CENTURION®

Compass® Cast™ and MAP

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Indications for Use

The Compass Cast and MAP disposable pressure transducer system with integrated digital display and wireless transmission capability is intended for direct measurement and monitoring of physiologic pressure, including during the infusion of fluids and therapeutic and diagnostic agents.

Device Description

The Compass Cast is a self-calibrating, sterile, single-use, disposable, wireless-enabled, physiological pressure transducer with integrated digital display. The Compass Monitor Accessory Plug (Compass MAP) receives the wireless pressure signal from the Compass Cast and inputs the pressure signal to a compatible vital signs monitor.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications not expressly approved by Centurion Medical Products could void the user's authority to operate the equipment.

Compass CAST FCCID: 2AF4Z-CWHG001
Compass MAP FCCID: 2AF4Z-CWM001

Suggested Instructions for Use:
Compass Cast Use with Compass MAP

1. Remove Compass MAP from its package.

2. Align the multi-pin Compass MAP connectors with the matching port of the compatible* vital signs monitor **(Figure 1)**.

3. Insert Compass MAP into a compatible* vital signs monitor **(Figure 2)** and power on the monitor (if it is not already on).

   If Compass MAP is already plugged into the patient monitor, either remove and reinsert Compass MAP or power cycle the patient monitor to put Compass MAP into "scanning mode". (Power cycling can be achieved by turning the monitor off then turning it on again).

4. With Compass MAP plugged in and the patient monitor turned on, Compass MAP LED will blink two times every four seconds to indicate that it is scanning for a compatible Compass Cast.

5. Zero the pressure signal on the patient monitor per the monitor's IFU.

6. Remove Compass Cast from its sterile package.

7. Remove the proximal luer cap **(Figure 3)**.

8. Activate and calibrate Compass Cast by depressing the power button for approximately one second until the LCD reads "00" **(Figure 4)**.

WARNING: Activate and auto-calibrate Compass Cast prior to attaching accessories to avoid incorrect baseline pressure.

9. The "mm" symbol on the Compass Cast display will blink on and off to indicate that it is searching for a Compass MAP **(Figure 5)**.

10. When a wireless connection is established between the Compass MAP and Compass Cast, the "mm" will stop blinking on Compass Cast, and the LED on Compass MAP will switch from flashing to solid.
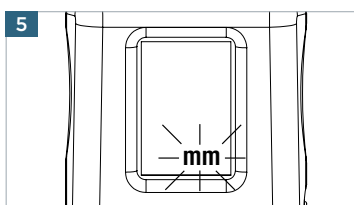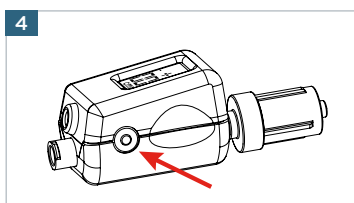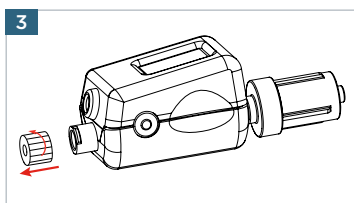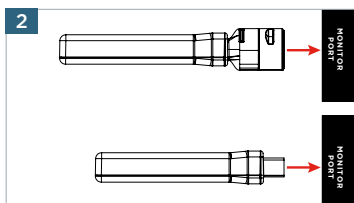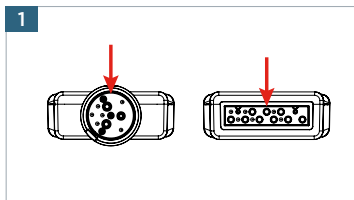
* Compatible vital signs monitors include GE Healthcare and Philips Medical Systems.

11. Depending on the application, attach accessory (e.g. flushing syringe, stopcock, extension or IV tubing, etc.) to the proximal, female luer lock port of the Compass Cast per hospital protocol **(Figure 6)**.

