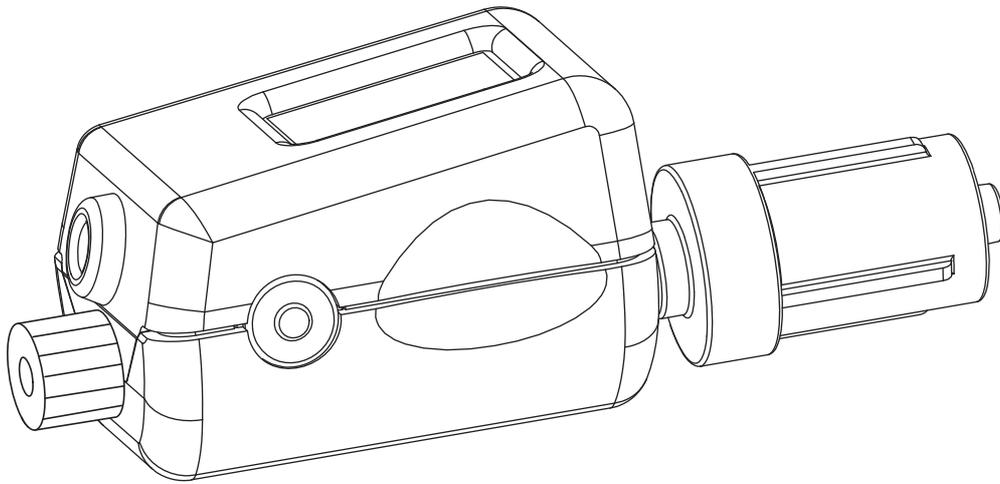


CENTURION®

Compass™ UniversalHg



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

Description

The Compass™ UniversalHg is a self-calibrating disposable pressure transducer with integrated digital display.

Intended Use

The Compass™ UniversalHg disposable pressure transducer with integrated digital display is intended for direct measurement and monitoring of physiological pressure, including during the infusion of fluids and therapeutic and diagnostic agents.

How Supplied

Intended for one-time use. Sterile if package is unopened or undamaged. Do not use the product if there is doubt as to whether the product is sterile. Avoid extended exposure to light. Upon removal from package, inspect the product to ensure no damage has occurred.

Suggested Procedure - CVC Insertion

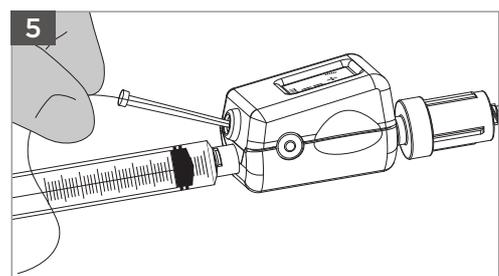
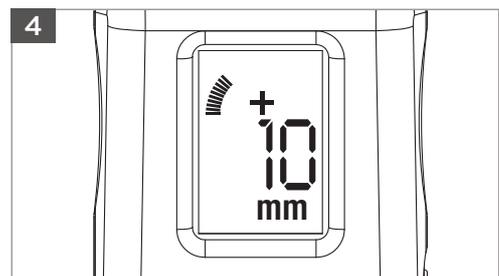
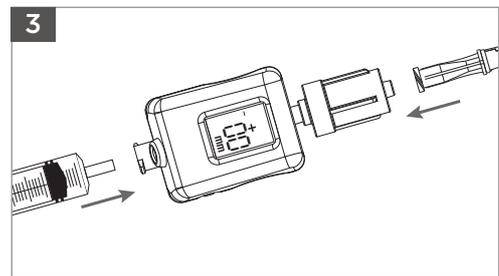
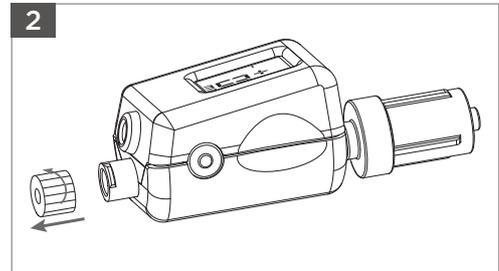
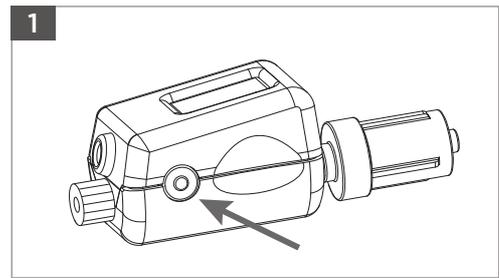
1. Remove Compass UniversalHg from its sterile package.
2. Activate and calibrate Compass UniversalHg by depressing power button for approximately one second until display reads "00 mm" (Figure 1).

