# AFFIRM®

EN - **INSTRUCTIONS FOR USE**

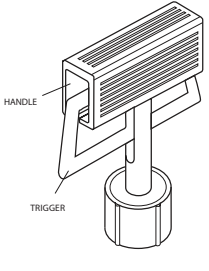
English

# AFFIRM®

## INFLATION DEVICE

## INSTRUCTIONS FOR USE

**DESCRIPTION:**




The AFFIRM® Inflation Device and Fluid Dispensing Syringe by Globus Medical is a 20ml disposable device with an integral pressure transducer, microcomputer, back-lit LCD, threaded plunger assembly with lock/release bar, a flexible high pressure extension tube, and a three-way medium pressure stopcock. The AFFIRM Inflation Device is designed to generate and monitor pressures over a range of -0.4 to +30.0 ATM/BAR (-6 to 441 PSI). The AFFIRM Inflation Device syringe dispenses 0.45ml of fluid ± 0.07ml for each 360° turn of the syringe plunger handle.

**℞ only CAUTION:** Federal (U.S.A.) law restricts this device to use by or on the order of a physician.

**INSTRUCTIONS FOR USE:**

Before use, inspect the device and packaging to verify that no damage has occurred as a result of shipping.


Ensure the line is open to atmospheric pressure by opening the stopcock. Press the blue button behind the LCD display near the tubing to power the device on. The LCD will display "2 E r o" for two seconds and then the device will be ready to use. At this point the syringe will begin its incremental time keeping.

The syringe will be set in the ATM/BAR mode when initially turned on. To change the pressure display to read in PSI, press and hold the blue button until "ATM/BAR" flashes four times. The user is now in "PSI" mode. To change back to ATM/BAR, press and hold the blue button once again.

**NOTE:** When in PSI mode, the tick marks on the left of the display that represent pressure will be limited to 300 PSI (20.4 ATM). If the AFFIRM Inflation Device is pressurized past 300 PSI, the grouping of tick marks on the left will flash. The numerical digits in the center of the display will continue to show actual pressure throughout the device's pressure range (-6 to 441 PSI).

After an inflation or pressure monitored injection has been made, a graph bar or tick mark will remain to mark the highest point of pressure. Pressing the blue button once quickly display last inflation information and a "↵" indicator on the display. After the next inflation has been started, the last inflation tick mark will disappear.

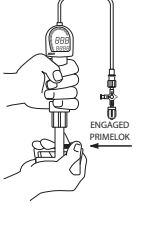
**CAUTION:** If "ER" is displayed in the pressure area and a number appears in the time window, the syringe is defective. Please return the syringe to Globus Medical for credit.

**NOTE:** To conserve power, the backlight will automatically turn off after ten minutes of inactivity. However, the microprocessor will continue to monitor the pressure. Pressing the blue button or inflating the balloon will reactivate the backlight. The device will power itself off after 90 consecutive minutes at zero pressure.

**DEVICE PREPARATION:**

To prep syringe, simply aspirate up to 20 ml of contrast solution or other fluid into the syringe by squeezing the trigger and pulling back on the handle.

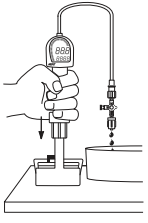
**PRIMING WITH PRIMELOK™**




The PrimeLok allows purging of air and excess fluid without squeezing the trigger. The AFFIRM Inflation Device is packaged with the PrimeLok in the disengaged position.

1. To engage PrimeLok, squeeze trigger and slide PrimeLok into slot.

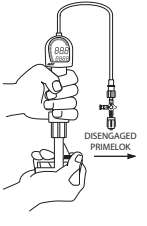
2. To prep syringe, simply aspirate up to 20ml of contrast solution or fluid to be dispensed into the inflation syringe by pulling back on the plunger handle.



**CAUTION:** Inspect the syringe tubing and stopcock (if used) to insure that there is no air in the system.

3. Push handle against table to remove air in syringe.

4. To disengage PrimeLok, squeeze trigger and slide PrimeLok out of slot. This will allow the plunger to lock in position and the device is now ready for use.




**NOTE:** The PrimeLok must be disengaged before pressure can be maintained by the lock/release mechanism.

**INFLATION DEVICE INDICATIONS AND USAGE:**
This inflation device is used to inflate and deflate an angioplasty balloon or other interventional devices, and to measure the pressure within the balloon.

**ATTACHING THE INFLATION DEVICE TO THE BALLOON:**

**NOTE:** Refer to the manufacturer's directions accompanying the balloon dilatation catheter or other interventional device for specific information on use, maximum inflation pressure, precautions, and warnings for that device.

1. Prepare and test the balloon catheter according to the catheter manufacturer's directions for use.

2. Create a fluid-fluid connection between the balloon and the syringe extension tube, connect the luer connectors securely.

