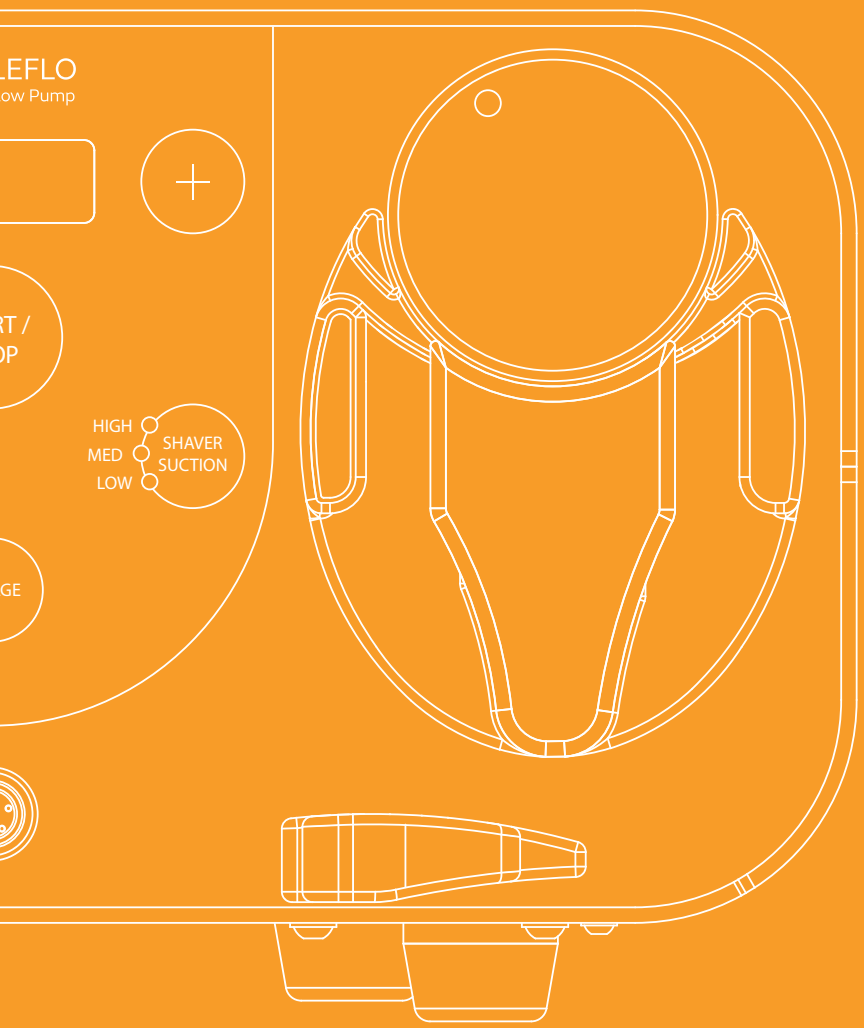
DOUBLEFLO

Inflow/Outflow Pump

Multilingual

104785-C- January, 2021



- EN Instruction Manual
- DE Bedienungsanleitung
- NL Handleiding
- IT Manuale di istruzioni
- FR Manuel d'instructions
- ES Manual de instrucciones
- TR Kullanım klavuzu
- PL Instrukcja obsługi
- PT Manual de instruções
- NO Bruksanvisningen
- SE Instruktionsmanual
- DK Instruktionsmanual
- FI Käyttöopas

EN

Instruction manual

Table of contents

EN

Table of contents

EN

Introduction: presentation of the pump

EN

Dear Customer,

Thank you for purchasing your arthroscopy pump. This device is delivered with the technical documentation. Please always ensure that this manual is close at hand; it describes your equipment and its operation.

This arthroscopy pump must be used with its own tubing. Its system manages irrigation automatically as a function of suction, thereby providing a flow rate and a precisely controlled pressure. Its user-friendly and easy to use Human/Machine Interface (HMI) allows optimum control of the device for the practitioner. The pump is intended for use during arthroscopy operations by orthopaedic surgeons and operating theatre nurses. The pump was developed in collaboration with surgeons in order to meet their expectations and be capable of offering them maximum convenience.

The performance of the pump allows:

- conveyance of the irrigation liquid from the bags of physiological saline to the joint via an arthroscopy sleeve, precisely controlling the pressure and flow rates,
- recovery of the contaminated fluids from the joint via a cannula or a surgical instrument to the waste collection bag,
- precise control of intra-articular pressure, regardless of the outgoing flow rate,
- selection of the appropriate suction level (LOW, MED, HIGH),
- communication with the shaver consoles,
- integration with the arthroscopic tower.

General description

EN

The arthroscopy system consists of a pump, accessories and consumables.