Warning: Turn on Compass UniversalHg prior to attaching accessories to avoid incorrect baseline pressure.

3. Remove the proximal luer cap (Figure 2).
4. Attach introducer needle and syringe to Compass UniversalHg (Figure 3).
5. Insert introducer needle into central vein or other vessel.
6. Verify vessel access using pressure reading. Pressure is displayed on Compass UniversalHg LCD (Figure 4).
7. Insert guidewire (0.025", 0.035", or 0.038" diameter) through Compass UniversalHg guidewire port and into vessel (Figure 5). Use of a guidewire insertion tool or "cheater" may be necessary for smaller devices.

Alternate Technique: Remove syringe and insert guidewire through syringe port on Compass UniversalHg.

8. Hold guidewire in place and remove introducer needle and Compass UniversalHg assembly.
9. Perform catheter insertion per catheter manufacturer's instructions.



Suggested Procedure - CVP Monitoring

1. Remove Compass UniversalHg from its sterile package.
2. Activate and calibrate Compass UniversalHg by depressing power button for approximately one second until display reads "00 mm" (Figure 1).

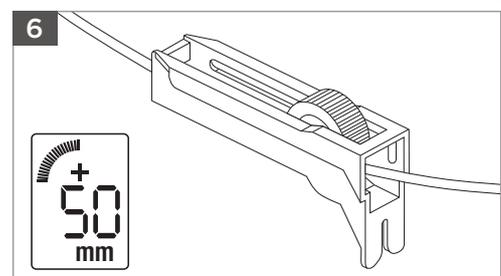
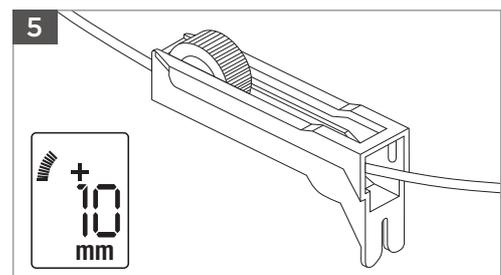
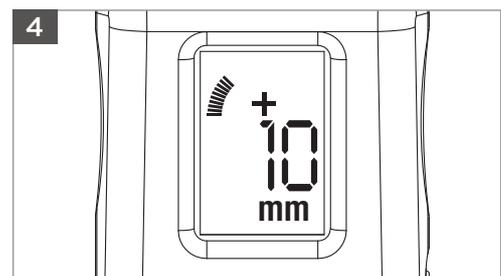
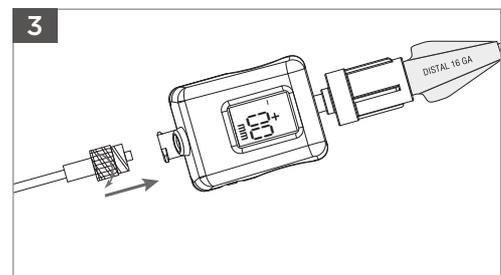
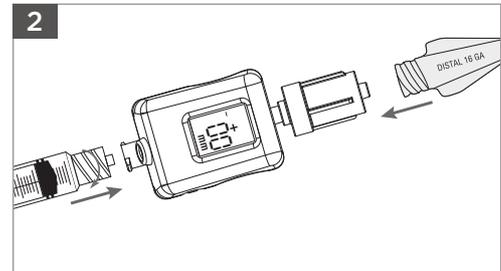
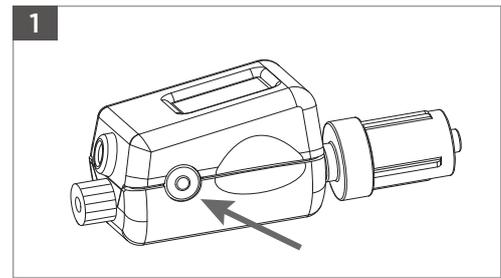
Warning: Turn on Compass UniversalHg prior to attaching accessories to avoid incorrect baseline pressure.

