Reason for change

- Improve warning time to the IABP operator of the impending end of battery operating run time.

## Description

- Currently, a **Medium Priority Alarm** exists for Low Battery Alarm when there are *less than 30 minutes* of battery operating time.
- With this software update, a **High Priority Alarm** is added for when *less than 15 minutes* of battery operating time is remaining.

# Low Battery Alarm

Current Medium Priority Alarm

## Alarm event

- Cumulative reserve of both batteries falls below 30 minutes of operating time.

## IABP response

- *Cardiosave will continue to deliver active IABP therapy.*
- The Medium Priority Alarm Icon - yellow flashing alarm icon with two (2) exclamation points will be visible on the Monitor Display.
- The uniform audio tone for Medium Priority Alarms will be played in the following sequence:
  - three notes - pause; the cycle repeats.

## Alarm reset event(s)

- Automatically removes message and turns off tone when an AC power source is restored or when a charged battery is inserted.



*Medium priority alarm icon*

# Low Battery Alarm

Newly added High Priority Alarm

## Alarm event

- Cumulative reserve of both batteries falls below 15 minutes of operating time.

## IABP response

- *Cardiosave will continue to deliver active IABP therapy.*
- The High Priority Alarm Icon - red flashing alarm icon with three (3) exclamation points will be visible on the Monitor Display.
- The uniform audio tone for High Priority Alarms will be played in the following sequence:
  - five notes - short pause - five notes - long pause; the cycle repeats.

## Alarm reset event(s)

- Automatically removes message and turns off tone when an AC power source is restored or when a charged battery is inserted.



*High priority alarm icon*



# Low Battery Alarm

Newly added High Priority Alarm Help Screen

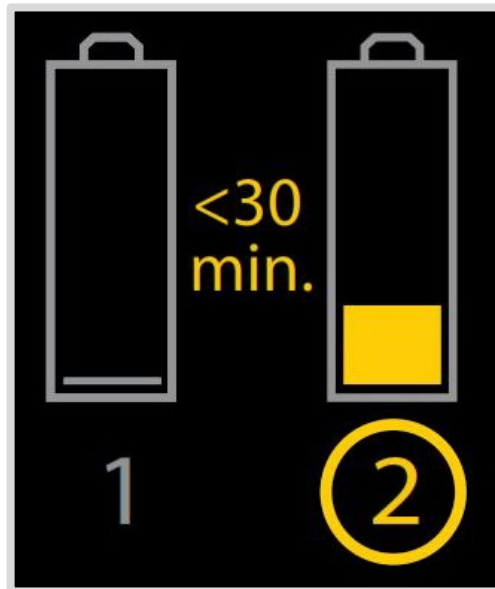
## Low Battery

**There is less than 15 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.

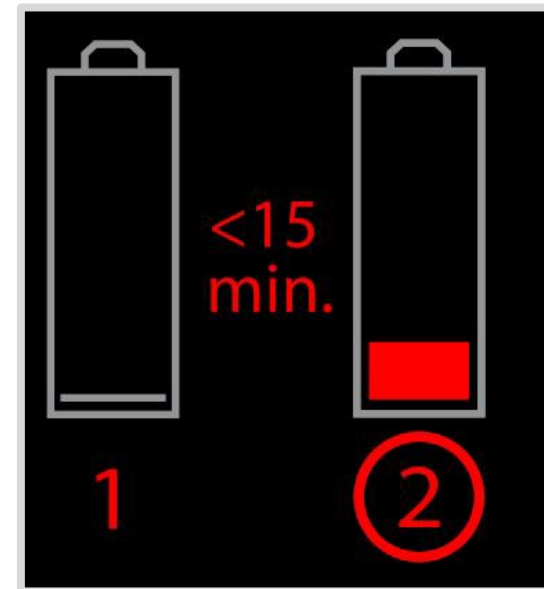
# Low Battery Alarm

Battery status on Monitor Display (examples)



## Medium Priority alarm

Battery 1 is depleted and battery 2 has less than 30 minutes of charge remaining.



## High Priority alarm

Battery 1 is depleted and battery 2 has less than 15 minutes of charge remaining.

# Video Executive Circuit Board

# Video Executive Circuit Board

## Board reset

### Description

- In the event of a loss of communication or unrecoverable error on the video processor, by allowing the executive processor to power down and repower the video head whenever communication is lost.
  - IABP will continue to deliver active therapy during resetting.
  - These reset events will cause a brief blanking of the Monitor Display.
  - An Informational Message will inform the operator that the IABP internal self-checks have detected a video communication condition, and the IABP may require service.

