

Double Pump RF

Operator's Manual



Double Pump RF maximizes visibility during arthroscopy through the SmartVision® technology by Medical Vision AB, Sweden.

Double Pump RF detects factors that impede visibility during surgery, and automatically adjusts for them. When engaged, the SmartVision® function automatically controls flow through and pressure in the joint to obtain maximum visibility.

Double Pump RF controls the Intra-Articular Pressure (IAP); not the pressure at the pump. The IAP is displayed on the pump display.

The user can easily change the outflow/pressure settings during surgery, if needed.

Double Pump RF supports interface connection to RF generators and most shaver systems.

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Description, Indications for Use and Contraindications

Description

The Double Pump RF provides liquid irrigation and aspiration for arthroscopic procedures in one unit through two individual roller pumps. Both roller pumps are software controlled and automatically manage fluid and joint pressure based on procedure settings chosen by the user. If needed, both outflow and pressure settings can be individually adjusted.

Disposable cassettes with tubing are used for liquid management from bags of irrigation liquid for inflow to the joint, and aspiration of liquid from the joint to a waste container.

By controlling both inflow and outflow, the Double Pump RF accurately regulates pressure in the joint, and outflow from it. The Double Pump RF also provides suction when used in conjunction with a shaver and / or a RF generator.

Product names and definitions:

The Double Pump RF comprises the following articles (non-sterile):

- Double Pump RF Unit
- Mains cable
- Foot Controls (sold separately)
- Shaver interfaces (sold separately)
- Interfaces for RF generators (sold separately)

Sterile Disposables:

- **Double Pump RF Day Cassette (Day Cassette):**
A disposable cassette for handling inflow of irrigation liquid from Irrigation liquid bags to the Single/Irrigation Tubing. It has a pump tubing segment for the inflow pump that pressurises the joint, and has 2 soft membranes to transfer pressure in the cassette to pressure transducers on the front of the pump.
- **Double Pump RF Patient Cassette (Patient Cassette RF):**
A disposable cassette for handling aspiration of liquid from the joint through an outflow cannula, shaver hand piece or RF Probe. It comprises a cuvette with reflector for detecting blood and debris emerging from the joint.
- **Double Pump Patient Cassette (Patient Cassette):**
A disposable cassette for handling aspiration of liquid from the joint through an outflow cannula or shaver hand piece (not RF Probe). It comprises a cuvette with reflector for detecting blood and debris emerging from the joint.
- **Double Pump RF Irrigation Tubing (Irrigation Tubing):**
A disposable tubing for administration of irrigation liquid from the Day Cassette to the arthroscope. It has a check valve and is packed together with Double Pump RF Patient Cassette in a tray.
- **Double Pump RF Single (Single tubing):**
Same as Irrigation tubing, with check valve, but packed and sold individually.
The check valve ensures that there is no back flow from the patient into the Irrigation/Single tubing.

Indications for Use

The Double Pump RF is a dual arthroscopic pump system intended to provide fluid distension and irrigation of the knee, shoulder, hip, elbow, ankle and wrist joint cavities and fluid suction during diagnostic and operative arthroscopic procedures.

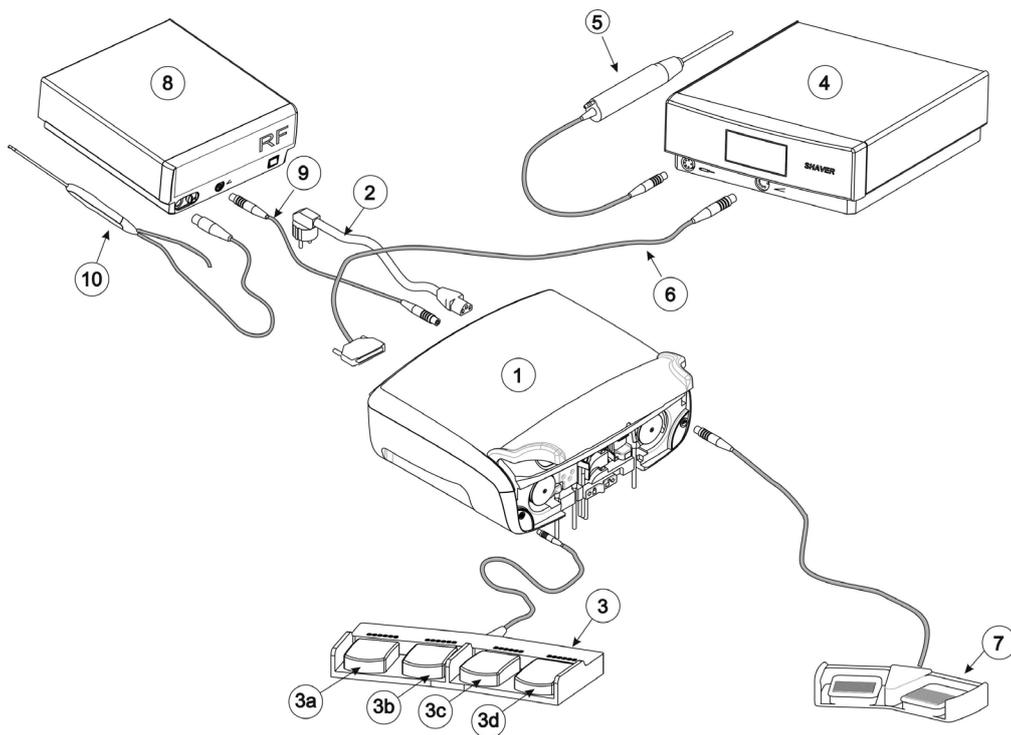
Contraindications

- **DO NOT** use the Double Pump RF for procedures such as gynecological, urological, for temporomandibular joints or any other non arthroscopic procedure.
- **DO NOT** use the Double Pump RF in instances where capsular integrity is suspected.
- **DO NOT** use the Double Pump RF with a gas distension medium. Use only with sterile irrigation solution for distension of the joint.
- **DO NOT** use the Double Pump RF to administrate drugs, IV-fluids, blood or blood substitutes.

System Overview

Connection Diagram

Shaver control by use of the pump's foot control.
RF generator ArthroCare®, Quantum 2 is used.

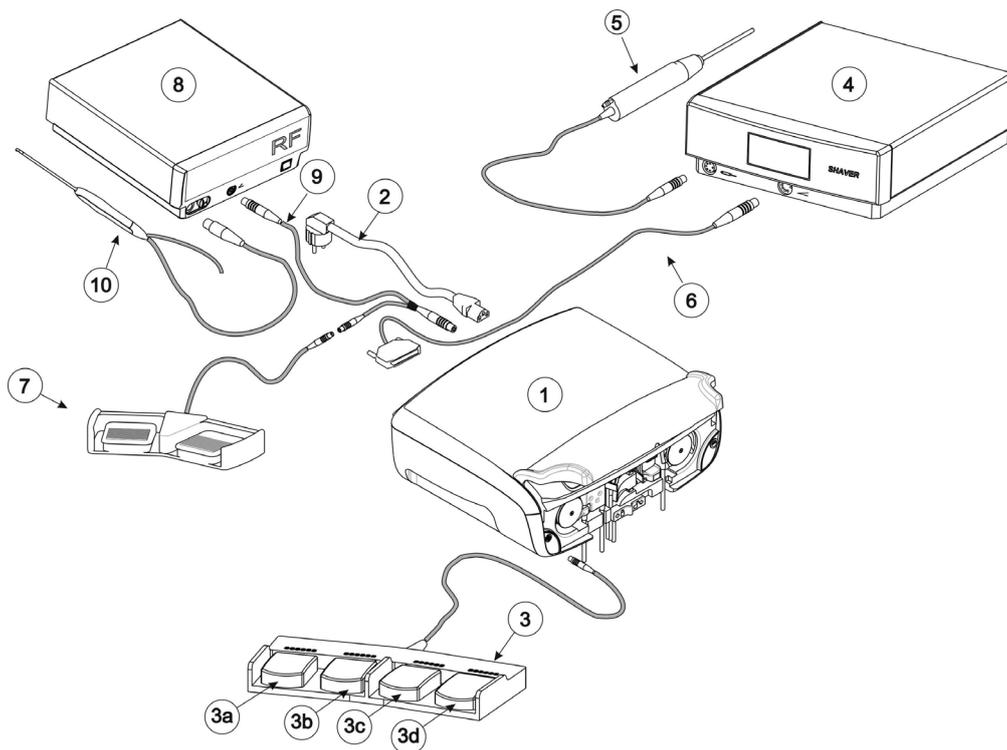


① Double Pump RF	④ Shaver console
② Mains Cable	⑤ Shaver Hand piece
③ Foot Control: a) Shaver Reverse b) Shaver Forward c) Cannula d) Rinse	⑥ Shaver Interface Cable
	⑦ RF Generators Foot Control
	⑧ RF Generator
	⑨ RF Cable A1
	⑩ RF Probe