12. Depending on the application, connect the distal, male luer lock end of the Compass Cast to accessory (e.g. needle, distal lumen of a central line, extension set or needleless valve in contact with patient) **(Figure 7)**.

WARNING: Pressure reading is NOT physiological if either the front or rear of the Compass Cast is open to atmospheric pressure.

13. Pressure is displayed on the Compass Cast LCD and the patient monitor **(Figure 8)**.

NOTE: If Compass Cast pressure reading does not return to zero after removal from accessories, flush device with saline, open it to atmospheric pressure, and then cycle device (power it off and then power back on) to recalibrate.

To Power Off and Recalibrate

Press and hold button for two seconds until "---" is displayed on the LCD **(Figure 9)**, then release button to power off the device. To recalibrate, depress the power button for approximately one second until the LCD reads "00".


If procedure warrants, insert guidewire (up to 0.038″ diameter) through the Compass Cast guidewire port and into vessel. Smaller guidewires may necessitate the use of the guidewire insertion tool accompanying the guidewire holder **(Figure 10)**.

WARNINGS

When finished using the Compass Cast, power it off before discarding to prevent inadvertent pairing.

Do not reinfuse blood or other bodily fluid into the patient after any such fluid is drawn into the Compass Cast.

Do not reuse Compass Cast for different procedures with different patients. Use a new Compass Cast device for each procedure with each patient.
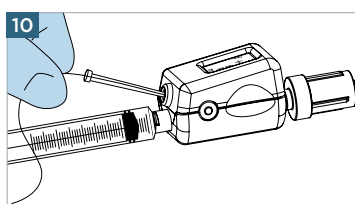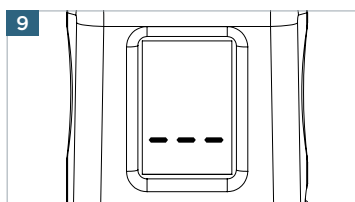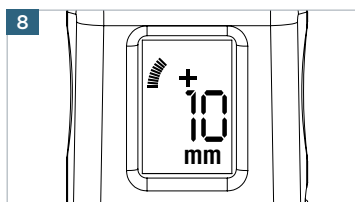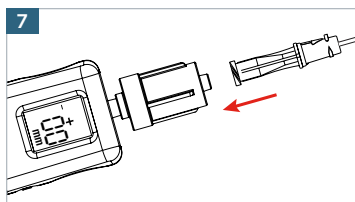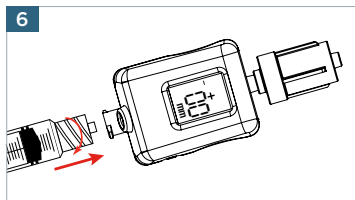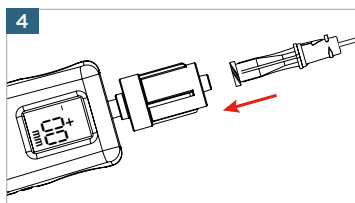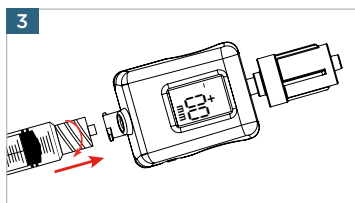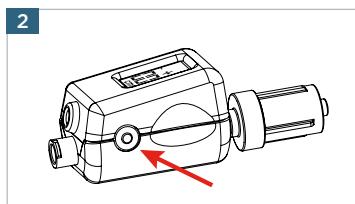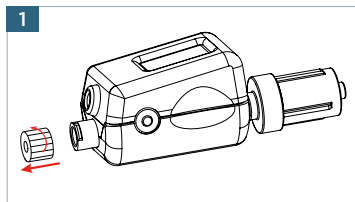
Suggested Instructions for Use:
Compass Cast Use without Compass MAP

1. Remove Compass Cast from its sterile package.

2. Remove the proximal luer cap **(Figure 1)**.

3. Activate and calibrate Compass Cast by depressing the power button for approximately one second until the LCD reads "00" **(Figure 2)**.