Accessories:

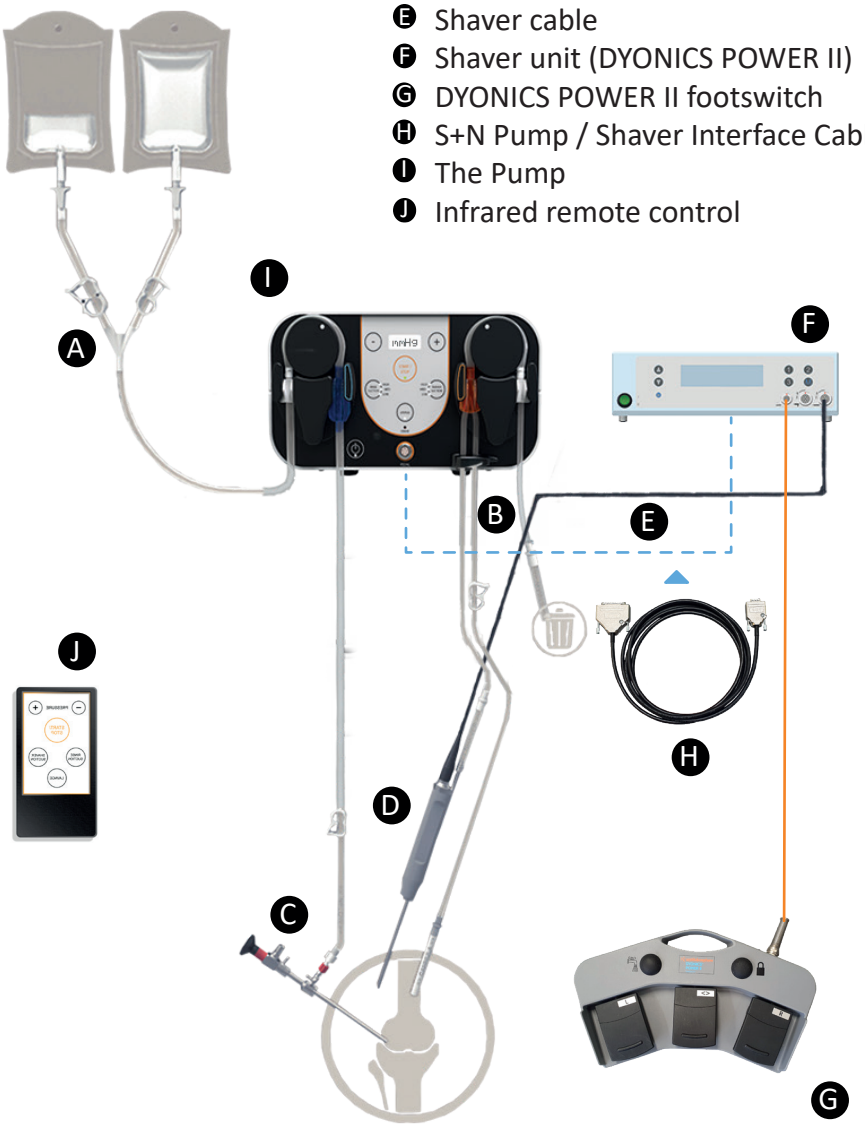
- Footswitch - Wired
- Hand Control Interfaces (HCI)
- Foot Control Interfaces (FCI)
- Infrared remote control

Consumable tubing:

- Day Tube Set
- Patient Tube Set
- Inflow Tube Set
- Outflow Tube Set

Reading this manual is compulsory before any use of the pump, its accessories and its consumable tubing.

Ⓐ Inflow Tube Set
Ⓑ Outflow Tube Set
Ⓒ Arthroscopy sheath / cannula
Ⓓ Handpiece
Ⓔ Shaver cable
Ⓕ Shaver unit (DYONICS POWER II)
Ⓖ DYONICS POWER II footswitch
Ⓗ S+N Pump / Shaver Interface Cable
Ⓘ The Pump
Ⓙ Infrared remote control