System Overview

Connection Diagram

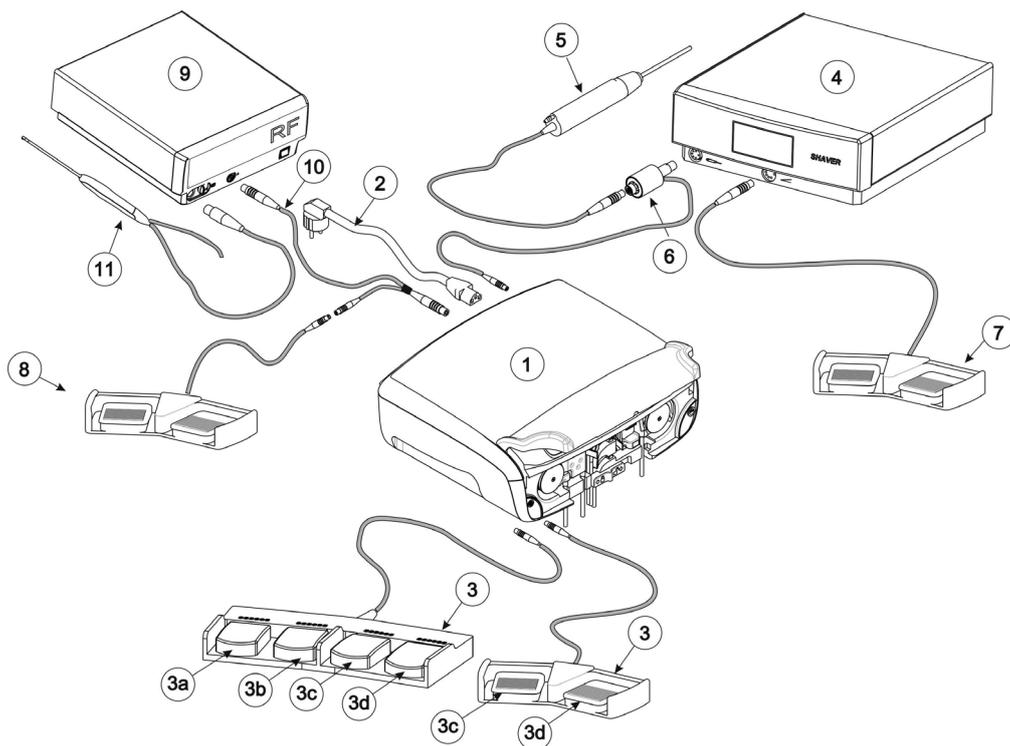
Shaver control by use of the pump's foot control.
RF generator Stryker® Serfas Energy is used.



① Double Pump RF	④ Shaver console
② Mains Cable	⑤ Shaver Hand piece
③ Foot Control: a) Shaver Reverse b) Shaver Forward c) Cannula d) Rinse	⑥ Shaver Interface Cable
	⑦ RF Generators Foot Control
	⑧ RF Generator
	⑨ RF Cable A2
	⑩ RF Probe

Connection Diagram

Shaver control by use of the shaver's foot control or hand control.
RF generator Stryker® Serfas Energy is used.



1 Double Pump RF	4 Shaver console
2 Mains Cable	5 Shaver Hand piece
3 Foot Control: A 4 pedal or 2 pedal Foot Control may be used: a) Shaver Reverse b) Shaver Forward c) Cannula d) Rinse	6 Shaver Interface Box
	7 Shaver Foot Control
	8 RF Generators Foot Control
	9 RF Generator
	10 RF Cable A2
	11 RF Probe

Principle of Operation

The Double Pump RF can operate in two different modes:

- 1) **Single (Inflow only)**
- 2) **Double pump**

During **Single** mode, the Double Pump RF regulates the pressure using the Double Pump RF Day Cassette only.

During **double pump** mode, the Double Pump RF controls the pressure and outflow using the Day and Patient Cassettes.

For optimal performance in double pump mode, an Outflow Cannula is recommended. The Double Pump RF Day Cassette is connected to the sterile saline bags and the Irrigation Tubing. The Irrigation Tubing is connected to the arthroscope sheath. The Irrigation Tubing is delivered separately or in the Double Pump RF Patient Cassette package.

The Double Pump RF Patient Cassette discharges the liquid from the joint into a waste container.

The Double Pump RF has the SmartVision® feature. SmartVision® will detect blood and/or debris when it emerges from the joint. It will automatically elevate pressure into the joint and outflow when blood is detected, or elevate outflow from the joint when debris is detected. SmartVision® can be disabled if desired.

The pump also has an Outflow Tracking feature, which controls the inflow to the joint to replace the amount of liquid removed by the outflow pump. The result is a constant volume of fluid in the distended joint. This helps to prevent collapse of the joint in cases with highly compliant joint. Outflow Tracking can be enabled if desired.

Furthermore, the system automatically compensates for liquid resistance in the irrigation system. This means that the pressure value displayed is the actual pressure in the joint, not the pressure at the pump or in the Day Cassette.

Warnings, Precautions and Adverse Events

Warnings

- The equipment shall only be operated by personnel trained in arthroscopy procedures.
- Failure to follow all applicable instructions may result in serious surgical consequences for the patient.
- Extravasation or other patient injury may occur if instructions and warnings are not followed. If extravasation occurs, orthopedic literature supports management by elevation and serial compression wrapping of the affected region. Fasciotomy is rarely indicated.
- **DO NOT** operate this device in the presence of flammable anesthetics, gases, disinfecting agents, cleaning solutions, or any material susceptible to ignition due to electrical sparking.
- **DO NOT** use the pump if dropped or shows signs of damage.
- **DO NOT** allow the pump to run unattended. Patient safety requires the pump to be continuously monitored throughout operation.
- For electrical safety reasons always use a non-conductive waste container for waste fluid.
- The use of Outflow Tracking does not warrant joint distention.
- If the Double Pump RF and other medical devices are interconnected as described in this manual they make up a system. Ensure that separate multiple portable sockets, if used, shall not be placed on the floor and additional multiple portable sockets or extension cord(s) shall not be connected to the system. Further, do not connect items which are not specified as part of the system to this system.

Precautions

- Prior to use, ensure that this Operator's manual including Warnings and Precautions are read and understood.
- Consult medical literature relative to techniques, complications, and hazards prior to performing any procedure.
- Evaluate patients for predisposing medical conditions that may become aggravated by the stress of surgery.
- Use only high flow inflow arthroscope sheaths with the Double Pump RF to avoid risk of loss of distension.
- When instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility prior to initiation of the procedure. All configurations shall comply with the standard IEC 60601-1 clause 16 for medical devices. When endoscopes are used with endoscopically used accessories, for instance video cameras, the patient leakage currents may be additive. Any individual who connects additional external equipment to signal input or output terminals or other terminals configures a medical system, and is therefore responsible for ensuring that the system complies with relevant requirements, e.g. the requirements of the standard IEC 60601-1. If in doubt, consult the technical service department or your Medical Vision AB representative.
- The Double Pump RF is equipped with a terminal for connection to a potential equalization conductor, to be used if local conditions or requirements call for equipotentialization.
- The Double Pump RF is a Class I device with Type BF applied part, ensure that you are using only Medical Vision AB approved Interface Cables, Interface Boxes and RF cables when connecting to a Shaver and/or RF System. In the system configuration, the shaver hand piece shall comply with requirements for BF applied parts according to the standard IEC 60601-1.
- When interconnecting the Double Pump RF with other devices to form a system, ensure that this is done to achieve optimal use. Carry out all cleaning, and adjustments for the system according to specified procedures for each device.

Warnings, Precautions and Adverse Events

Precautions (continued)

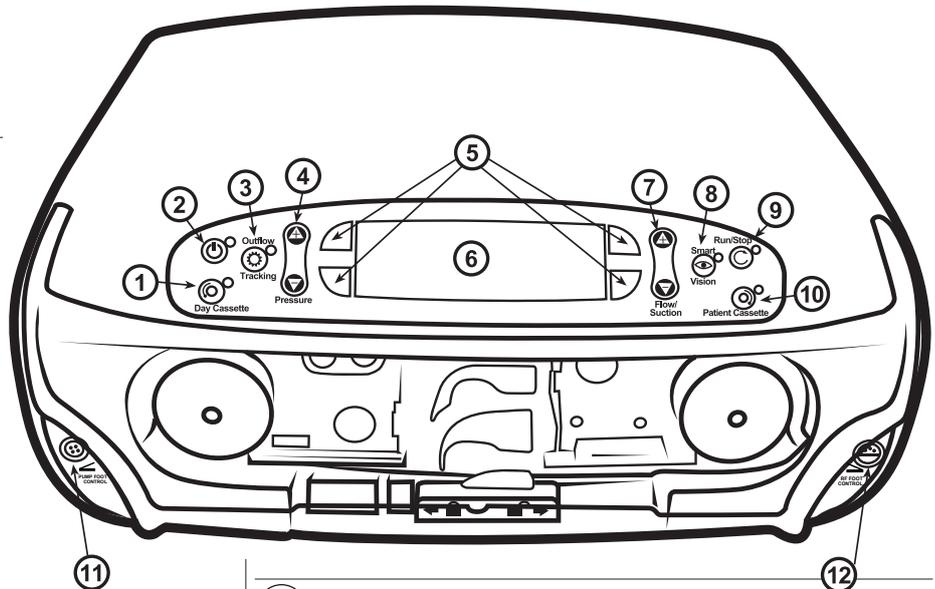
- Annual preventive maintenance is required to be performed by an authorized service technician.
- **DO NOT** connect the device to a power source that is not properly earthed (grounded).
- To prevent electrical shock hazard, unplug the mains cable from the power source before detaching the cable from the pump. By means of the mains plug, disconnect the device from the mains power source when cleaning, servicing, or inspecting.
- Avoid risk of damage to the cord of the foot controls by lifting, dragging on the floor or tightly wrapping it around the foot controls.
- **DO NOT** connect or disconnect the foot control when the pump is powered on.
- **DO NOT** connect or disconnect interface cables to a Shaver or RF generator when the pump is powered on.
- **DO NOT** modify the Double Pump RF without written authorization from Medical Vision AB.
- To avoid risk of fire, only replace the fuses with the specified type and rating.
- Avoid fluid contact with the Double Pump RF. In case of liquid spillage that results in a risk that liquid has entered the pump, it must be immediately turned off and mains cable removed. Contact a service technician authorized by Medical Vision AB.
- If a shaver cutter blade is larger than 4,5 mm, excessive debris may in rare cases accumulate by the outlet port of the Patient Cassette. If this occurs, the debris should be put into motion by the non sterile personnel by tapping the cassette. A temporarily increase in the outflow by pressing the Cannula Pedal or increasing the shaver delay should be favorable in the occurrence of accumulated debris.
- Do not immerse the pump, shaver interface boxes or any cables in liquid.
- If the Double Pump RF is taken out of service during a procedure, gravity may be used for an emergency procedure to irrigate the joint directly from the saline bags. The Day Cassette may stay, and inflow is achieved by opening the Day Cassette pressure arm with button "Day Cassette". The shaver or RF Probe, if used, may be connected to an external vacuum source.
- **DO NOT** insert foreign objects into the Double Pump RF. This constitutes a safety hazard and can cause extensive damage or injury.
- The two pressure transducers (white discs) on the front panel of the pump where the Double Pump RF Day Cassette is fitted are sensitive to scratching and pressure. If the pressure transducers are damaged the pump is inoperable.
- Do not use other cassettes than Double Pump RF Day Cassette, Double Pump Day Cassette, Double Pump RF Patient Cassette, Double Pump Patient Cassette or Double Pump RF Single /Irrigation Tubing provided by Medical Vision AB, or the Double Pump RF may malfunction.

