

Section: Division of Nursing
Approval: _____

PROCEDURE

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HACKETTSTOWN REGIONAL MEDICAL CENTER

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OR
(Scope)

TITLE: DYONICS ACCESS 15 ARTHROSCOPIC FLUID IRRIGATION SYSTEM

PURPOSE: To instruct the OR Nurse on the proper use of the Dyonics Access 15 Arthroscopic Fluid Irrigation System.

CONTENT:

A. Purpose of the Dyonics Access 15 Arthroscopic Fluid Irrigation System.

Intended Use

This device provides fluid distention of articular cavities for diagnostic and / or operative arthroscopic procedures. Such procedures may include:

- Ligament injuries
- Meniscus injuries
- Cartilage injuries
- Operation planning and re-examination

Refer to your arthroscope User's Manual for specific indications for use.

The intra-articular pressure and flow can be preselected. Once the preselected pressure level has been reached, the device automatically interrupts the flow of fluid. If the intra-articular pressure falls below the preselected level, the fluid flow will be automatically reinitiated.

Recommended Pressure

The device is indicated for use in the following joints. The listed pressure levels are generally considered appropriate, although circumstances may vary from patient to patient and procedure to procedure. These values are recommendations and are not intended to substitute or replace the expertise of the surgeon.

Knee	max. 90 mmHg
Shoulder	max. 60 mmHg
Elbow	max. 50 mmHg
Ankle	max. 70 mmHg
Wrist	max. 60 mmHg

Contraindications For Use

Use of this device for fluid distention is contraindicated whenever arthroscopy is contraindicated. Refer to your arthroscope User's Manual for absolute and relative contraindications.

The device is contraindicated for:

- Ankylosis
- Inflammation or bacterial contamination of an open wound.

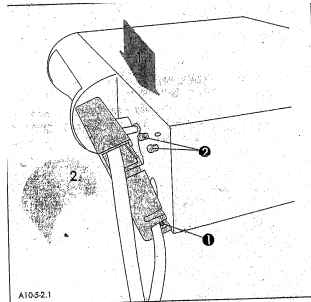
The device is not intended for the injection of medication.

B. Preoperative Setup of the Device

1. Turning the Device On

Turn the device on using the power switch **WITHOUT** the tubing cassette inserted.
The power switch and the digital displays will illuminate.
The device performs an automatic self check test.

2. Attach the Disposable Tubing Cassette

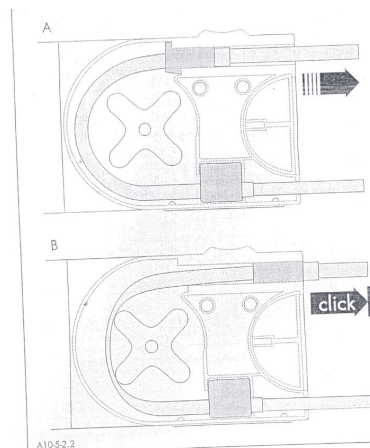


- Position the tubing cassette on the device at the two lower cassette holders ❶.
- Press the cassette into the two upper holders until you hear it latch into place ❷.
- Pull the irrigation tubing until the tubing coupler latches firmly into place (Illustr. A10-5-2.2).
- The digital displays should read:

Desired pressure	0 (mmHg)	initial values set by
Desired flow	0.10 (1/min)	the manufacturer
In-joint pressure	0 (mmHg)	

Each time you switch the device on and off, the device saves the last entered desired pressure and flow levels and shows the values in the display.

- Connect the cannula and open the inflow stopcock completely.

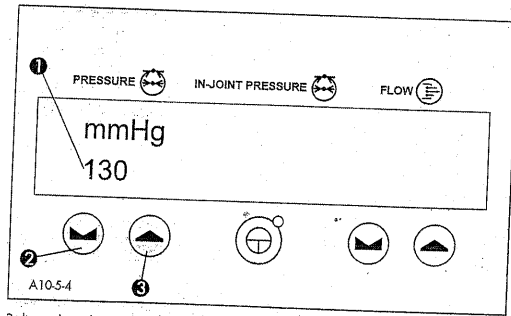


3. Connecting the Fluid Bag


The height of the fluid bag influences the flow rate. Fluid bags can be hung 20-39 in (0.5-1.0 m) above the mounting surface of the device. Optimal flow rate is achieved at 39 in (1.0m).


- The irrigation tubing (❷ Illustr. A10-4-3.1) has been prepared to accept irrigation fluid from two irrigation bags. Close both clamps on the irrigation tubing.
- Grasp the bag spike at the appropriate grip.
- Insert the spike, sterilized by the manufacturer, into the bag using prescribed aseptic technique.
- Open the clamp of the irrigation tubing.