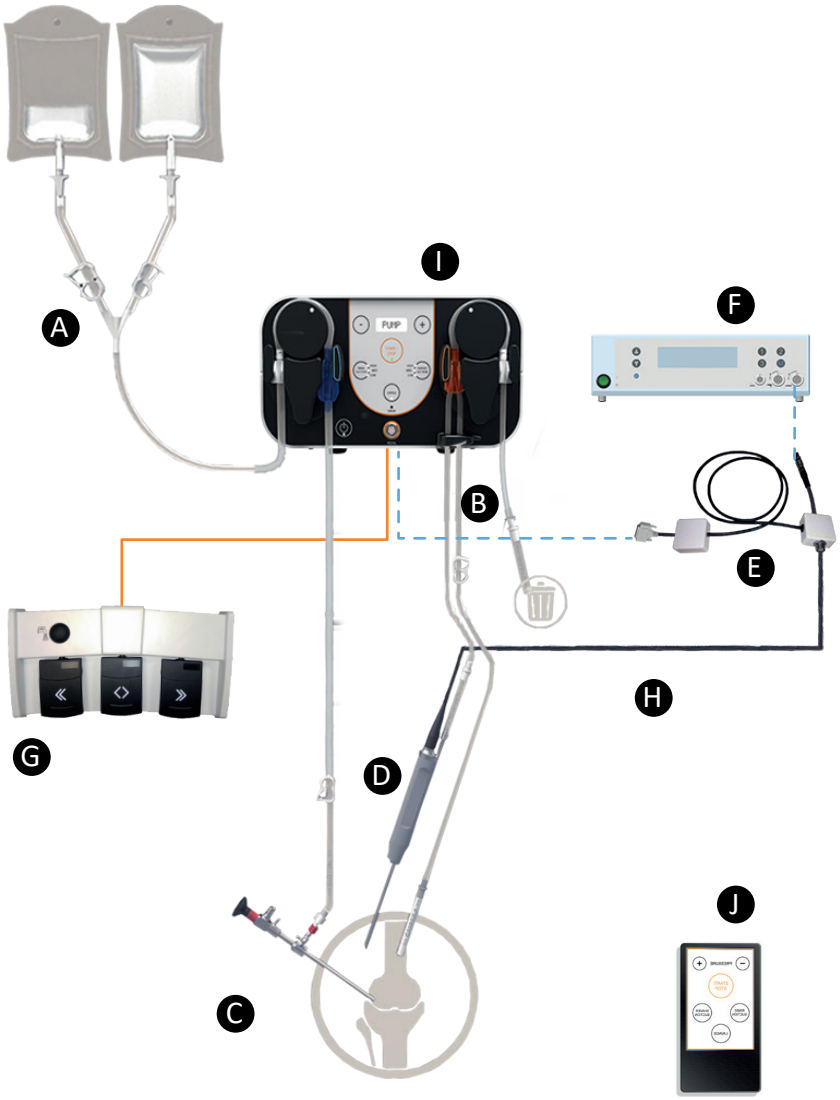


This diagram represents the arthroscopy system with the use of the S+N Pump / Shaver Interface Cable.

General description

EN

Ⓐ Inflow Tube Set
Ⓑ Outflow Tube Set
Ⓒ Arthroscopy sheath / cannula
Ⓓ Handpiece
Ⓔ Hand Control Interface
Ⓕ Shaver unit
Ⓖ Footswitch - Wired
Ⓗ Shaver cable
Ⓘ The pump
Ⓙ Infrared remote control

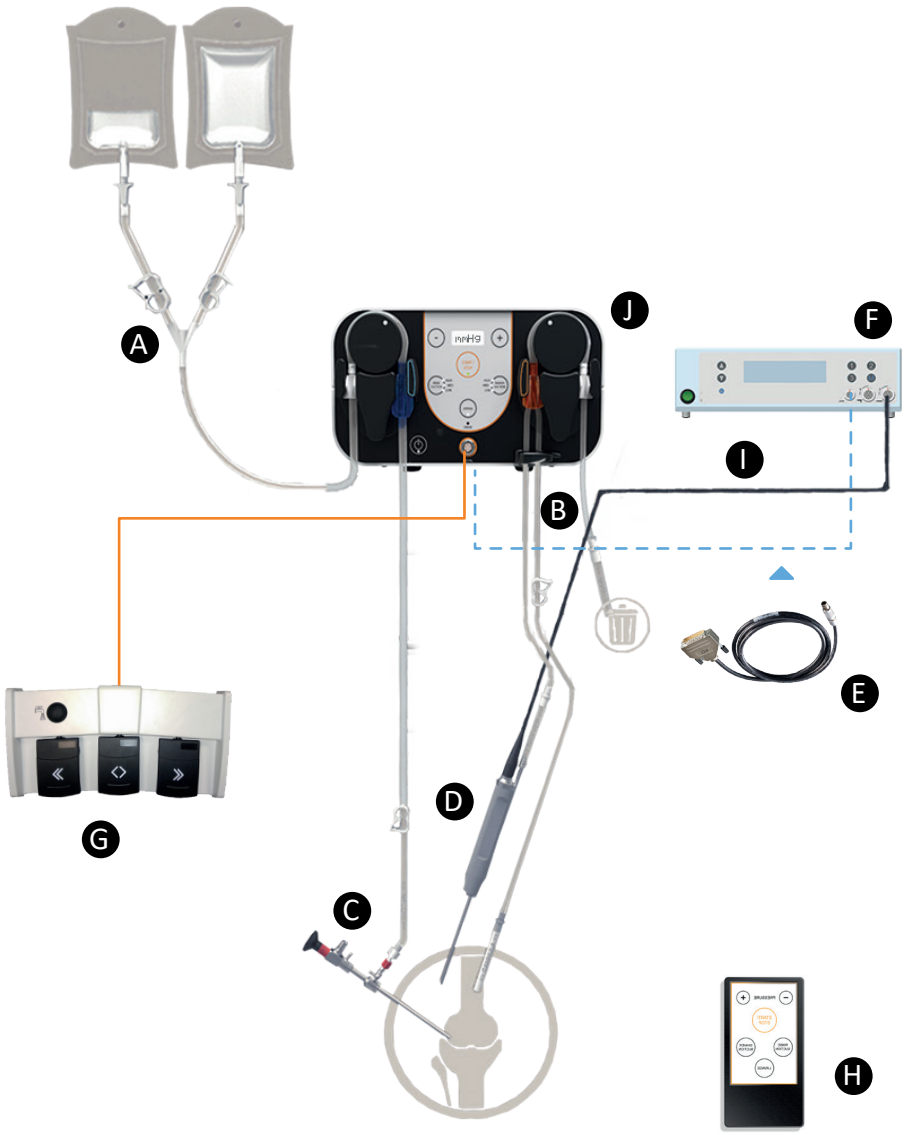


This diagram represents the arthroscopy system with the use of a hand control interface except for S+N Hand Control Interface.