Adverse Events

As a consequence of diagnostic and operative arthroscopic procedures, damage to surrounding tissue through iatrogenic injury could occur.

Controls and indicators

Front Panel



1 Day Cassette button

This button opens or closes the Day Cassette pressure arm.

The green LED adjacent to the button indicates the following status:

- Off when the Day Cassette is not positioned in the pump and the pressure arm is open.
- Blinking when the Day Cassette is correctly positioned in the pump and the pressure arm is closing.
- Blinking if the Day Cassette is incorrectly positioned in the pump but the pressure arm is closed.
- On when the Day Cassette is correctly loaded and the pressure arm is closed.

2 On/Standby button

This button toggles the Double Pump RF between On or Standby mode. From Standby, press the button once to turn the Pump On. To enter Standby, press and hold the button for two seconds. The green LED adjacent to the button will blink in Standby and will be lit when the Double Pump RF is 'On'.

3 Outflow Tracking button

This button activates/deactivates the Outflow Tracking function. The green LED is illuminated when Outflow Tracking is on.

4 Pressure increase/decrease buttons

These buttons adjust the pressure setting controlled by the pump.

5 Soft Keys (4)

The function of these buttons is indicated by the adjacent text in the Display. The functions vary as the Display text changes.

6 Display

This Display indicates settings, Soft Key functions, alarm situations, pressure and outflow values.

7 Flow/Suction increase/decrease buttons

These buttons adjust the outflow settings through an outflow cannula, shaver hand piece and RF probe. A flow adjustment is only relevant in double pump mode as it refers to the outflow through the Patient Cassette.

8 SmartVision® button

This button activates/deactivates the SmartVision® function. The green LED is lit when SmartVision® monitoring is on.

9 Run/Stop button

This button starts and stops the fluid flow and pressure control. When the pump is running, the green LED light will illuminate and blink when the pump is stopped and is ready to Run.

10 Patient Cassette button

This button loads and unloads the Patient Cassette pressure arm.

The green LED adjacent to the button indicates the following status:

- Off when the Patient Cassette is not positioned in the pump and the pressure arm is open
- Blinking when the Patient Cassette is correctly positioned in the pump and the pressure arm is closing
- Blinking if the Patient Cassette is incorrectly positioned in the pump and the pressure arm is closed
- On when the Patient Cassette is correctly loaded and the pressure arm is closed

11 Pump Foot Control Receptacle

The Pump Foot Control plugs into this receptacle. Either a 4 pedal or 2 pedal Foot Control can be used.

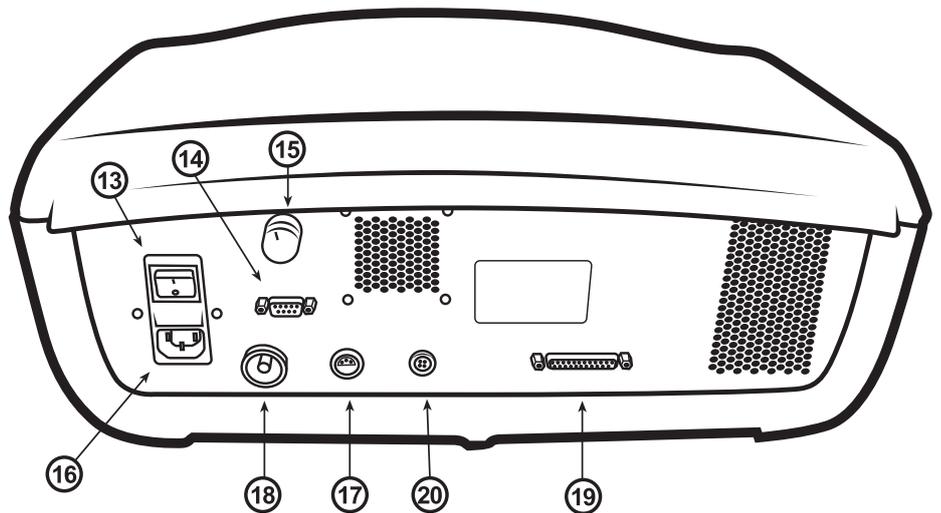
12 RF Generator Foot Control Receptacle

This receptacle is for RF foot control when RF cable type A1 is used.

Controls and Indicators

Controls and Indicators

Rear Panel



13 On/Off Switch

This switch turns the mains power On and Off. Note that the pump may be set in a standby mode with On/Standby button on the front panel. If the green LED on the front panel is blinking, the pump is in standby mode, press On/Standby button to switch the pump On.

14 Serial communications port

This connector is only for use by technical personnel. Do not connect to it.

15 Acoustic Volume Control

The Volume Control regulates tone volume for acoustic alarms and indications. To increase volume, turn the knob clockwise. To reduce volume, turn the knob counterclockwise.

16 Mains Cable Receptacle / Fuse Holder

The Pump mains cable plugs into this receptacle. The fuse holder is located between the mains cable receptacle and the mains On/Off switch.

Removing the mains cable disconnects the pump from mains.

17 Receptacle for RF Cable

The RF cable shall be connected to this receptacle and the Foot Control receptacle of the RF Generator, if used.

18 Equipotential Connection

This connection can be used for potential equalization.

19 Shaver Interface Cable Receptacle

The shaver Interface Cable shall be connected to this receptacle. The cable shall also be connected to the foot control receptacle on the shaver console.

20 Shaver Interface Box Receptacle

The interface box itself is connected to the front panel output receptacle on the shaver console. The shaver hand piece is then connected to the shaver interface box. The cable from the Shaver Interface Box is connected to this receptacle.

Signal Tones

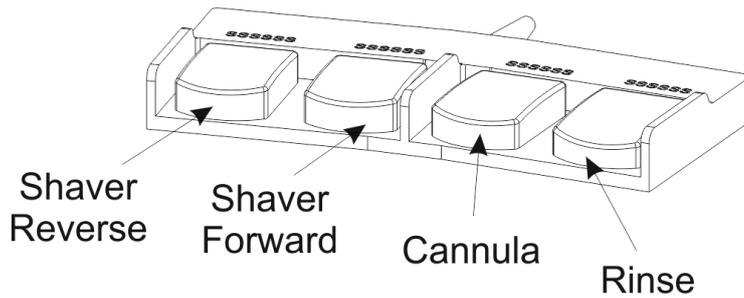
If enabled (in Extended Setup), a signal tone is given to give notice that the front visor is opened in Run Mode. This stops the pump and “Close front visor” appears on the display.

A signal tone is given when the pressure control system is reconfirming “zero pressure”. This occurs when the pump is turned on if no Day Cassette is present and the front visor is closed.

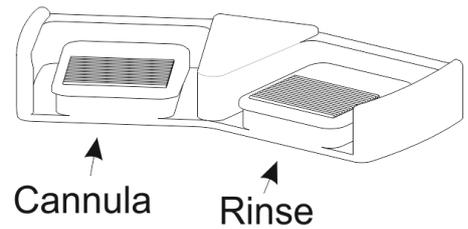
A signal tone is given as confirmation when a setting is saved.

Foot Controls

4 pedal Foot Control



2 pedal Foot Control



Shaver Reverse Pedal

The first black pedal activates a shaver system that is connected with a Shaver Interface Cable. The shaver blade will rotate counter clockwise.

Shaver Forward Pedal

The second black pedal activates a shaver system that is connected with a Shaver Interface Cable. The shaver blade will rotate clockwise.

Shaver Oscillate

Pressing Reverse and Forward simultaneously will initiate the oscillating mode of the shaver.

Cannula Pedal

The blue pedal activates the Cannula function of the pump while depressed.

Rinse Pedal

The red pedal activates/deactivates the Rinse function of the pump.

Signal Tones

One short tone:

Rinse Mode is activated

Two short tones:

Rinse Mode is deactivated

Adjustments for system devices

If the Double Pump RF is part of a system as depicted in chapter "System Overview", adjustments for the other devices shall be made according to specified procedures for those devices.