3. Remove the proximal luer cap, then prime Compass UniversalHg with saline and attach Compass to distal hub of central venous catheter (Figure 2).

Note: Extension tubing (sold separately) may be needed to position Compass UniversalHg at phlebostatic axis.

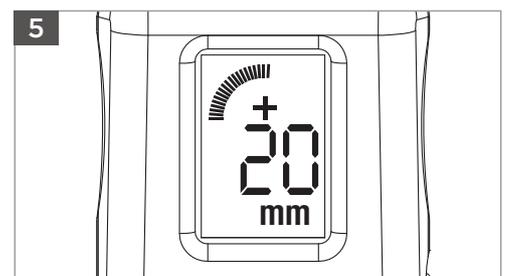
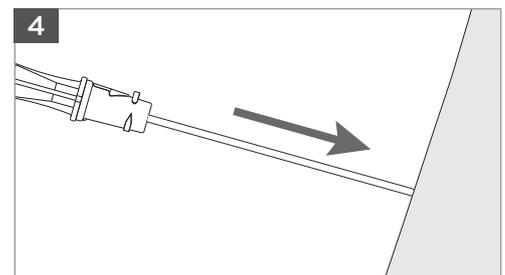
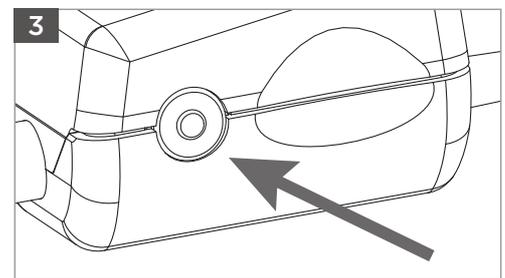
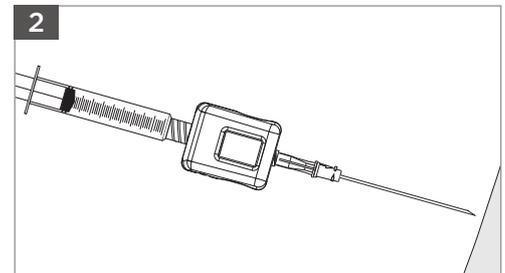
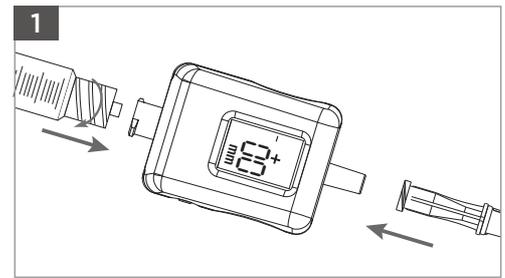
4. Attach infusion tubing (sold separately) to rear of Compass UniversalHg (Figure 3), or close rear of Compass UniversalHg with needleless connector.
5. Position Compass UniversalHg at phlebostatic axis, then measure central venous pressure. Pressure is displayed on Compass UniversalHg LCD (Figure 4).
 - If Compass UniversalHg is connected to infusion fluid, close roller clamp (Figure 5).
 - If Compass UniversalHg is capped, flush to ensure patency before CVP measurement.

Note: When roller clamp is open during fluid infusion, the Compass UniversalHg will report the pressure of the infusion fluid, **NOT** the central venous pressure (Figure 6).