General description

EN

- Ⓐ Inflow Tube Set
- Ⓑ Outflow Tube Set
- Ⓒ Arthroscopy sheath / cannula
- Ⓓ Handpiece
- Ⓔ Foot Control Interface
- Ⓕ Shaver unit
- Ⓖ Footswitch - Wired
- Ⓗ Infrared remote control
- Ⓘ Shaver cable
- Ⓙ The Pump



This diagram represents the arthroscopy system with the use of a Foot Control Interface.

EN

1.1 Operator profile

The DOUBLEFLO system is to be used in the operating theatre; the users include nurses and orthopedic surgeons.

1.2 Target population

8-years-old or older pediatric and adults patients requiring an arthroscopic surgery, regardless of gender.

1.3 Intended use and contraindications

Indications

The DOUBLEFLO system represents an arthroscopy system using fluid from saline bags (0.9% NaCl). This arthroscopy system is intended to provide fluid distension and irrigation of the knee, shoulder, hip, elbow, ankle and wrist joint cavities, and fluid suction during arthroscopy procedures.

Contraindications

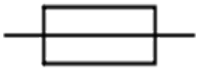
The use of the DOUBLEFLO system is prohibited whenever arthroscopy is disallowed.

1.4 Symbols description

A- Symbol used within this user manual

Symbol	Name	Description
	Warning	Indicates a hazardous situation which, if not avoided, could result in serious injury or damage. Obey all safety messages that follow this symbol to avoid possible injury or damage.

B- Symbols for pumps and accessories

Symbol	Name	Description
	Fuse	External fuse rating: T5AH-250V
	Manufacturer	Identifies the manufacturer of the medical device
	Manufacturing date	Indicates the date on which the medical device was manufactured
	Equipotential bonding symbol	Indicates presence of an earth contact on the rear of the pump
	Symbol for electrical and electronic equipment waste	This device is subject to separate collection. Return the device to Hemodia at the end of its service life
	Refer to the instruction manual	Reading the manual is compulsory before using the pump for the first time
	Consult the instruction for use	Indicates to the user that it is necessary to consult the instruction for use

EN

Symbol	Name	Description
SN	Serial number	Indicates the serial number assigned by the manufacturer in order to formally identify a specific medical device
LOT	Manufacturing batch	Indicates the number of the manufacturing batch
CE	CE marking	Indicates that this equipment complies with the medical device regulations (MDR 2017/745). If applicable, there is also the identification of the notified body (four digits).
MD	Medical device	Indicates that a medical device as defined by the regulations (MDR 2017/745).
	Distributor	Indicates the entity that distributes the medical device in the region concerned.
	UL marking	Certification mark for components recognized by Underwriters Laboratories in Canada.
	RFID technology	Allows communication between the tubing and the pump.
	Standby	Identifies the button or button position as well as the activated piece of equipment to put it on standby, and identifies the control to switch to or the state of low power consumption. Each of the power consumption states can be indicated with a corresponding color.
QTY	Quantity	Indicates the quantity of product present in the packaging.
Rx Only	Prescription device	Federal law restricts this device to sale by or on the order of practitioner
REF	Catalog reference	Indicates the manufacturer's catalog reference to allow formal identification of the medical device

C- Symbol for tubing

Symbol	Name	Description
	Use-by date	Indicates the date after which the medical device may no longer be used
	Do not reuse	Indicates that a medical device may only be used once or on a single patient for one treatment only
	Manufacturing date	Indicates the date on which the medical device was manufactured
	Sterilized using ethylene oxide	Indicates that the medical device was sterilized with ethylene oxide
	Manufacturing batch	Indicates the number of the manufacturing batch
	Do not re-sterilize.	This product has not been designed to be re-sterilized
	Prescription device	Federal law restricts this device to sale by or on the order of practitioner
	Manufacturer	Identifies the manufacturer of the medical device
	Warning	Informs the user that the precautions for use need to be consulted for any important information concerning safety, such as warnings and precautions to be taken, which for various reasons cannot appear on the device itself
	Protect from humidity	Indicates that the medical device is humidity-sensitive
	Catalog reference	Indicates the manufacturer's catalog reference to allow formal identification of the medical device