Unpacking, Assembly and System Check

Unpacking

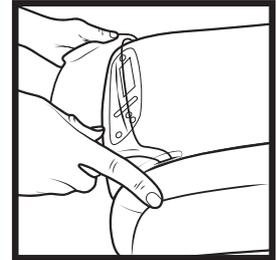
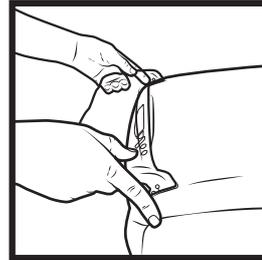
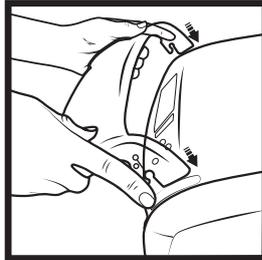
Verify that all items have been received and are not damaged. Damage should be reported immediately to the carrier and to your Medical Vision AB representative.

PLEASE NOTE:

Save all containers and packaging material. They will be required if the Double Pump RF is shipped.

Assembly and System Check

1. Fit the front visor by holding it with both hands as illustrated. Note the angle of the arrows and slide both sides in gently as illustrated in the second picture. Thereafter turn the visor up fully and push both sides simultaneously all the way in. Close the front visor with both hands.



See illustrations on pages 11 and 12.

2. Connect the mains cable to the mains receptacle **(16)** on the rear panel of the Pump. Connect the other end of the mains cable to a grounded electrical outlet.
3. Attach the Pump Foot Control Receptacle **(11)** on the front panel.
4. If the pump shall be interconnected to a shaver and/or a RF generator to form a system, ensure that this is done to achieve optimal and practical use, for instance by placing all devices the same rack/tower, to avoid long cable routing.
5. If an ArthroCare®, Quantum generator is used, plug the RF Cable A1 into the RF Cable Receptacle **(17)** on the rear of the Pump and into the Foot Control Receptacle of the RF Generator. Connect the RF Generator Foot Control into the RF Generator Foot Control Receptacle **(12)** on the front of the Pump. See Connection diagrams on pages 4 and 5. See Connection diagrams on pages 6 and 7 for other RF systems.
6. There are several alternatives for connecting a shaver system to Double Pump RF as shown in the Connection diagrams on pages 4 -- 7.
7. If the shaver is to be controlled by the Double Pump RF an appropriate Shaver Interface Cable must be used. Refer to page 30 of this manual to select the right Shaver Interface Cable. Connect the Shaver Interface Cable **(6)** to the Shaver Interface Cable receptacle **(19)** on the rear panel of the Pump, and connect the other end to the foot control connector of the shaver console **(4)**. A 4 pedal Foot Control REF No. 1404176 must be used.
8. If the shaver, having a finger controlled hand piece, is to control the Double Pump RF an appropriate Shaver Interface Box must be used. Refer to page 30 of this manual. Connect the cable of the Shaver Interface Box to the Shaver Interface Box Receptacle **(20)** on the rear panel of the Pump. The Shaver Interface Box is fitted on the front panel of the shaver console **(4)**, and the shaver hand piece is connected to the box as shown in the Connection diagram. Attach the Pump Foot Control to the Pump Foot Control Receptacle **(11)** on the front panel. A 2 or 4 pedal Foot Control REF No. 1404003 or 1404176 respectively must be used.
9. Turn the On/Off Switch on the rear panel of the pump to the 'On' position. The system will proceed through a self test. Turn on the pump by pressing On/Standby button **(2)** and the software version number will be displayed. During this sequence, verify that the Display and LED lights are working properly and that the alarm tone is audible. The Display should show 'START' and 'Setup' options associated with the Soft Keys **(5)** or procedure selection menu if Quick Start is enabled. If an error code appears instead, the pump should not be used. Contact Medical Vision AB representative, and report the error code number.
10. To change display text language: Select "Setup" by pressing the right lower Soft Key **(5)**. In the SETUP menu, scroll down with the left lower Soft Key **(5)** until the display shows "Language". Press OK, and scroll down with ▼ until the display shows the users' language. Press OK, and escape from the Setup menu by pressing ◀ twice.
11. If Double Pump RF malfunctions or shows signs of damage, contact Medical Vision AB representative.

Operator Training Requirements

The operator must be experienced in arthroscopic techniques. The user shall endeavor to remain current with advances in orthopedic procedures. Additional training on the use of Double Pump RF from a Medical Vision AB representative is recommended.

See illustrations on pages 11 and 12.

Starting up

Turn on the pump with On/Off switch (13). at the rear and On/Standby button (2). Press the Soft Key 'START'.
The cassette loading selection menu appears.

Load the cassette(s)

The Cassette Loading menu can also be accessed by pressing either the Day Cassette or Patient Cassette button on the keyboard.

To use **Single** only mode, only load the Day Cassette and connect the Single tubing, REF No. 1002052.

To use both Inflow and Outflow (**double pump** mode), load the Day Cassette and the Patient Cassette. If a RF generator is to be used in the procedure, a Double Pump RF Patient Cassette REF No. 1003059 must be used. This has a third suction port for the RF Probe. If a RF generator is not to be used, either a Double Pump RF Patient Cassette REF No. 1003059 or a Double Pump Patient Cassette REF No. 1002059 can be used. See Cassette Loading illustrations below.

Once the cassette has been correctly loaded and the corresponding LEDs are lit, 'OK' will be visible on the Display next to a Soft Key. Press the Soft Key 'OK' to continue to the procedure selection menu. Pressing the Soft Key ◀ will return to the cassette loading menu.

WARNING: Before and after opening, carefully examine the sterile packages for the cassettes and or Single Tubing. If any damages are detected, the sterile barrier is broken and the product may not be used as sterility cannot be guaranteed.

Also, make sure that the expiry date not has been passed. If it has, the sterility and/or the function cannot be guaranteed.

Procedure selection

The procedure selection menu provides four options for joint type: 1) Shoulder 2) Knee 3) Hip 4) Small Joint (i.e. wrist, elbow and ankle joints). Each of these procedure types has specific user default settings for pressure, outflow, shaver suction and SmartVision® Outflow Tracking on/off. Changing the user default settings is described in 'Changing user default Settings' (page 21).

Select the appropriate joint type by moving the arrow with the Soft Keys ▲ or ▼. When the arrow is adjacent to the appropriate joint type, press the Soft Key 'OK'. Pressing the Soft Key ◀ will take you back to the cassette loading menu.

Quick Start

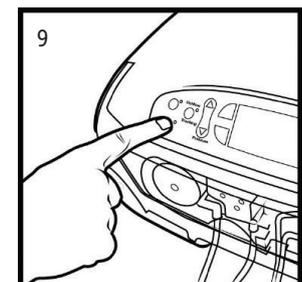
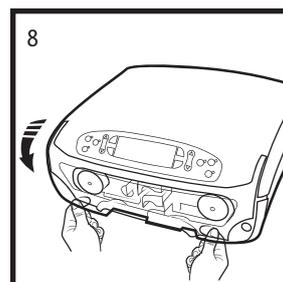
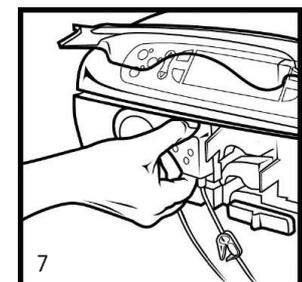
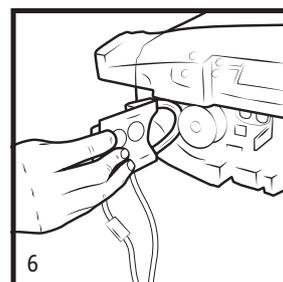
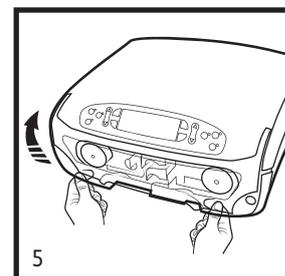
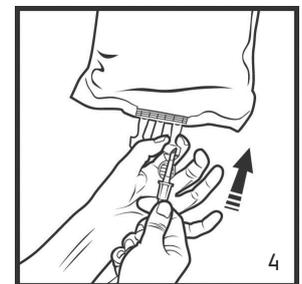
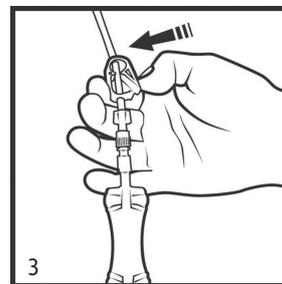
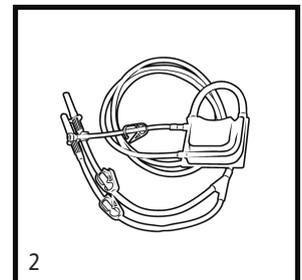
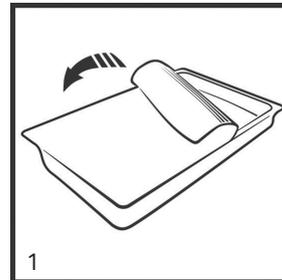
In Extended Setup, Quick Start can be enabled. Quick Start shortcuts most steps when setting up the Double Pump RF.

After loading the cassettes as described in the Load Cassette(s) section, a selection of the four procedure settings appear. After selecting, just press Run/Stop to start liquid flow. When the pump is stopped it is possible to reach the cassette loading menu by pressing "Day Cassette" button. Then, the Start and Setup menus can be reached by pressing Soft Key ◀.