WARNING: Activate and auto-calibrate Compass Cast prior to attaching accessories to avoid incorrect baseline pressure.

4. Depending on the application, attach accessory (e.g. flushing syringe, stopcock, extension or IV tubing, etc.) to the proximal, female luer lock port of the Compass Cast per hospital protocol **(Figure 3)**.

5. Depending on the application, connect the distal, male luer lock end of the Compass Cast to accessory (e.g. needle, distal lumen of a central line, extension set or needleless valve in contact with patient) **(Figure 4)**.

WARNING: Pressure reading is NOT physiological if either the distal or proximal luer connections of the device is open to atmospheric pressure.

6. Pressure is displayed on the Compass Cast LCD **(Figure 5)**.

NOTE: If Compass Cast pressure reading does not return to zero after removal from accessories, flush device with saline, open it to atmospheric pressure, and then cycle device (power it off and then power back on) to recalibrate.

To Power Off and Recalibration

Press and hold button for two seconds until "---" is displayed on the LCD **(Figure 6)**, then release button to power off the device. To recalibrate, depress the power button for approximately one second until the LCD reads "00".

7. If procedure warrants, insert guidewire (up to 0.038˝ diameter) through the Compass Cast guidewire port and into vessel. Smaller guidewires may necessitate the use of the guidewire insertion tool accompanying the guidewire holder **(Figure 7)**.

WARNINGS

Do not reinfuse blood or other bodily fluid into the patient after any such fluid is drawn into the Compass Cast.

Do not reuse Compass Cast for different procedures with different patients. Use a new Compass Cast device for each procedure with each patient.
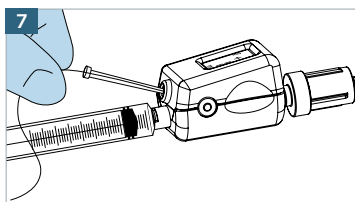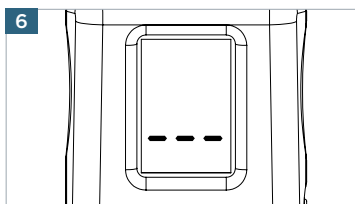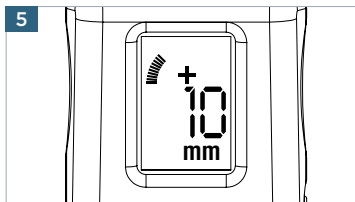
Connectivity Details

When Compass MAP enters scanning mode after being powered on with the connection to a patient monitor, it will select the strongest available Compass Cast signal.

Once a Compass Cast and a Compass MAP are paired, the devices will no longer be able to pair with other Compass devices unless they are power cycled to force them back into general scanning mode.

If the connection is temporarily lost (e.g. because the Compass MAP is disconnected and therefore powered down, and reattached to a different patient monitor), the previously paired devices will automatically reinitiate a connection.

If the Compass Cast is used without the Compass MAP, after 10 minutes of broadcasting without a paired connection, Compass Cast will no longer advertise and the "mm" displayed will change from flashing to off.

If Compass Cast is unable to establish a wireless connection, after 10 minutes of broadcasting, Compass Cast will no longer advertise and the "mm" displayed will change from flashing to off. The device must be power cycled for it to restart advertising for a wireless connection.

Once a Compass MAP has established a wireless connection to a Compass Cast, it will only pair to that particular Compass Cast. The Compass MAP must be power cycled to have it search for any available Compass Cast.

Device Power Off and Recalibration

Press and hold button for two seconds until "---" is displayed on the LCD, then release button to power down device.

Cleaning Instructions

The Compass MAP, the data receiver and monitor interface, is non-patient contacting and intended for multiple uses.