Precautions for use

Symbol	Name	Description
	Unique sterile barrier system with inner protective packaging	Indicates a unique sterile barrier system with a packaging of protection inside.
	Do not use if the packaging is damaged and consult the instructions for use	Indicates a medical device which should not be used if the packaging has been damaged or opened and whose user should consult the instructions for use for more information
	Quantity	Indicates the quantity of product present in the packaging

1.5 Warnings and general precautions

The hospital staff are urged to read this manual before using and cleaning this product and its accessories. Failure to abide by these instructions may cause injuries and possible damage to, or malfunction of the equipment. The manufacturer of this device cannot be held liable for direct or consequential injuries or damage resulting from inappropriate use of the single-use products other than the products. Any modification of the device, any repairs performed by an unauthorized service center or any use of single-use products other than the single-use products specified by the manufacturer shall invalidate the manufacturer warranty and the civil liability coverage in case of material damages or bodily harm.

The white silicone membranes from the two force sensors on the front panel of the pump have been designed for normal use and all misuses may lead to breakage of the pump which will no longer be covered by the warranty:

- Do not use abrasive tools or sharp objects (like knives, scalpels,...) to avoid to tear the white silicone membranes
- Do not remove the irrigation tube set with pressure inside to avoid to deform the white silicone membranes

The equipment must only be used by personnel trained in arthroscopy procedures. This medical qualified staff must wear standard operating theater protective equipment (mask, gloves, gown, hood). All electro-medical devices have to be located in the non-sterile zone (except for the remote control).

Tubing must not be modified. Reprocessing is liable to change the characteristics of the materials, particularly by deformation and degradation, which may have repercussions on the durability of the device and compromise its performances. These risks may potentially jeopardize patients' safety. Tubing may contain tissues or cells of animal origin or their derivatives, referred to in the EU regulation n°722/2012.

The user has to avoid contact with any liquid to the pump and its accessories during the operation.

Do not connect the device to an unearthed or poorly earthed source of power. In order to avoid any risk of electric shock, this equipment must only be connected to a power supply equipped with a protective earth. Do not remove the casing (risks of electrocution). In order to avoid any risk of fire, replace spent fuses with fuses of the same characteristics.
The system may be affected by electromagnetic interferences generated by other instruments. Check that the other instruments used in the operating theater comply with electromagnetic compatibility (EMC) standard IEC 60601-1-2.
The pump is a class 1 device in accordance with electrical safety standard IEC 60601-1, the currently applicable version.
The pressure adjustments (chapter 6.2) suggested by the legal manufacturer are based on observations; the values in the table may be modified and should be adapted depending on the operation. Any serious incidents that have occurred in connection with these devices must be notified to the manufacturer and the competent authority of the Member State in which the user is based.

EN

1.6 Technical characteristics

A- Sterilization

The device and the accessories are not sterile. On the other hand, they must be decontaminated after each day of use (see chapter 7.1).
The tubing are sterilized by ethylene oxide (EtO).

On receiving the tubing, check that the packaging items have not been damaged. If a consignment is opened or damaged, or the expiry date is exceeded, contact the distributor by telephone or email for advise.

 Never use a product if its sterile packaging is damaged or if the expiry date is exceeded.

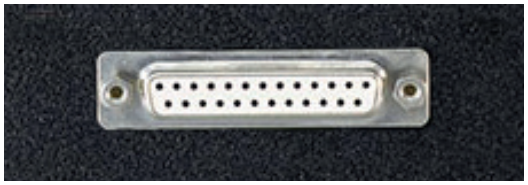
 This symbol applied to a packaging item means that the tubing are for single use in accordance with harmonized practices in the EU (MDR). They cannot therefore be reused.

Retreatment is liable to change the characteristics of the materials, particularly by deforming and degrading the latter, which may have repercussions on the durability of the device and compromise its performance. These risks may potentially jeopardize patients' safety.

B- Electrical characteristics

- Input voltage: 100-240 VAC
- Frequency: 50-60 Hz
- Current draw: 500 VA
- External fuse rating: T5AH-250V

The pump is not a BF part but it is considered as a BF part for shaver input according to the IEC 60601-1 standard. There is one part considered as BF part: input dedicated for Hand Control Interfaces and Foot Control Interfaces (25 pin connector) situated on the back of the DOUBLEFLO pump.



EN

2.1 System indicators

A- Front panel of the Pump

1 Irrigation pump head

2 Suction pump head

3 Retaining bracket for the irrigation tubing
Note : The two circles on the right opening are silicone membranes from force sensors.