Instructions for Use

Loading a Day Cassette

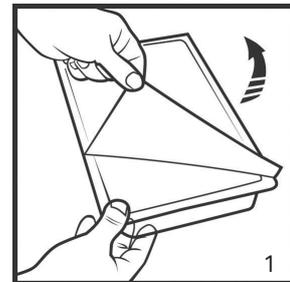
1. Open the sterile package. The Day Cassette can be used for more than one patient during a whole operating day. Maximum use is eight hours. Use aseptic technique when opening the package.
2. Remove the cassette with tubing from the package.
3. Close all three clamps.
4. Remove the cap from one of the spikes and connect the spike to a sterile saline bag. The second spike can be connected to a secondary bag in the same way.
5. Open the front visor of the Pump with both hands.
6. Push the cassette tubing loop of the left-hand pump straight in as illustrated.
7. Then fit it completely over the pump wheel. Stretch the tubing by pulling the cassette to the right. Press the left side of the cassette in place first, and then fit the right side by pressing it firmly in place. Push each corner of the Cassette to ensure correct fitting. The green LED light beside the Day Cassette button will blink when the Day Cassette is correctly positioned in the pump.
8. Close the front visor. Use both hands when closing the front visor.
9. Press the Day Cassette button. Proper loading is verified in the Display, and the green LED stays lit. If the LED is still blinking, press Day Cassette button again and ensure that the cassette has clicked in place.
10. Open the clamp for the primary saline bag.



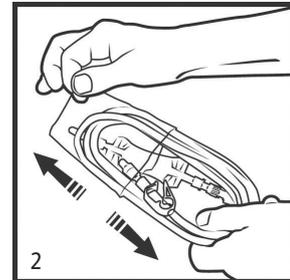
Connecting the Irrigation Tubing/Single tubing

1. Use aseptic technique when opening the package.

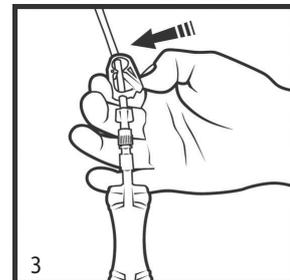
Sterile operator: Remove the Irrigation Tubing with check valve from the pouch for a Single tubing for Single mode, or from the package for a Patient Cassette (see below) for double pump mode.



2. Remove the transparent wrapping.

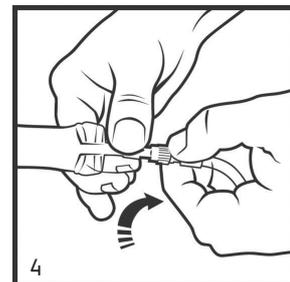


3. **Sterile operator:** Close the red clamp on the Irrigation Tubing and hand over the proximal end (end with blue cap) of the tubing to the non-sterile operator.



4. **Sterile operator:** Tighten the transparent Luer lock connection between the tubing and the check valve.

5. **Non-sterile operator:** Connect the check valve on the Irrigation Tubing to the Luer connector of the Day Cassette.



6. **Non-sterile operator:** If present from a previous procedure that day, remove the used check valve from the Day Cassette.

7. **Non-sterile operator:** Remove the blue cap from the Irrigation Tubing and connect the blue Luer connector to the transparent female Luer lock connector on the Day Cassette.

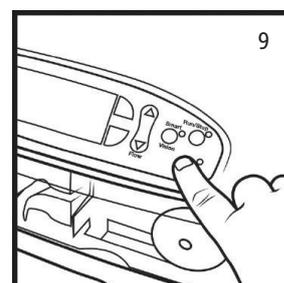
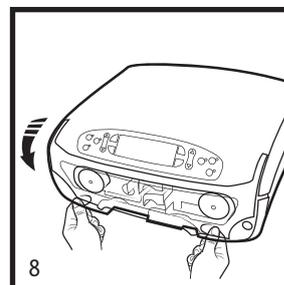
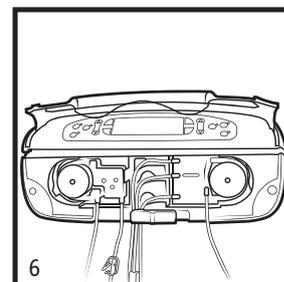
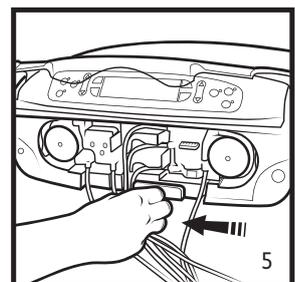
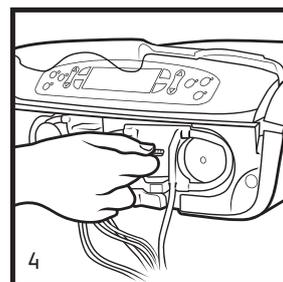
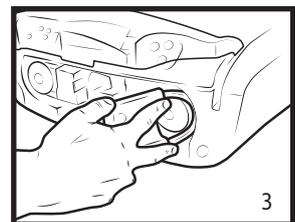
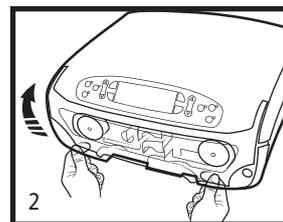
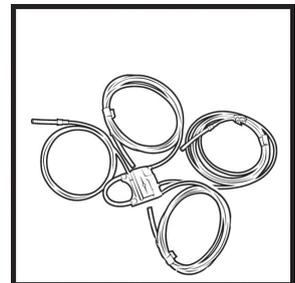
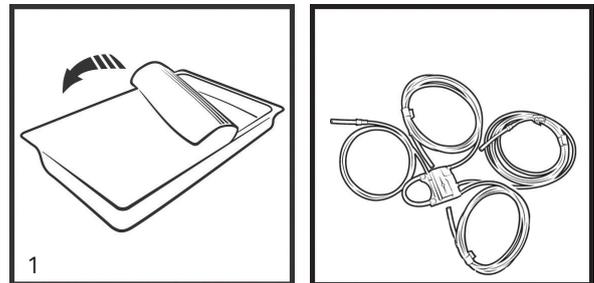
8. **Non-sterile operator:** Open the white clamp near the Day Cassette and the red clamp on the Irrigation Tubing.

9. The Day Cassette and Irrigation Tubing can now, optionally, be filled with sterile saline per the pump priming procedure. When the tube is filled, the red clamp on the Irrigation Tubing can be used to open or close the flow.

Instructions for Use

Loading a Patient Cassette for double pump mode

1. **Sterile operator:** Remove the Patient Cassette from the package. Hold the Cannula, RF Probe and shaver tubing, and hand the cassette over to the non-sterile operator to load onto the pump.
2. **Non-sterile operator:** Open the front visor of the Pump with both hands.
3. Push the cassette tubing loop of the right-hand pump straight in as illustrated.
4. Fit the pump tubing completely over the pump wheel. Stretch the tubing by pulling the cassette to the left. Press the right side of the cassette in place first, and then fit the left side by pressing it firmly in place. Push each corner of the Cassette to ensure correct fitting. The green LED light adjacent to the Patient Cassette button will blink when the Patient Cassette is correctly positioned in the pump.
5. **Non-sterile operator:** The three tubings attached to the left side of the Patient Cassette will align with the slots on the pump. Push the tubing completely into the slots as far as they will go. Align the tubing together where they exit the slots and secure them by closing the slide lock.
6. The correct tubing setup is shown in this figure.
7. **Non-sterile operator:** Place the tubing marked WASTE in a waste collection container.
8. **Non-sterile operator:** Close the front visor. Use both hands when closing the front visor.
9. **Non-sterile operator:** Press the Patient Cassette button. Proper loading is verified in the Display, and the green LED stays lit. If the LED is still blinking, press Patient Cassette button again and ensure that the cassette has clicked in place by pressing the four corners of it.



Loading a Patient Cassette for double pump mode

10. Sterile operator: Connect the end of the tubing marked OUTFLOW CANNULA tubing to the cannula, and the tubing marked SHAVER to the suction port of the shaver hand piece. If a shaver is not used, the tubing can remain disconnected.

Connect the end of the tubing marked RF PROBE to the RF Probe. If a Double Pump RF Patient Cassette is used but a RF Generator is not used, this tubing can remain disconnected.

Priming the Day Cassette and Irrigation Tubing

To optionally slowly prime the Day Cassette and Irrigation Tubing with saline, press the Soft Key 'Prime' on the Run/Stop menu. The pump will automatically prime the tubing, counting down from 10 sec.

To stop the priming, press the Soft Key ◀. When priming stops, the Display will return to the Run/Stop menu. Priming can be repeated if necessary. Pressing Run/Stop during Priming, the pump starts Running immediately.

Adjusting the pressure and outflow

The Run/Stop menu displays the pressure and outflow settings for the selected joint type. The initial settings can be adjusted using the Pressure increase/decrease buttons and the Flow increase/decrease buttons. Flow adjustment is only relevant if a Patient Cassette and an outflow cannula is being used (double pump mode) as the Flow settings refer to the outflow from the joint as controlled with the Patient Cassette. Pressure can be set to 20-180 mmHg. Outflow can be set to 0-600 ml/min, but will be reduced at high pressures.

Starting the fluid flow

To start the fluid flow, press the Run/Stop button on the front panel. The pump will run and control the pressure and fluid outflow. Fluid outflow is only controlled if a Patient Cassette or Patient Cassette RF is used.

Stopping the fluid flow

To stop the fluid flow, press the Run/Stop button on the keyboard. When the flow is stopped, pressing the Soft Key ◀ will take you back to the procedure selection menu.

Removing the Irrigation Tubing when the Day Cassette will be used again the same day

1. Stop the pump and close all clamps on the Day Cassette and the red clamp on the Irrigation Tube.
2. Disconnect the Irrigation Tubing near the check valve, leaving the used check valve attached to the Day Cassette. The used check valve must stay to maintain sterility of the connection on the Day Cassette.
3. Discard the disconnected Irrigation Tubing in accordance with local hospital procedures.

