

DI164A
(REV. B)

ACCUMETER

02/2016

Algea
therapies

ALGEA THERAPIES

A Division of Globus Medical
Valley Forge Business Center
2560 General Armistead Avenue
Audubon, PA 19403
USA
Customer Service:
Phone 855 639-6612
Fax 855 639-6611

IMPORTANT INFORMATION ON ACCUMETER

CE REP: RMS – UK Limited
28 Trinity Road, Nailsea, Somerset, BS48 4NU England

CE 0297



FOR WITHIN THE UNITED STATES ONLY

ENGLISH

IMPORTANT INFORMATION ON ACCUMETER

INDICATIONS

For use in diagnosis of herniated or otherwise diseased intervertebral disks in the human spine. The ACCUMETER has not been evaluated for use in vertebroplasty.

SPECIFICATIONS

Pressure Range: 0-125 PSI	Maximum Pressure: 180 PSI
Battery Voltage: 2-3 V	Accuracy: ±3% of full scale

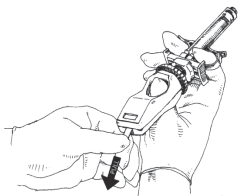
SPECIAL FEATURES

- Display flashes once 125 PSI is reached
- Clear Vue Barrel
- Precise Pressure Control
- Ergonomic Design

INSTRUCTIONS FOR USE

**This device has not been evaluated for use in vertebroplasty.*

1. Using sterile technique, remove the ACCUMETER from the peel pouch and open the CSR wrap in a sterile field.
2. Leaving Luer connection open ensures that the ACCUMETER is **OPEN TO ATMOSPHERE**. This ensures that the ACCUMETER recognizes atmospheric pressure as the reference "zero" value.
3. Pull the tab to start the electronics. ACCUMETER counts down, calibrates to "0" and is ready for use.

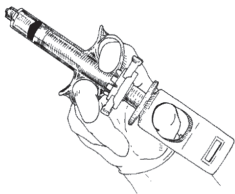


4. If ACCUMETER detects pressure in the barrel, display flashes "h.P.". Should this be observed, release pressure, ACCUMETER will automatically start.
5. Fill the Accumeter and de-bubble.

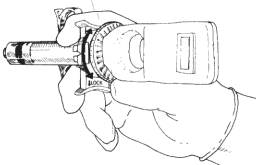


6. Using a dead-end, close off the fluid path and apply a test pressure by applying force to the plunger. Ensure the ACCUMETER responds to the application of pressure by monitoring an increase in digital values as seen from the display. (NOTE: This test inflation will appear on the procedural printout.)

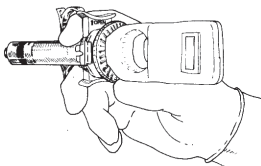
7. In normal use, pressure may be applied by applying force with the thumb and squeezing as with any syringe.



8. Pressure may be controlled by sliding the slide lock bar into the "Locked" position, and rotating the thumb wheel clockwise to **INCREASE** the pressure, or counter clockwise to **DECREASE** pressure.



9. Pushing the slide lock bar into the open position immediately releases pressure. This allows the plunger to move freely in and out of the barrel.



10. Proceed with the discography procedure, allowing a minimum pause of 2 seconds following opening pressure. During the procedure the ACCUMETER may be used to generate pressures up to 125 Psi.

11. Procedure printout occurs at any point during the procedure by placing the ACCUMETER on the printer docking station. To do so, release all pressure from the syringe by sliding the lock bar to the open position.

12. Place the syringe display side down on the docking station with the post fitting through the thumb hole of the ACCUMETER. Data is downloaded and printed within seconds of seating the device.

13. Following the procedure, the ACCUMETER is simply discarded. It is a SINGLE USE, DISPOSABLE device that will remain on until the batteries run down.

For disposal, the ACCUMETER may be disinfected using autoclave, or chemical disinfectant, discard in landfill. However, it should not be incinerated.

CAUTION

- Federal Law restricts this device to sale by or on the order of a physician.
- The ACCUMETER will generate high pressure very rapidly in a closed low compliance system.
- If the pressure in the ACCUMETER exceeds the specified operating pressure range, the digits will begin to flash indicating the normal operating range has been exceeded.
- Based on the Radiographic materials used there may be some risk to surrounding tissue due to dye leakage from the disk.

ATTENTION

- Application of excessive pressure to the intervertebral disk may damage the disk.
- Emergency pressure release can be achieved by sliding the slide lock bar to the open position and pulling back on the plunger.
- In the remote case of leakage into the electronic cavity of the device, shorting of the transducer may cause:
 - The display to go blank and be unresponsive to the application of pressure.
 - The display to show "0" and be unresponsive to the application of pressure.
 - The Accumeter display to flash, show a value greater than 170 and be unresponsive to the application of pressure.
- The ACCUMETER provides monitored fluid pressure through an open-ended cannula/needle to the interior of the vertebral disk, utilizing a needle or cannula in the range of 18-25 gauge.

ACCUMETER Prt #: KEM3000 & KEM4000 ACCUMETER Printer Prt #: KAD1000
US Patent Nos. 7291131, D562447, 7351223, D579561

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Manufactured in USA by: Globus Medical • Audubon, PA 19403 U.S.A. (855) 639-6612

SYMBOL TRANSLATION	
QTY	QUANTITY