Avoid touching these white silicone membranes

4 Retaining bracket for the suction tubing

5 Pressure decrease

6 Pressure increase

7 White LCD screen: Displays the pressure setting and the error messages (colour of the characters is black)

8 **“START/STOP”** button: Starts or stops the fluid management. The indicator flashes when the pump is stopped (upon stop)

9 **“RINSE SUCTION”** button: Cannula suction adjustment: Adjusts the flow rate of the cannula **(LOW, MED, HIGH).** The LED lights up when the flow rate is activated

EN

10 **“SHAVER SUCTION”** button: Adjusts the flow rate of the “shaver” **(LOW, MED, HIGH)**. The LED lights up when the flow rate is activated

11 **“LAVAGE”** button: Activates the **“LAVAGE”** mode. The LED lights up when the **“LAVAGE”** mode is activated

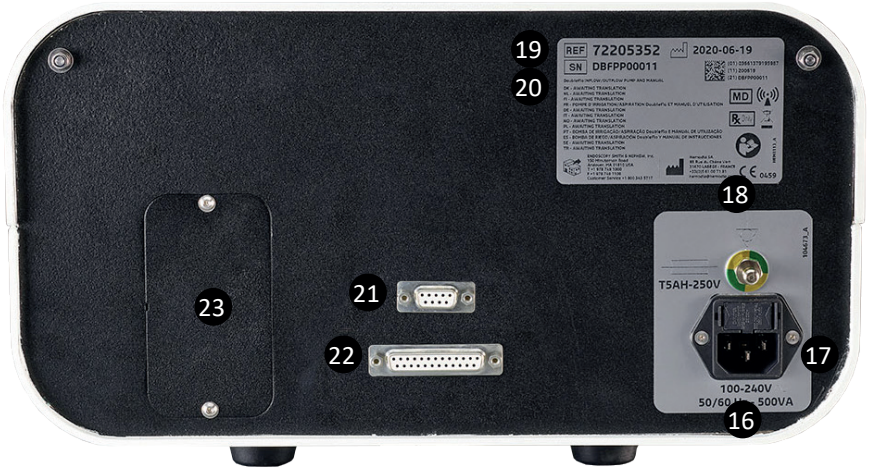
12 Red **“ERROR”** LED. The LED lights up when the device detects a problem

13 **“POWER”** button: Turns the unit on or off. If the pump is enabled, “mmHg” appears on the display screen.

14 **“PEDAL”** connector: Allows the wired DOUBLEFLO footswitch to be connected

15 **Infrared opening**: Allows the communication with the wireless remote control

B- Back panel of the Pump

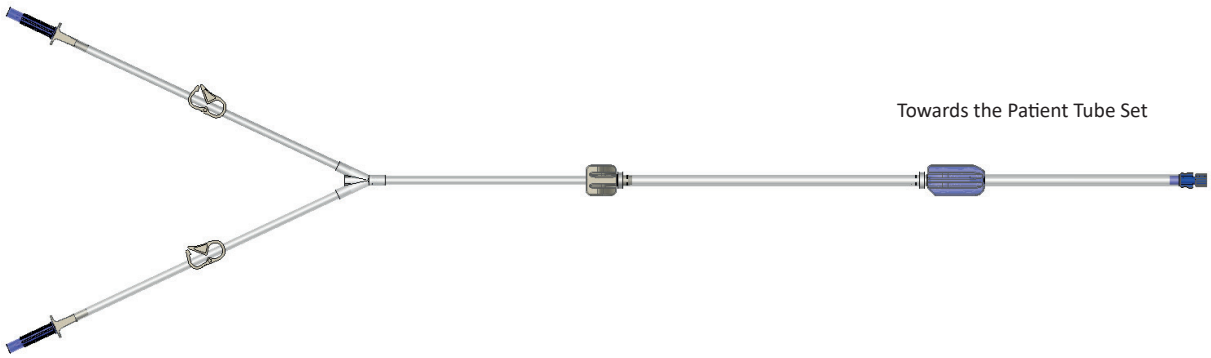


16 Main connector
17 Fuse holder and mains plug
18 Equipotential terminal
19 Product reference number (REF)
20 Device serial number (SN)
21 9 pin connector dedicated to LINK DFP
22 25 pin connector dedicated to DOUBLEFLO interface
23 USB connector hidden behind metal sheat to update the software

EN

2.2 Consumable tubing

Day Tube Set



The Day Tube Set connects the irrigation bags to the Patient Tube Set. The pressure is read through the pressure sensor membranes situated in the blue connector connected on the pump.
No contamination is possible among patients if, and only if, the tubing is used in conjunction with a Patient Tube Set. The procedure for installing and changing the tubing is explained in chapters 4.2, 5.1, 5.2 and 5.3.

The Day Tube Set is intended for one day use and can be used for several consecutive operations for different patients.

Patient Tube Set

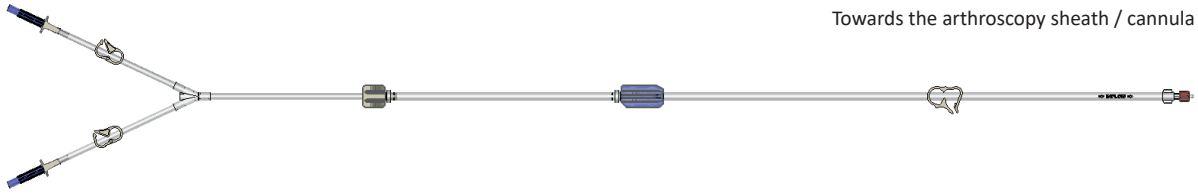
The Patient Tube Set is used to convey the sterile saline solution from the Day Tube Set to the arthroscopy sheath / cannula.