Instructions for Use

Double Pump RF functions and adjustments

Aspiration Switching

In double pump mode, the outflow from the joint is via the Cannula. While a shaver or RF probe is activated, the outflow from the joint is switched over to pass through the shaver hand piece or RF probe respectively. A "*" symbol on the Display indicates outflow path: shaver, cannula or RF Probe. The pump can optionally delay the switching back to cannula for optimal pressure control. The delay is set in Extended Setup. 5 seconds delay should be selected if an Outflow Cannula is not used, but the shaver or RF Probe is used as outflow fluid path.

Pressure Adjustment

The pressure setting can be adjusted with the Pressure increase/decrease buttons (4).

Outflow Adjustment

If a Patient Cassette is used, The outflow setting can be adjusted with the Flow/Suction increase/decrease buttons (7). The buttons will adjust the outflow from the joint of the mode that is currently active: If the Outflow Cannula is active, the outflow for the Outflow Cannula will be adjusted.

Shaver Suction Setting

When a shaver is active, the suction can be increased/decreased with the Flow/Suction buttons. When the shaver is connected but not active, the outflow through the shaver hand piece setting can be modified by pressing the Soft Key 'Shaver' on the display. A shaver flow menu will appear on the display, and the flow setting can be modified with the Flow increase/decrease buttons (7). Soft Key 'OK' can be pressed to return to the procedure screen.

RF Probe suction setting

When a RF generator is active, the suction can be increased/decreased with the Flow/Suction increase/decrease buttons. When a RF system is connected but not active, the suction setting can be modified by pressing the Soft Key 'RF Probe' on the display. A RF Probe suction menu will appear on the display, and the suction setting can be changed in the range of 1 - 8 with the Flow increase/decrease buttons (7). Factory setting is 8. These settings are based on experience and may be used as a guideline and are not intended to replace the experience and expertise of the user. Soft Key 'OK' can be pressed to return to the procedure screen.

Cannula Function

When a Patient Cassette is used, pressing and holding the Cannula pedal will increase flow through the joint without increasing joint pressure. This feature is useful for eliminating debris. The Display will indicate when Cannula function is active. The pressure and outflow can be adjusted when Cannula function is active.

Rinse Function

Pressing the Rinse pedal or lower right Soft Key will activate the Rinse mode for 120 seconds. Rinse mode will increase the pressure in the joint in Single mode, and also the outflow from the joint in double mode. The pressure increase and outflow is delayed after Rinse activation. The delays can be adjusted in Extended Setup (factory setting is 0 delay for pressure and 2 seconds for outflow to avoid pressure drop). This feature is useful for removing blood and controlling bleeding in the joint. The Display will indicate when Rinse function is active. The Rinse function can be turned off by pressing Rinse foot pedal a second time or Soft Key "Rinse off". When active, SmartVision® is inhibited. If a shaver or RF system is used during the Rinse period, the Rinse function sets the pressure; but the shaver or RF suction settings prevail. Rinse function outflow is set again when the shaver or RF is deactivated. The Pressure and outflow settings can be adjusted when Rinse function is active.

SmartVision®

SmartVision® is a function to automatically increase pressure in and flow through the joint if debris or blood is detected. This feature can be turned On and Off with the SmartVision® button (8), and related LED is illuminated when SmartVision® monitoring is on. If blood is detected this is indicated in the display. The pressure is increased by a set value (default value is 50 mmHg), and outflow is increased by 50 ml/min.

When the liquid is clear of blood, the outflow and pressure resumes the previously selected values. If the liquid is not clear of blood within 8 seconds, the outflow is further increased by 50 % of the already increased outflow. The pressure increment can be adjusted in Extended Setup. Factory default setting is 50 mmHg increase.

If debris is detected this is indicated in the display, and the outflow is increased by a value (in percent). Factory default setting is 50 %.

Outflow Tracking

The LED adjacent to the Outflow Tracking button (3) on the keyboard indicates the status of Outflow Tracking. If the LED is on, Outflow Tracking is active. The status of Outflow Tracking can be changed by pressing the Outflow Tracking button. This function regulates inflow to the surgery area to precisely replace liquid removed by the outflow pump. The result is a constant volume of fluid in the distended joint. Outflow Tracking is available only when the Patient Cassette is used. A High Flow Sheath for Arthroscopy is recommended for best performance.

Automatic reset to user default values

The Double Pump RF will reset the procedure settings for the last procedure to user default values for the next patient when the Patient Cassette is replaced. In Single mode, if the pump has been stopped for more than 30 minutes, the user default values are set.

Setup Menu

In the Setup Menu it is possible to:

- Set User Default settings for each joint type. See below.
- Select RF Probe suction. Save value with 'S'.
- Select the language for the display. Use ▲, ▼ to select and press 'OK'.
- Select extended setup. See below.

Changing User Default Settings

When the Double Pump RF is turned on, user default settings will be set; per definition. Factory default settings are applied as user default settings when the Double Pump RF is delivered. These settings are based on experience and may be used as a guideline and are not intended to replace the experience and expertise of the user. See Table 1 for factory default settings.

Table 1. Factory Default Settings for Double Pump RF

Joint	Joint Pressure (mmHg)	Outflow Cannula Flow Rate (ml/min)	Shaver Suction Setting (ml/min)	SmartVision®	Outflow Tracking
Shoulder	100	130	250	On	Off
Knee	70	100	250	On	Off
Hip	100	130	250	On	Off
Small Joint	70	50	250	On	Off

User default settings can be modified for the four selectable joint types including the suction when a shaver is used. To access the user default settings, turn the pump on and press the Soft Key "Setup" (5) on Start/Setup menu.

Select the joint type by moving the arrow with the Soft Keys and press the Soft Key "OK" to view the default settings. The suction level can also be adjusted for shaver usage.

For each joint type, the following user default settings are available:

- 1) Pressure (joint pressure, IAP)
- 2) Outflow
- 3) Shaver suction: Level in ml/min when a shaver is active
- 4) SmartVision® Technology On or Off
- 5) Outflow Tracking On or Off

Pressure and Outflow settings are available on the first screen. The pressure settings are changed with the Pressure increase/decrease buttons. Press the Soft Key "More" to access the second screen. Shaver suction setting is available here and on the third screen SmartVision® Technology and Outflow Tracking On or Off settings are changed by pressing the Soft Keys "+/-".

The shaver suction settings are changed with the Flow increase/decrease buttons.

To store new values and settings press "S" in the respective menu.

Extended Setup

In **Extended Setup** it is possible to:

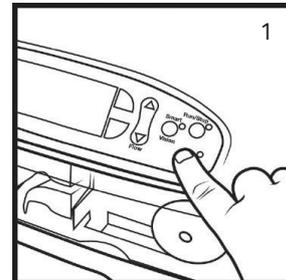
- Set Rinse: Outflow increase in % and pressure level increase in % of set values.
- Set Cannula pedal outflow increase in % of set value.
- Set outflow increase in % when debris is detected by SmartVision® Technology.
- Set pressure increase in mmHg when blood is detected by SmartVision® Technology.
- Enable/disable signal tone if front visor is opened in Run mode.
- Shaver Delay: Sets the time for switching fluid path back to Outflow Cannula after the use of a shaver. Select '--' for no switching back.
- RF Probe Delay: Sets the time for switching fluid path back to Outflow Cannula after the use of a RF generator. Select '--' for no switching back.
- Rinse Delay: Sets the delay time of pressure and outflow increase after Rinse activation.
- Enable Quick Start.
- Reset memory: Resets all settings to factory default settings. Note that the minimum pressure setting will be 50 mmHg. For other values, please contact your representative or authorized service technician.
- Read Data log (a list of time stamped generated error codes).
- Set time.
- Set date.

Instructions for Use

Cassette removal

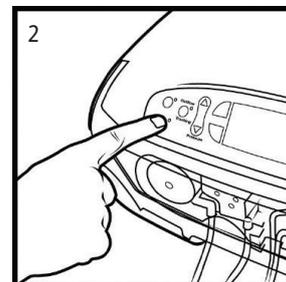
1. Stop the pump with Run/Stop and close all clamps on the cassette tubing.

If the cassette loading screen is not visible on the Display, push either the Day Cassette or Patient Cassette button on the keyboard.

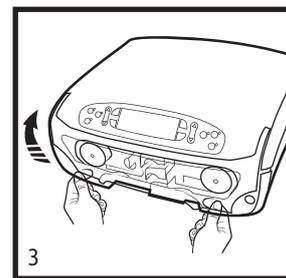


2. When the cassette loading screen is visible on the Display, press the Patient Cassette or Day Cassette button respectively to release the cassette.

If another procedure is intended during the day, only the Patient Cassette should be removed.

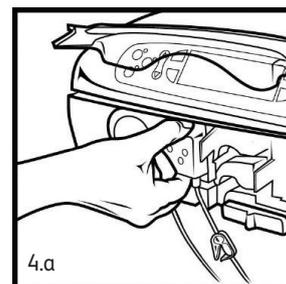


3. Open the front visor with both hands and open the slide lock.



4. Remove the cassettes by unlatching them with the lever by the cassette and by pulling the cassette out and away from the pump.

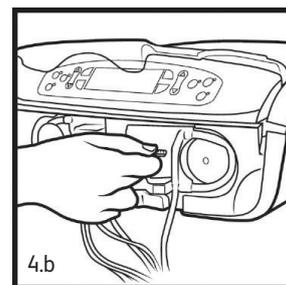
Unloading is verified in the Display.