4. Preselecting the Desired Pressure




Select the desired pressure. The desired pressure display shows the preselected value ❶ in mmHg.

One short press on the Pressure  button ❷ will reduce desired pressure by 1 mmHg within the whole selectable range.

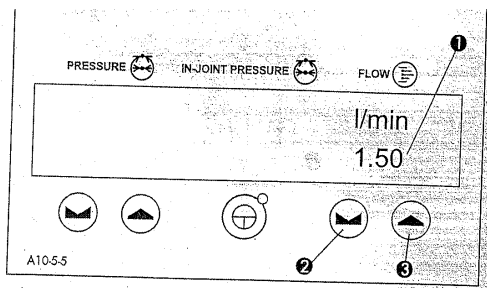
One long press on the Pressure  button ❷ will allow continuous reduction of the desired pressure in increments of 10 mmHg within the whole selectable range.

One short press on the Pressure  button ❸ will increase desired pressure by 1 mmHg within the whole selectable range.


One long press on the Pressure  button ❸ will allow continuous increase of the desired pressure by 10 mmHg within the whole selectable range.


For preoperative setup, the desired pressure must be set above 50 mmHg. Following calibration, the user may adjust desired pressure to any value within the selectable range.


5. Preselecting the Desired Flow




Select the desired flow in between 0.1 - .50 l/min. The desired flow display shows the preselected value ❶ in l/min.

One short press on the Flow  button ❷ will reduce desired flow by 0.05 l/min within the whole selectable range.

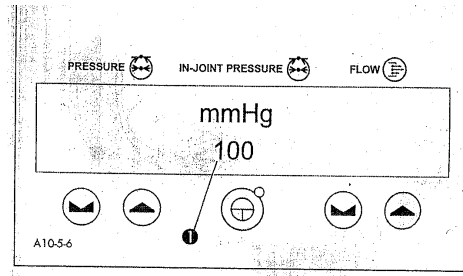
One long press on the Flow  button ❷ will allow continuous reduction of the desired flow in increments of 0.10 l/min within the whole selectable range.

One short press on the Flow  button ❸ will increase desired flow by 0.05 l/min within the whole selectable range.

One long press on the Flow  button ❸ will allow continuous increase of the desired flow by 0.10 l/min within the whole selectable range.

For preoperative setup, the desired flow rate must be set above 0.80 l/min. Following calibration, the user may adjust desired flow rate to any value within the selectable range.

6. In-Joint Pressure Display



The pressure is measured at the pressure chamber. The in-joint pressure display is calculated by means of the measured pressure and the following operating parameters:

- hydrostatic admission pressure;
- flow;
- instrument resistance.

The pressure is shown in the in-joint pressure display ① in millimeters mercury column (mmHg).

Follow the instructions in Chapter 5-7, Advanced Flow Regulation System (AFR System), for the most accurate intra-articular pressure measurement.

7. Calibrating the Device

The device is equipped with the Advanced Flow Regulation System (AFR System) which enables the achievement of optimal flow rates with most standard instruments on the market.

For the achievement of optimal flow rates recommended settings are 150 mmHg for pressure and 1.5 l/min for flow. These settings are necessary for the AFR System to calibrate optimally with the chosen instrument combination. Calibration has to be performed with the scope/sheath combination that will be used during the operation. Calibration has to be performed outside the joint.

NOTE! For low flow scope/sheath combinations maximum pump settings are required for efficient calibration.

Minimum required settings are 50 mmHg for pressure and 0.80 l/min for flow. Lower settings will result in decreased performance and longer calibration time. Settings must be preselected when starting the device. After initialization, adjust pump to the desired operating settings.

1. Ensure the fluid bags, tubing cassette and cannula are connected as described previously. Ensure the inflow stopcock is open completely. Ensure clamps to both fluid bags are open.

WARNING

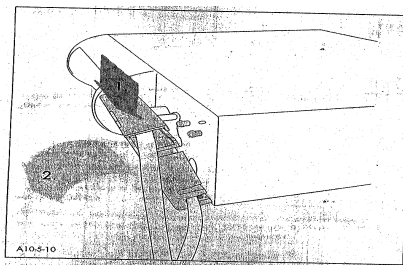
Failure to fully open the stopcock on the inflow cannula during calibration by the Advanced Flow Regulation feature may result in inaccurate measurement of intra-articular pressure.