Suggested Procedure - Compartment Pressure

1. Remove Compass UniversalHg from its sterile package.
2. Remove the proximal luer cap and connect Compass UniversalHg to 18G needle and saline filled syringe (**Figure 1**), then prime Compass UniversalHg and needle with saline.
3. With the Compass UniversalHg and needle positioned at the insertion angle (**Figure 2**), activate and calibrate Compass UniversalHg by depressing power button for approximately one second until display reads "00 mm" (**Figure 3**).
4. Insert needle tip (**Figure 4**) and inject 0.3 cc of saline.
5. Pressure is displayed on Compass UniversalHg LCD (**Figure 5**).



General Use

1. Remove Compass UniversalHg from its sterile package. If accessories (e.g. stopcock or syringe) are to be attached to the proximal end of the Compass UniversalHg, remove the proximal luer cap.
2. Activate and calibrate Compass UniversalHg by depressing power button for approximately one second until display reads “00 mm” (Figure 1).

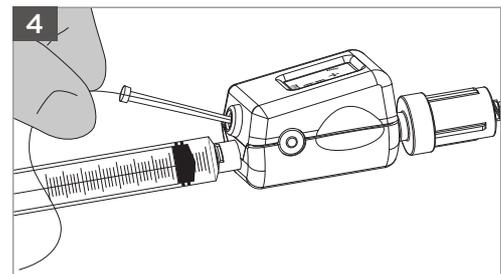
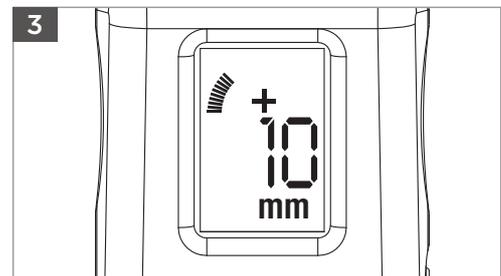
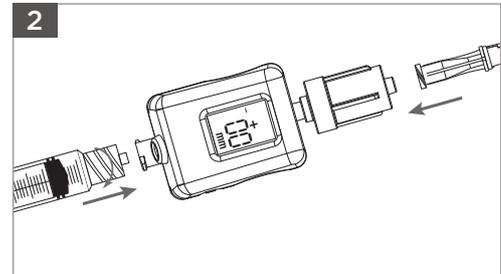
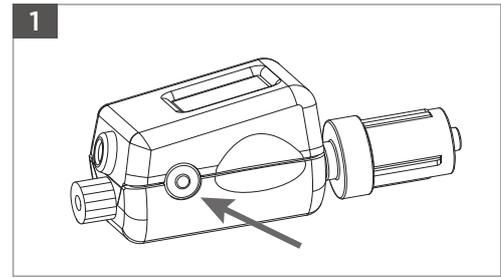
Warning: Turn on Compass UniversalHg prior to attaching accessories to avoid incorrect baseline pressure.

3. Connect Compass UniversalHg to accessory monitoring equipment (e.g. needle, catheter, stopcocks, flush devices, tubing administration sets, etc.) per hospital protocol (Figure 2).

Note: Attach distal (male luer) side of Compass UniversalHg to needle or catheter in contact with patient.

4. Pressure is displayed on Compass UniversalHg LCD (Figure 3).

If desired, insert device (maximum 0.038” diameter) through Compass UniversalHg guidewire port (Figure 4). Use of guidewire insertion tool or “cheater” may be necessary for smaller devices.