5. Remove the spike(s) of the Day Cassette from the saline bag (s).

6. Discard the cassettes in accordance with local hospital procedures.

7. Turn off the Double Pump RF with the On/Standby button.



Shaver Interface Instructions

Double Pump RF Control of shaver

Please refer to Connection diagrams on pages 4 -- 7.

The Shaver Interface Cable (6) is an accessory to the Double Pump RF (1) that sends signals to a shaver console (4).

When the 4 pedal Foot Control (3) is used to activate the shaver system, the liquid outflow from the joint is taken via the shaver hand piece (5) instead of a cannula.

The outflow is elevated to effectively remove debris resulting from the shaver usage.

This mimics foot switch activity to the shaver console and starts the shaver in forward or reverse rotation, or oscillating mode.

Shaver functions are activated by the 4-pedal foot control (3), with the following functions:

Left black pedal (3a) = Reverse

Right black pedal (3b) = Forward

Both black pedals = Oscillating.

Shaver control of the Double Pump RF

The shaver may be controlled by foot control of the shaver console or by fingertip control of the shaver hand piece.

The Double Pump RF needs to know when the shaver is active for outflow control as described above.

To achieve detection of shaver activity, a shaver interface box (6) (Ref Connection diagrams on pages 4 -- 7) is needed in this case.

To avoid malfunction:

- Be sure you are using the correct Shaver Interface box when you are connecting the pump to a shaver controller.
- Avoid fluid contact with the Shaver Interface box or connectors.

Cleaning Instructions

Disconnect the shaver interface box or cable from the Pump. Wipe off the interface body, cable and connector with a soft cloth damped with alcohol. Never use hard-surface, low pH, high pH or chlorine-based detergents.

PRECAUTION: DO NOT IMMERSE THE SHAVER INTERFACE BOX OR INTERFACE CABLE IN LIQUID.

Troubleshooting Guide Shaver Interface Box

Problem	Cause	Possible Solutions
The shaver runs but the pump does not react.	Pump or shaver interface box fault.	See diagram on pages 4 -- 7. Verify that connections (5) and (6) are properly mated and tight. If the pump still does not react, contact your Medical Vision AB representative.
The shaver does not run.	Shaver console or shaver hand piece defective.	See diagram on pages 4 -- 7. Disconnect (6) - (5), then connect directly (5) to shaver. If the shaver still does not run, try another hand piece if available, or contact the representative of the shaver.

Alarms and Warnings

Alarms and Warnings

Cause	Description	How to Resolve
<p>Front visor partially opened Warning:</p> <p>The front visor is partially open, is not pushed properly in place when installed, has a defective sensor for the front visor position or is defective.</p>	<p>Acoustic tone sounds. The pump stops and “Check front visor” appear on the Display.</p>	<p>Check that the front visor is positioned correctly in the pump and is properly closed. If this does not help, turn off pump and contact your Medical Vision AB authorized representative.</p>
<p>Pressure measurement mismatch Warning:</p> <p>This may occur if the Day Cassette is not fully inserted in place.</p>	<p>Acoustic tone sounds. “Check Day Cass.” appears on the display, The pressure arm opens to relief pressure.</p>	<p>Open front visor and press firmly on all four corners of the Day Cassette. The warning may repeat once if cassette is not correctly mounted, but on a third warning an error situation occurs.</p>
<p>Low pressure Warning:</p> <p>The pressure in the joint can not reach 40 mmHg.</p>	<p>Acoustic tone sounds. The pump stops. To mute: press Soft Key M.</p> <p>Low Pressure Warning appears on the Display A “*” symbol indicates if the acoustic tone is muted.</p>	<p>Check the saline bag and replace the bag if empty. Check for kinked tubing or closed clamps by the spikes.</p> <p>Press Run/Stop button to continue.</p>
<p>High Pressure Warning:</p> <p>The pressure in surgical site exceeds 250 mmHg.</p> <p>This may occur if the outflow is obstructed and the joint is bent by the surgeon.</p>	<p>Acoustic tone sounds. The pump stops. To mute for one minute: press Soft Key M.</p> <p>High Pressure Warning appears on the Display A “*” symbol indicates if the alarm is muted.</p>	<p>Check that flow to and from the joint is not obstructed. Check the condition of the joint.</p> <p>Press Run/Stop to continue.</p>
<p>Overpressure Alarm:</p> <p>The pressure in the Day Cassette exceeds 300 mmHg.</p>	<p>The pump stops, the pressure arm opens to relieve pressure and a continuous acoustic alarm sounds</p> <p>The display indicates</p> <p>“Error code: OVERPRESSURE ALARM! Read Op. manual and switch off”</p>	<p>Close all clamps. Turn off and then on the pump. If the alarm comes back, turn off pump and contact your Medical Vision AB representative</p>
<p>Internal Hardware Error.</p>	<p>The pump stops and a continuous acoustic alarm sounds.</p> <p>The display indicates</p> <p>“Error Code: XXXXXXXXXXXXXXXXXXXXX Read Op. manual and switch off”</p>	<p>Close all clamps, turn off and then on the pump. If the alarm comes back, turn off pump and contact your Medical Vision AB representative.</p>

System Environmental Requirements

The Double Pump RF may be safely stored and transported at an ambient temperature range of -40°C (-40°F) to +70°C (+158°F), relative humidity between 10 and 85 %, and atmospheric pressure of 500 hPa (7.2 psi) to 1060 hPa (15.3 psi).

The Double Pump RF may be safely operated at an ambient temperature range of 10°C (65°F) to 40°C (104°F), relative humidity between 10 and 85 %, and atmospheric pressure of 700 hPa (10.1 psi) to 1060 hPa (15.3 psi).

PRECAUTION: Storing or operating Double Pump RF outside these temperature ranges may cause the Pump to malfunction or to cause damage to the Pump.

Equipment Disposal

Double Pump RF contains electronic printed circuit board assemblies and should not be disposed in any waste container. It should be disposed of in accordance with any applicable national or institutional policies relating to obsolete electronic equipment. Contact your Medical Vision AB representative for return of Double Pump RF for proper disposal. Discard the disposables in accordance with local hospital procedures for potentially contaminated items. Double Pump RF does not contain NiCd or lead batteries.

Surface Cleaning of Double Pump RF, Foot Controls and system devices

Wipe the pump and foot controls with a soft damp cloth. Alcohol based agents may be used.

PRECAUTION: DO NOT apply pressure or use any sharp objects when cleaning the pressure transducers as damage may result to them. These are the two white plastic discs on the front that have contact with the Day Cassette.

Carry out all cleaning for other parts of the system according to specified procedures for each device.

Maintenance and Troubleshooting

Maintenance

Other than mains fuse and front visor replacement, the Double Pump RF has no user-serviceable parts. Do not remove top or bottom covers. If the Double Pump RF malfunctions or shows signs of damage, contact your Medical Vision AB representative. An annual preventive maintenance of the Double Pump RF is required to assess its functionality and technical safety. Please contact your Medical Vision AB representative for instructions on the annual preventive maintenance.

Troubleshooting Guide

The Pump does not power up after the power switch is set to On

Check that the mains cable is properly connected to the pump and plugged into an appropriately grounded outlet. If the unit is plugged in properly, check if the fuses have blown. To change the fuses, follow the instructions for Fuse Replacement below.

Fuse Replacement

The fuse holder is located on the back of the Double Pump RF in the fuse holder between the mains cable receptacle and the On/Off switch on the rear panel. To replace a fuse, turn off the power to the Pump and unplug the mains cable from the mains receptacle and at the rear of the Pump. After waiting at least 10 seconds, pull the fuse holder out. Replace both fuses with T 3.15A; 5 x 20 mm fuses. Reinsert the fuse holder. Reconnect the mains cable and restore power to the Double Pump RF. If a fuse breaks again, disconnect all power to the Double Pump RF and contact your Medical Vision AB representative.

Replacement of the front visor

If the front visor is cracked or broken, it shall be replaced. To do so, open it fully, grasp firmly at the hinges, and pull it straight out. Fit the new front visor as illustrated on page 14.

Error Codes

If the Double Pump RF detects a technical failure a continuous two tone alarm is generated, the Double Pump RF stops, the keyboard is disabled and an error code is displayed. If this occurs Double Pump RF can not be used.

Should this happen, do the following:

- Turn off the pump by the rear mains switch and close the clamp(s) at the saline bag(s). Relieve the Day cassette from pressure by the arthroscope if the cassette already has been pressurized.
- Verify that the Day Cassette has been properly inserted eg. by opening the front visor and by pressing the four corners of the Day Cassette. Upper and lower clasps and the locking lever must click to ensure that the Day Cassette is well in place. If the Day cassette is not properly in place, an error code can be generated. Correct the insertion.
- Try to start the pump again by turning the mains power on. Refer to «Assembly and System check» (page 14).
- If an error code appears again, turn off mains power. The pump may not be used, but the surgical procedure can continue by use of gravity: Close all clamps remove both cassettes, elevate the saline bags for pressure and continue the surgery after opening the clamps again. The "Waste" connection on the Patient Cassette should be connected to a vacuum source if a shaver is used.