# Video Executive Circuit Board

Newly added probable cause for existing Informational Message Help Screen

## IABP May Require Maintenance

**IABP Internal self-checks have detected a video communication 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. IABP may reset the User Interface display causing a brief blanking of the video display screens.
3. Once IABP use is discontinued, contact MAQUET Service for system diagnosis.

# Cybersecurity vulnerabilities - Ripple20

# Cybersecurity vulnerabilities - Ripple20

## Description

- With this Field Safety Corrective Action users were instructed to disconnect the Ethernet cable from the Cardiosave Ethernet Port identified [Figure 1].
- Additionally customers were given instruction for turning off Network Connections.
- With the installation of D.00 software this issue is resolved.
- The user is now able to reconnect the Ethernet cable to the Cardiosave Ethernet port and turn on Network Connections via the Network Connections settings in the Pump Options menu [Figure 2].

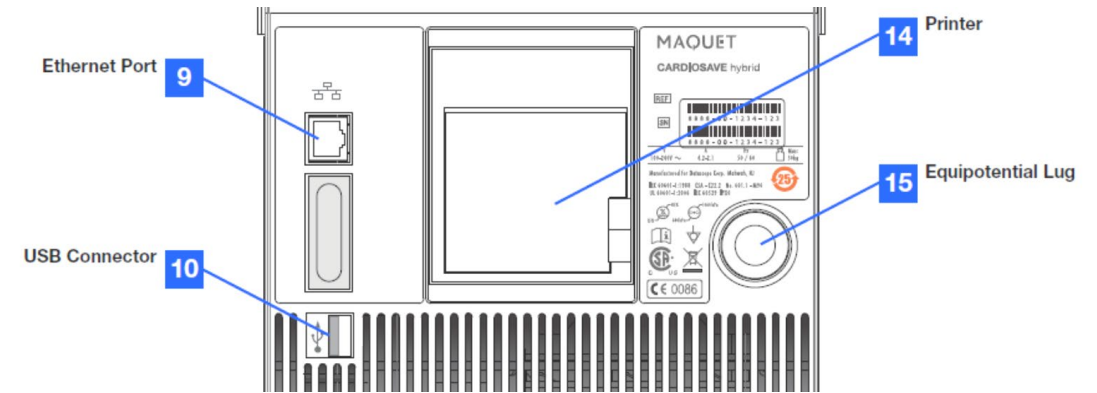


Figure 1



Figure 2

# Intra-Aortic Balloon Pumps & Catheters Video Library

## Educational Videos

Visit <https://getinge.training/iabp-int/videos/>

### Intra-Aortic Balloon Pumps & Catheters Video Library


#### Educational Videos



**Sensation Plus IAB Catheter Insertion**  
16min 30sec

Review the insertion steps of the Sensation Plus IAB catheter and the initial setup of the Cardioase intra-aortic balloon pump.


[Download insertion guide](#)



**Sensation 7 Fr IAB Catheter Insertion**  
25min 52sec

Review the insertion steps of the Sensation 7 Fr IAB catheter.


[Download insertion guide](#)



**Getinge IAB Sheathless Insertion**  
6min 19sec

Review the insertion steps for sheathless insertion of Getinge IAB catheters.

[Download insertion guide](#)




**Cardioase Software Revisions**  
Version B.17 or C.06 to D.00 Software  
26min 54sec

This video is intended for Cardioase users outside of the US.

*This video does not generate a certificate. If you need to generate a certificate, please view this presentation [\[link\]](#).*


[Download here: D.00 presentation slides](#)



**IABP the Numbers Game**  
10min 28sec

Characteristics of the intra-aortic balloon pump (IABP) and differences between the IABP pressure vs. non-invasive blood pressure and bedside monitor pressures are discussed in this video.

[Download here: program booklet](#)



**Cardiogenic Shock It Is Not One-Size-Fits-All**  
19min 21sec


The need for early identification of cardiogenic shock (CS) and its underlying etiology to develop an appropriate treatment plan and differences between CS attributed to acute myocardial infarction (AMI) vs. acute heart failure are presented.

[Download here: program booklet](#)



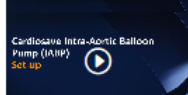
**Intra-aortic Balloon Catheter Removal**  
1min 29sec

[Download here: bedside insertion guide](#)




**StatLock Application & Removal**  
1min 42sec

[Download here: bedside insertion guide](#)



**Cardioase IABP Set-up**  
4min 33sec  
*(this video has no audio)*

[Click here: Cardioase quick reference guides](#)



**Cardioase Intra-aortic Balloon Pump (IABP) Inservice**  
48min 17sec





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