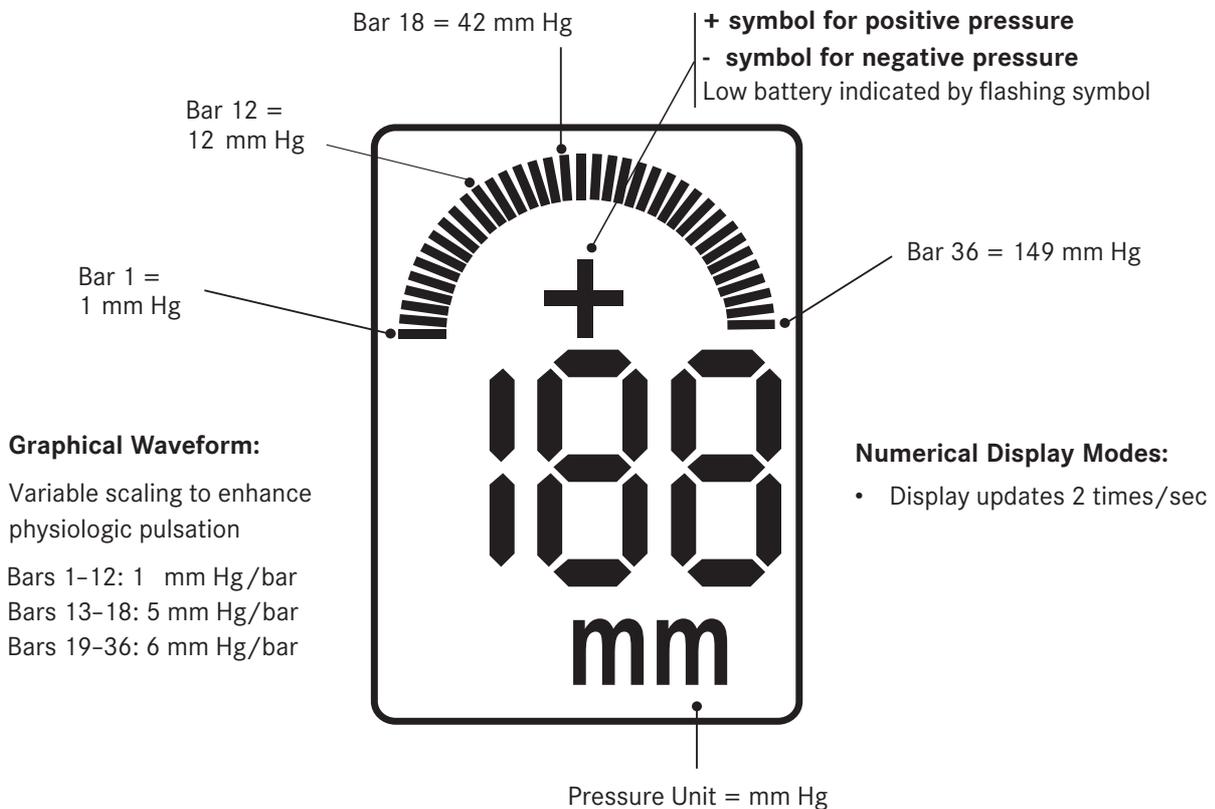
Warnings

- Do not reinfuse blood or other bodily fluid into the patient after any such fluid is drawn into the Compass UniversalHg.
- Do not reuse Compass UniversalHg for more than one procedure in the same patient. Use a new Compass UniversalHg device for each procedure.
- To avoid a non-physiological pressure reading, do not move syringe plunger while measuring vessel pressure.
- Pressure reading is not physiological if either front or rear of the device is open to atmospheric pressure.

Device Power Off and Recalibration

Press button three times in a “PUSH - PUSH - HOLD” sequence (i.e. quickly push button twice and then hold third button push until device turns off). To recalibrate and zero the device, open the device to atmosphere and depress power button until display reads “00 mm”.

Display



Compass™ UniversalHg Specifications

Characteristic	Value
Pressure Range	-199 mm to +999 mm Hg
Accuracy	±2 mm Hg 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 to 104° F)
Storage Temperature	-29 to 49° C (-20 to 120° F)
Light Sensitivity.....	< 1 mm Hg
Lithium Ion Battery Voltage	3 Volts

Software Error Codes

Code	Meaning
SF	Software Failure
HF	Hardware Failure
PF	Pressure Sensor Failure
bF	Battery Failure
EE	Environmental Error - Device outside operating temperature
CE	Calibration Error - Pressure values outside operating range