3. Squeeze the trigger and pull back on the plunger handle to apply a vacuum to the balloon.

**BALLOON INFLATION AND DEFLATION:**

1. To inflate the balloon, squeeze the trigger allowing the plunger to return to a resting position (0 ATM/BAR or PSI). Release grip on the trigger, locking the plunger into position. To increase pressure, rotate handle clockwise until the desired pressure is achieved. Pressures above the maximum range will be indicated with flashing numbers.

The tick mark will remain at the highest point of the last pressure reading. As the pressure decreases from the maximum pressure, the tick mark will begin to flash.

**NOTE:** Significant loss of pressure may indicate a leak in the system.

**CAUTION:** To protect the threads of the lock release handle, the pressure must be reduced to 25 ATM or lower before the quick release mechanism is used to deflate the angioplasty balloon.

2. To deflate balloon, rotate handle counterclockwise to release pressure to 25 ATM or lower. Squeeze the trigger and pull back to generate a negative pressure. Release grip to lock the plunger in a negative pressure position. Pressures below the minimum range of the syringe will be indicated by flashing bars and a "NEg" in the pressure area.

**FLUID DISPENSING INDICATIONS AND USAGE:**
This device is intended for use by healthcare professionals to dispense fluids to the body from the AFFIRM Inflation Device syringe and monitor the pressure of that fluid.

**DISPENSING FLUIDS AND MONITORING PRESSURES USING THE AFFIRM INFLATION DEVICE SYRINGE**

1. To slowly dispense fluids to the body rotate the plunger clockwise until the desired fluid is injected. To rapidly dispense fluids to the body squeeze the trigger while pushing the plunger forward. The injection pressure will be displayed on the LCD and the timer automatically starts once the device generates a positive pressure. Pressures above the maximum range of the syringe will be indicated with flashing numbers on the display.

2. A negative pressure may be generated by squeezing the trigger and pulling back the plunger. Release grip on the trigger to lock the plunger in the negative pressure position.

3. The timer will reset once the pressure returns to zero or less. Data associated with the last injection will be displayed when the blue button is depressed and held and the pressure is zero or less.

**CAUTION:** This syringe is capable of generating high fluid pressures in a closed fluid system. The volume change of fluid dispensed may not be accurate due to compliance of the plastic components as pressure changes.

**CAUTION:** If applied pressure does not indicate on gauge/digital display, discontinue use immediately and replace it with a new unit.

## SPECIFICATIONS

| | |
|---|---|
| Operating Range: | -0.4 ATM to 30 ATM (1 ATM = 1 BAR = 14.7 PSI) |
| Accuracy: | ±3.0 % of full scale typical |
| Fluid Dispensed: | 0.45ml ±0.07ml fluid dispensed for each 360° clockwise turn of the syringe plunger handle |
| Liquid Temp: | 10° C to 40° C |
| Humidity Operation Range: | 20% to 90% Non-condensing humidity |
| Battery Life: | Fully active device, up to 10 hours |

**REUSE PRECAUTION STATEMENT**

For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

**RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RADIO FREQUENCY (RF) COMMUNICATIONS EQUIPMENT AND THE AFFIRM INFLATION DEVICE**

The AFFIRM Inflation Device is intended for use in an electromagnetic environment in which RF radiated disturbances are controlled. The user of the AFFIRM Inflation Device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AFFIRM Inflation Device as recommended below, according to the maximum output power of the communications equipment.

| | Separation distance according to frequency of transmitter (in meters) m | | |
|---|---|---|---|
| Rated maximum output power of transmitter (in watts) W | 150 kHz to 80 MHz $d = \left[ 1.2 \right] \sqrt{P}$ | 80 MHz to 800 MHz $d = \left[ 1.2 \right] \sqrt{P}$ | 80 MHz to 800 MHz $d = \left[ 2.3 \right] \sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.2 |
| 0.1 | 0.37 | 0.37 | 0.7 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.7 | 3.7 | 7.3 |
| 100 | 12 | 12 | 23 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated 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 applies.
NOTE 2 – These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

**GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY**

The AFFIRM Inflation Device is intended for use in the electromagnetic environment specified below. The customer or the user of the AFFIRM Inflation Device 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 61000-4-20 | ±6 kV contact ±8 kV air | ±6 kV contact ±8 kV air | Increasing relative humidity will reduce the potential for ESD related difficulties |

Users should follow local guidelines and practices regulating the disposal of infected waste products.

STERILE EO EtO Sterilized

Use once and destroy

Non-pyrogenic

Sterile if package is unopened and undamaged.

U.S. Patent Nos. 5,047,015 5,057,078 5,135,488
Other U.S. and Foreign Patents Pending.

Interference may occur in the vicinity of equipment marked with this symbol

Caution! Consult accompanying documents

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