1. Inspect the Compass MAP for signs of damage, wear, or abuse.

2. Do not use if worn or damaged, e.g. connection pins bent or missing, or if the casing seal's integrity is compromised.

3. The Compass MAP may be low-level disinfected per hospital protocol.

4. Do not immerse Compass MAP in solutions.

5. Do not super saturate the cloth or the device.

6. Avoid liquid contact with the pin connectors.

7. Do not use abrasive or scouring materials.

8. Do not use staining solutions.

Display

Bar 18 = 42 mm Hg

+ symbol for positive pressure
- symbol for negative pressure

Bar 12 =
12 mm Hg

Bar 36 = 149 mm Hg

Bar 1 =
1 mm Hg

Graphical Waveform:

Variable scaling to enhance
physiologic pulsation

Bars 1–12: 1 mm Hg / bar
Bars 13–18: 5 mm Hg / bar
Bars 19–36: 6 mm Hg / bar

Numerical Display Modes:
• Display updates 2 times/sec

Pressure Unit = mm Hg
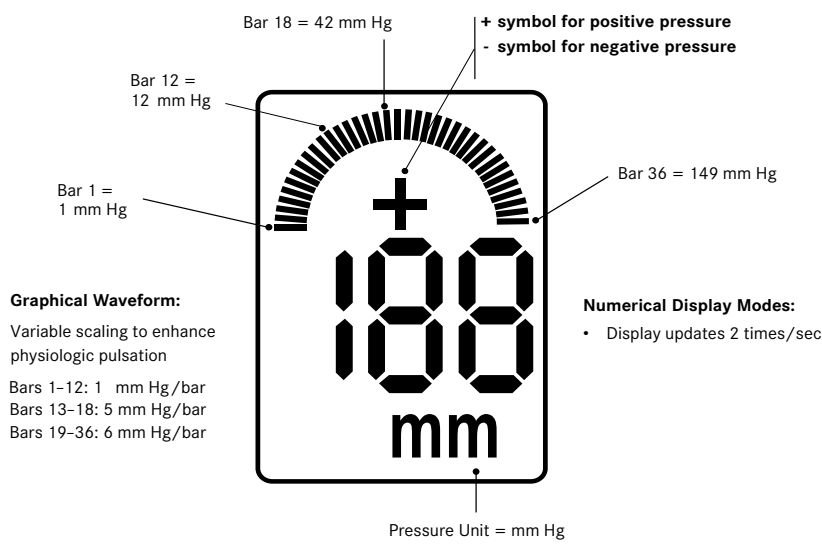
Specifications

Pressure Range	-199 mm to +999 mm Hg
Compass MAP Output	25 µV per mm Hg
Accuracy: Compass LCD	±2 mm Hg below 50 mm Hg
	±3% of reading above 50 mm Hg
Accuracy: Compass MAP	±2% below 50 mm Hg
	±3% of reading above 50 mm Hg
Zero Drift	±1 mm Hg per 4 hours
Operating Life	> 8 hours
Operating Temperature	15° to 40°C (59° - 104°F)
Storage Temperature	-29° to 49°C (-20° - 120°F)
Light Sensitivity	< 1 mm Hg
Lithium Ion Battery Voltage	3 Volts

Compass Cast: Software Codes

UF	Bluetooth Radio Check Failure
SF	Software Failure
HF	Hardware Failure
bF	Battery Failure
EE	Environment Error - Device outside operating temperature
CE	Calibration Error – Pressure values outside operating range
Lb3	Less than 8 hours battery life remaining
Lb2	Less than 6 hours battery life remaining
Lb1	Less than 4 hours battery life remaining
Lb0	Less than 2 hours battery life remaining

Compass MAP: LED Codes

Solid LED	Wireless connection established
Two Flashes Every Four Seconds	Scanning for wireless connection
Flashing Sixteen Times Per Second	Compass MAP non-functional