DiamondTOUCH™

English

INFLATION DEVICE AND FLUID DISPENSING SYRINGE

INSTRUCTIONS FOR USE

DESCRIPTION

The DiamondTOUCH™ Inflation Device and Fluid Dispensing Syringe by Merit Medical is a 30mL 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 stopcock. The DiamondTOUCH™ is designed to generate positive and negative pressure, and monitor positive pressures over a range of zero to +35ATM/BAR (zero to 514 PSI).

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

INDICATIONS FOR USE

The DiamondTOUCH Inflation Syringe is used to inflate and deflate balloon angioplasty catheters or other interventional devices and to measure the pressure and time of inflation within the balloon during the procedure. It is also used to dispense fluids into the body and monitor the pressure of that fluid.

DEVICE PREPARATION:

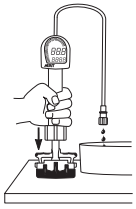
1. Ensure the system is open to atmospheric pressure by opening the stopcock. Press the blue button behind the LCD display near the tubing to power the device on. The LCD will display "ZEro" for two seconds and then the device will be ready to use. At this point the syringe will begin its incremental time keeping.
2. To prepare syringe, turn the device with digital display facing down and aspirate up to 30 mL of contrast solution or other fluid into the syringe by squeezing the lock/release bar and pulling back on the handle.
3. Push handle against table or other solid surface to remove air in syringe.

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

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 display 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 350 PSI (23.8 ATM). If the DiamondTOUCH is pressurized past 350 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 514 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 will 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 the LCD displays anything besides the pressure and time windows shown above, the syringe is defective. Please return the syringe to Merit 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.

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

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 lock/release bar 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 lock/release bar allowing the plunger to return to a resting position (0 ATM/BAR or PSI). Release grip on the lock/release bar, 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 bar, 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 lock/release bar 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.

DISPENSING FLUIDS AND MONITORING PRESSURES USING THE DIAMONDTOUCH 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 lock/release bar 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 lock/release bar and pulling back the plunger. Release grip on the lock/release bar 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/BAR to 35 ATM/BAR (-6 PSI to 514 PSI)
Accuracy	±3.0% of full scale at 10°C to 40°C
Fluid Dispensed	0.57ml ± 0.10ml fluid dispensed for each 360° clockwise turn of the syringe plunger handle.
Liquid Temp	10° C to 40° C
Humidity	20% to 90%
Operation Range	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 re-sterilize. Reuse, reprocessing or re-sterilization may compromise the integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or re-sterilization 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 DIAMONDTOUCH™ INFLATION DEVICE

The DiamondTOUCH Inflation Device is intended for use in an electromagnetic environment in which RF radiated disturbances are controlled. The user of the DiamondTOUCH Inflation Device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the DiamondTOUCH 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=[1.2]P*	80 MHz to 800 MHz *d=[1.2]P*	800 MHz to 2.5 GHz *d=[2.3]P*
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
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 equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should ensure 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.

	Do not reuse
	Do not use if package is damaged
	Interference may occur in the vicinity of equipment marked with this symbol
STERILE EO	
CE	EC mark logo - Notified body identification
	Non-pyrogenic
	Contains Batteries - Do Not Remove

CE 2797

MERIT MEDICAL®

merit.com

Manufacturer:
Merit Medical Systems, Inc. 1600 West Merit Parkway,
South Jordan, Utah 84095 U.S.A. 1-801-253-1600
U.S.A Customer Service 1-800-356-3748

EC REP

Authorized Representative:
Merit Medical Ireland Ltd,
Parkmore Business Park West, Galway, Ireland
EC Customer Service +31 43 3588222

401768001_002 2020-06-13