2. Ensure that the
 - recommended pressure of 150 mm/Hg and
 - recommended flow of 1.5 l/minor that the
 - minimum required pressure of 50 mmHg and
 - minimum required flow of 0.80 l/minhave been selected.
3. To start the irrigation process:
If tube set is not attached and the Start/Stop button is pressed, three short warning signals will be heard and the roller wheel will not rotate:
Press Start/Stop Button.
The green Start/Stop LED illuminates and roller wheel starts to rotate. The AFR System adjusts flow to an optimum and display flashes "Calibrating" followed by a short acoustic signal.
4. When successful calibration is obtained close the inflow stopcock. Pump and instrument are ready for use. Do not press Start/Stop button or calibration will be lost.
5. If flashing default symbol (O) appears on the display after calibration, pump performance will not be optimal. Pump will utilize a factory default calibration curve for instrument impedence. To exit default mode press Start/Stop button to stop pump, press again to start and repeat calibration.
6. To change instrument configuration during operation, press Start/Stop button to stop pump, the green LED will go out. Connect new instrument configuration outside joint and open inflow stopcock completely. In-joint pressure display will continually display updated in-joint pressure.

WARNING

DO NOT perform the calibration of the instrument with the Advanced Flow Regulation (AFR) feature with the cannula in the joint. When using rotatable cannulas, ensure that maximum outflow is established (by rotating inflow ring with respect to cannula body) prior to pressing the Start/Stop button. The device must be recalibrated after connecting a new instrument.

7. Press the Start/Stop button again. The green Start/Stop LED illuminates. The AFR System optimizes the flow for the newly connected instrument.
8. Removing the Tubing Cassette



To remove the tubing cassette from the device, press down on the upper part of the cassette.

WARNING

The choice of irrigation fluid to be used must be decided by the physician based on the surgical technique to be employed.

1. Setup and calibrate the system (refer to Chapter 5).
2. Select the desired pressure and flow rate.
3. Insert the instrument into the joint.
4. Start the irrigation process:
Open the stopcock at the cannula.

The device will adjust the process of joint distention in accordance with the preselected pressure and flow values. Once the desired pressure has been reached the actual flow will be automatically reduced.

During the Surgery

A wide range of in-joint pressures can occur during any arthroscopic surgical procedure. The in-joint pressure is affected by changes in joint cavity volume during motion of the joint, the opening and closing of inflow and outflow cannulas, activation of shaver and suction equipment, and the type of procedure performed. Even under conditions of low in-joint pressure, certain actions by the surgeon can result in the development of high transient in-joint pressures.

All motion of the joint during arthroscopic surgery should be done slowly, using open inflow and outflow tubes to allow drainage of the appropriate quantity of irrigation fluid from the joint. Doing so may help to prevent gross extravasation of irrigation fluid, vascular compromise, or compartment syndrome caused by high in-joint pressures. Do not allow the outflow to become blocked with tissue.

The following steps can be taken to minimize the risk of extravasation of irrigation fluid beyond the joint space when using the Access 15 Arthroscopic Fluid Irrigation System:

1. Avoid unneeded punctures of the joint space and maintain snug access portals.
2. Inspect the joint for compromise or weakness before increasing the desired set pressure.
3. Use the lowest desired set pressure for adequate joint distension, visualization and desired clinical effect. The minimum required pressure will vary on a case by case basis.
4. Check the position of all cannulas within the joint space frequently during the procedure to ensure cannulas are properly supplying and draining the operative space.
5. If pump is not able to reach the desired set pressure, even at low flow rates, inspect the operative area for problems. Carefully palpate around the operative area during the procedure for signs of gross extravasation of irrigation fluid generally perceived as increased tissue tension.

Delicate arthroscopic procedures may divert the surgeon's attention from the volume of fluid input and output and the initial subtle signs of fluid extravasation may be missed. The surgeon should be aware of any lack of joint distention, increased fluid to dislodge the joint or increased joint tension or extremity circumference on palpation during the procedure which may indicate extravasation.

The Access 15 Arthroscopic Fluid Irrigation System is designed to keep joint pressure at safe levels during the surgical procedure. It employs an active pressure relief system that works to reduce joint pressure spikes caused by:

- The outflow from the joint becoming blocked.
- The joint being suddenly flexed.
- The rapid shut off of suction or shaver devices.

The active pressure relief system will reduce the pressure quickly by back pumping irrigation fluid into the bag lines.

After the Surgery

1. Stop the irrigation process
Close the stopcock at the cannula.
2. Press the Start/Stop button. The Start/Stop LED will go out.
3. Turn the pump off using the power switch.

WARNING

Follow standard procedures for biohazardous waste when disposing of the tube set, collected fluid and the secretion container.