The Patient Tube Set is intended for single use and must not be reused.

EN

Inflow Tube Set

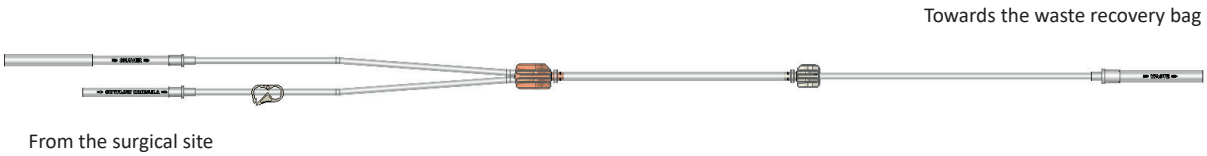
The Inflow Tube Set tubing delivers irrigation fluid from the bag to the arthroscopy sheath / cannula. The pressure is read through the pressure sensor membranes situated in the blue connector connected on the pump.



The Inflow Tube Set is intended for single use and must not be reused.

Outflow Tube Set

The Outflow Tube Set allows suction from the joint, either via a cannula (when the “SHAVER” tube is pinched) or via another suction device, a shaver (when the “OUTFLOW CANNULA” tube is pinched). Both modes are controlled by the “Pinch Valve”.



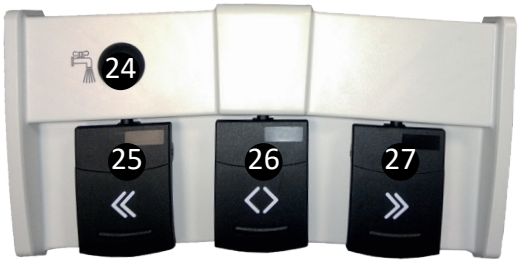
The Outflow Tube Set is intended for single use and must not be reused.

2.3 Accessories

Only connect the accessories dedicated for the pump. Please, check the accessories available on chapter 10. Perform functional tests (as mentionned part 3.2) before use on the patient.

A- Footswitch - Wired

The wired 4-way footswitch is connected to the **Pump** (PEDAL connector 14). This footswitch allows activation of suction by the “cannula” and “shaver” tubes at the preconfigured levels and activation or deactivation of **“LAVAGE”** mode.



24 This “  ” button makes it possible to:

- Activate the LAVAGE mode: the user has to momentarily press the button
- Activate the RINSE mode: the user has to press and keep pressed the button
- Deactivate the LAVAGE mode: when the LAVAGE mode is activated, the user has to momentarily press again the button (LAVAGE mode deactivated) or press and keep pressed the button (LAVAGE mode deactivated and RINSE mode activated)

There are two operational mode types when the FCI is connected:

TYPE 1 - WHEN USING FCI COMPATIBLE WITH ARTHREX SHAVER CONSOLE

25 The **“<<”** control makes it possible to control a shaver in REVERSE mode from a shaver console and activate suction by the shaver at the preconfigured level.
26 The **“<>”** control makes it possible to control a shaver in OSCILLATION mode from a shaver console and activate suction by the shaver at the preconfigured level.
27 The **“>>”** control makes it possible to control a shaver in FORWARD mode from a shaver console and activate suction by the shaver at the preconfigured level.

TYPE 2 - WHEN USING FCI COMPATIBLE WITH CONMED SHAVER CONSOLE

The **“<<”** control makes it possible to choose the mode on the handpiece (FORWARD, REVERSE or OSCILLATION).
The **“>>”** control makes it possible to activate the pre-selected mode of the handpiece and activate the suction through the SHAVER tube.

EN

B- Foot Control Interface (FCI)

The Foot Control Interfaces (FCI) compatible with ARTHREX and CONMED shaver consoles are connected on the back of the DOUBLEFLO pump 22 and on the front panel of the shaver console. All FCI control the shaver handpiece and activates “Shaver suction” at the preconfigured level from the DOUBLEFLO footswitch.

C- Hand Control Interfaces (HCI)

The S+N Pump / Shaver Interface Cable is connected on the back of the DOUBLEFLO pump 22 and on the back of the DYONICS POWER II shaver console.
The other Hand Control Interfaces (compatible with ARTHREX, CONMED and STRYKER shaver consoles) are connected on the back of the DOUBLEFLO pump 22, on the front panel of the shaver console and on the handpiece.
All HCI detect the operation of a shaver from a console and activate “Shaver suction” at the preconfigured level.

In addition, when using the S+N Pump / Shaver Interface Cable, the DYONICS POWER II footswitch allows the activation of the DOUBLEFLO footswitch functions, as described in the part A: LAVAGE, RINSE, REVERSE, FORWARD and OSCILLATION.