Technical Specifications

Double Pump RF	
Input Voltage	100–120/220–240V~ (Auto range)
Input Frequency	50/60 Hz
Power Consumption	230 VA (Peak)
Fuse Rating	T 3,15A 250V 5 by 20 mm slow blow glass fuse with rating 3.15 amperes. Only use certified fuse: e.g. CSA, ETL, or UL marked
Pressure range	20-180 mmHg \pm 10 mmHg
Outflow range	0 – 600 ml/min \pm 10 %

Double Pump RF Dimensions	
Weight	18 kg (40.5 lbs)
Height (front panel closed)	18.1 cm (7.1 inches)
Width	47.1 cm (18.5 inches)
Length	39.7 cm (15.5 inches)

Mains Cable	
Length	3m (10 ft)

Foot Control	
Foot Control Cable Length	3m (10 ft)

Interface Cable for Shaver (Optional)	
For different shaver systems, length	2m (6.5ft)

Shaver Interface Box (Optional)	
For different shaver systems	2m (6.5ft)

Symbols used

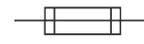
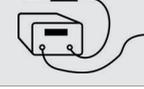
Symbols used - front

 Day Cassette	Press to open/close pump pressure arm for the Day Cassette
	Toggles the pump between On and Standby mode
 Outflow Tracking	Activates/deactivates the Outflow Tracking function
	Pressure increase/decrease buttons
	Outflow/shaver and RF Probe Suction increase/decrease buttons
 Smart Vision	Activates/deactivates the SmartVision® function
 Run/Stop	Run/Stop button. Starts/stops pump after setup
 Patient Cassette	Press to open/close pump pressure arm for the Patient Cassette
 PUMP FOOT CONTROL	Receptacle for the pumps' 2 or 4 pedal foot control
 RF FOOT CONTROL	Receptacle for RF generator foot control (ArthroCare® and S&N only)

Symbols used - packaging

	Humidity limitations
	Fragile – Handle with care
	Pressure limitations
	Keep dry
	Keep away from sunlight
	Do not stack more than 3 boxes
	Indicates correct upright position of the transport package
	Indicate the sides of the box which shall not be clamped when handled by mechanized means

Symbols used - rear

	Name, Address and Country of Manufacturer
	Unit Serial Number
	Reference number
	Caution, consult accompanying documents / Operator's manual
	Consult Instructions for Use / this Operator's manual
	Type BF according to standard IEC60601-1
	Connection for potential equalization
	Fuse
	Do not dispose in waste bin
	Receptacle for Shaver Interface Box
	Receptacle for Shaver Interface Cable
	Receptacle for RF Cable
	Serial communications port used for service only
	Tone volume control
	Caution: Federal law restricts this device to sale by or on the order of a physician

Safety

The Double Pump RF meets the requirements of the harmonised standard IEC 60601-1 (ed.3) and is classified as follows:

- Type of protection against electrical shock: Class I equipment
- Applied part type BF.

Degree of protection against harmful ingress of water:

- The Double Pump RF meets requirements of IEC 60601-1; spillage of a liquid on the pump does not wet parts which may cause a safety hazard.
- Foot Controls meet requirements of IEC 60601-1, watertight construction (IPX8).

Equipment is not suitable for use in the presence of a flammable anesthetic mixture.

Mode of operation: capable of continuous operation.

Preventive Maintenance

An annual preventive maintenance of the Double Pump RF is required to assess its functionality and technical safety. Please contact your Medical Vision AB representative for instructions on the annual preventive maintenance.

Ordering Information

Double Pump RF Unit	
1028511	Double Pump RF

Double Pump RF Foot Control

1404176	4 pedal Foot Control
1404003	2 pedal Foot Control

Double Pump RF Cassettes

1002053	Day Cassette RF 20 pcs/Box
1002059	Patient Cassette 20 pcs/Box
1003059	Patient Cassette RF 20 pcs/Box

Double Pump RF Single (Irrigation Tubing)

1002052	Package of 100 pcs/Box
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RF Cabels for connection to RF Generators		Compatible with
1402008	RF Cable A1	For connection to RF generator ArthroCare®, Quantum 2
1402007	RF Cable A2	Stryker® Serfas Energy

Double Pump RF Shaver Interface Boxes and Cables		Compatible with
1407200	Interface Box B1	ConMed-Linvatec Advantage D3000: Red shaver port.
1407201	Interface Box B2	S&N Dyonics Power; S&N Dyonics Power II
1407204	Interface Box B5	Stryker® TPS 12K B/BF/Core; Biomet (Arthrotek) PowerTek II Plus
1407205	Interface Box B6	FMS Duo+; Atlantech Revolution, Arthrex APS II
1407208	Interface Box B10	Eberle C2
1407250	Interface Cable C1	ConMed-Linvatec Advantage D3000
1407251	Interface Cable C2	S&N Dyonics Power, S&N Dyonics Power II
1407254	Interface Cable C5	Arthrex APS II
1407255	Interface Cable C6	FMS Duo+; Atlantech Revolution
1407257	Interface Cable C8	Eberle C2
1407264	Interface Cable C15	Biomet (Arthrotek) PowerTek II Plus (NOTE: Pump setting must be made prior use by authorised service technician)

Warranty Information

The Double Pump RF and Foot Control are warranted for one year from the date of shipment to the original purchaser. Any component of the system, which develops defects resulting from defective material or workmanship during this time period will be replaced or repaired without charge.

PLEASE NOTE:

Warranty is void if the Double Pump RF is shipped in any other transportation box/case than those provided by Medical Vision AB.

Product Complaints

All questions or concerns related to the quality, reliability and/or durability of this product should be directed to a Medical Vision AB representative.

Please contact your Medical Vision AB representative for a return authorization before sending any products.

Manufacturer's declaration on electromagnetic interference

The Double Pump RF is intended for use in normal domestic and hospital environments.

The Double Pump RF uses RF energy for its internal function. Therefore, its RF emission is very low and is not likely to cause interference with nearby electronic equipment.

NOTE

The Double Pump RF can be used together with an RF generator and an RF probe in which case the emission from such devices should be obtained from the manufacturer of these devices.

The Double Pump RF may be affected in the vicinity of equipment marked with the symbol .

Electromagnetic interference can be prevented by maintaining a minimum distance between the Double Pump RF and portable or mobile RF communications equipment, including antennas, as recommended by the table below. If the Double Pump RF is used inside of the recommended separation distances, the Double Pump RF should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Double Pump RF. Electromagnetic interference may cause the pump display to stop functioning normally and require power cycling of the pump to restore normal operation of the display.

Rated maximum output power of transmitter [P]	Separation distance, including stacking, according to frequency of transmitter [m]	
	150 kHz-800 MHz	800 MHz -2,5 GHz
0,01	0,12	0,12
0,1	0,38	0,73
1	1,2	2,3
10	3,8	7,3
100	12	23

Emission Test	Compliance	Electromagnetic Environment
RF Emissions	Group 1	Double Pump RF uses RF energy only for its internal functionalities. Thus, device emission is very low without causing damage to units placed in the surrounding environment.
RF Emissions	Class B	Double Pump RF can be used in every kind of environment such as domestic and low voltage power supplier for building.
Harmonic Emission	Class A	
Flicker and voltage burst emissions	Compliant	

NOTE

The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

The electromagnetic interference testing referenced here was performed according to the relevant standards without deviation.

Manufacturer's declaration on electromagnetic interference

Immunity Test	IEC 60601 test level	Compliance Level	Electromagnetic Environment (distance between a transmitter and the unit)
Conducted Radio frequency	3 Veff	3 Veff	$d = 1.17 (P)^{1/2}$ where : P = maximum output nominal power of the transmitter (Watts) d= separation distance (meters)
Radiated Radio frequency	10 V/m (26 MHz÷1 GHz) 3 V/m (1GHz÷2,5GHz)	10 V/m 3 V/m	$d = 0.35 (P)^{1/2}$ from 80 MHz to 800 MHz $d = 0.7 (P)^{1/2}$ from 800 MHz to 1 GHz $d = 0.7 (P)^{1/2}$ from 1 GHz to 2.5 GHz where : P = maximum output nominal power of the transmitter (Watts) d= separation distance (meters)

Immunity Test	IEC 60601 test level	Compliance Level	Electromagnetic Environment
ESD test	± 6 kV contact ± 8 kV by air	± 6 kV contact ± 8 kV by air	Material requirements for floor: •Wood •Piling •Ceramics If synthetic material floors are present relative humidity has to be 30 % as minimum.
Voltage Bursts	± 2 kV between phase and ground ± 1 kV between phases	± 2 kV common mode ± 1 kV differential mode	Mains supply quality has to be typical of hospital or commercial environment.
Over voltage	± 2 kV between phase and ground ± 1 kV between phases	± 2 kV common mode ± 1 kV differential mode	Mains supply quality has to be typical of hospital or commercial environment.
Supply voltage interruptions and supply voltage variation level	< 5 % Ut (95 % interruption) for 0,5 cycles 40 % Ut (60 % interruption) for 5 cycles 70 % Ut (30 % interruption) for 25 cycles < 5 % Ut (95 % interruption) for 5 seconds	< 5 % Ut (95 % interruption) for 0,5 cycles 40 % Ut (60 % interruption) for 5 cycles 70 % Ut (30 % interruption) for 25 cycles < 5 % Ut (95 % interruption) for 5 seconds	Mains supply quality has to be typical of hospital or commercial environment. If the user wants to use the Double Pump RF in a voltage interruption condition a UPS device must be adopted.
Magnetic Field at 50 Hz frequency	3 A/m	3 A/m	Supply frequency magnetic field must be the same as hospital or commercial environment.

For further details please contact Medical Vision AB or your local Medical Vision AB representative.



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0413



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Double Pump RF

The Double Pump RF and its disposables are covered by Swedish patents SE529738 and SE526008, European Patent Application 07748355, EPO patent 2265944, Japanese patent JP5623383, US Patents US746547, US7661582, US7981073, US8411266, US8608682, US8746547, USD721801, USD773037 and D745963, European Community design registrations EM001635657-0001, EM001601824-0001 and EM001528464-0001, and other utility-, design-, continuation patents and patent applications in different geographical areas; all of these owned by or licensed to Medical Vision AB.

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