24 This “  ” button makes it possible to:

- Activate the LAVAGE mode: the user has to momentarily press the button
- Activate the RINSE mode: the user has to press and keep pressed the button
- Deactivate the LAVAGE mode: when the LAVAGE mode is activated, the user has to momentarily press again the button (LAVAGE mode deactivated) or press and keep pressed the button (LAVAGE mode deactivated and RINSE mode activated)

When using a handpiece without buttons, the **“L”** control 25, the **“<>”** control 26 and the **“R”** control 27 make it possible to control a shaver in REVERSE, OSCILLATION or FORWARD mode from a shaver console and activate suction by the shaver at the preconfigured level.

EN

D- Remote control

The wireless remote control is an accessory of the pump with infrared technology which allows controlling functions of the pump keyboard and the **“LAVAGE”** function of the DOUBLEFLO footswitch. This remote control must be used in the sterile area but to guarantee sterility, the remote control must be placed in a sterile protective bag (not provided by Hemodia).

28 Pressure increase.
29 Pressure decrease.
30 Shaver suction adjustement: adjusts the flow rate of the “ shaver ” (LOW – MED – HIGH).
31 Rinse rate adjustment: adjusts the flow rate of the cannula (LOW – MED – HIGH).
32 Activating “**LAVAGE**” mode.
33 **“START/STOP”** button: Starts or stops the fluid management of the pump.

E- AC power cord

The AC power cord is used to connect the pump to the power supply.
Please use the appropriate AC power cord to any local AC mains outlet.
The AC power cord can be used as a means of emergency stop; disconnecting the AC power cord makes it possible to isolate the device from the power supply.

There are multiple types of AC power cords kit supplied, please refer to chapter 10.

Install the device such that it is easy to disconnect the AC power cord from the power supply.

EN

2.4 Audible indicators

A double signal sounds when the pump is switched on (when the "**POWER**" button 13 is pressed) and when "**LAVAGE**" mode is stopped.
A single audible signal sounds each time a button is pressed.

2.5 Light indicators

Numbers below refer to descriptions in chapter 2.1.

8 This indicator light illuminates when the pump is set to "START" mode; the indicator light flashes when the pump is set to "STOP" mode

9 10 These illuminated indicator lights show the flow rates selected (LOW, MED, HIGH)

11 This indicator light illuminates when "LAVAGE" mode is active

12 This red indicator light illuminates when the device detects a problem

2.6 Error messages

When an error occurs, the fluid management goes automatically to STOP mode (LED START/STOP = OFF) and the error code is displayed on screen. After the correction, the user must press momentary the **"START/STOP"** button to start fluid management.

When the error LED is ON without error code displayed on the pump screen, the user must wait until the pressure drops.

Displayed on the screen	Description	Action
E00	Device was switched on with tube set inserted; the sensor could not be checked.	Remove irrigation tube set
E01A	Attempted pump activation without day tube set or inflow tube set inserted	Insert day tube set or inflow tube set
E02A	Used day tube set or inflow tube set has been inserted	Remove used day tube set or inflow tube set & insert new day tube set or inflow tube set
E02B	Used outflow tube set has been inserted	Remove used outflow tube set & insert new outflow tube set
E03A	Inoperative day tube set or inflow tube set has been inserted	Remove inoperative day tube set or inflow tube set & insert new day tube set or inflow tube set
E03B	Inoperative outflow tube set has been inserted	Remove inoperative outflow tube set & insert new outflow tube set
E04A	Day tube set or inflow tube set incorrectly inserted	Remove day tube set or inflow tube set & reinsert day tube set or inflow tube set properly
E04B	Outflow tube set incorrectly inserted	Remove outflow tube set & insert outflow tube set properly

EN

Displayed on the screen	Description	Action
E05	Pressure sensor error	Remove current day tube set or inflow tube set & insert new day tube set or inflow tube set. If error appears again, call service
E06	Motor error or low battery	Check if pump heads can rotate freely. If not, remove any object blocking rotation. If yes, call service
E07	Unable to identify tube set	Remove current tube sets and insert new ones. If errors appears again, call service
E08	Low pressure, the dynamic pressure is less than 15 mmHg	Check saline bag (may be bags are empty) and check clamps under bags (at least one must be open)
E50	Communication error with peripheral equipment	Check connections or replace the communication cable between the pump and peripheral equipment. If error appears again, call service
E60	Pressure sensor verification issue	Turn off the pump and try again (call service if applicable)

3.1 Transport

If the device is dropped or in case of damage to the equipment and its accessories, do not use the pump or any of its accessories.

3.2 Service life listing

Prior to each use, inspect each device to ensure it is functioning properly and is not damaged.

For that, perform a performance check for the installation and before each case begins. Check the following items to ensure that they function properly and the system is ready to use.

- Connect the power supply cable to the pump and to an electrical socket and check that all the leds on the front panel are off and that the LCD screen 7 is off
- Press the **“POWER”** button 13 and check that a double audible signal occurs, the **“START/ STOP”** 8 LED is blinking and the **“ERROR”** led is off
- Check that the LCD screen 7 displays **“mmHg”**
- Check front panel to ensure that all buttons are functioning properly (each activated button should emit an audible signal)
- Confirm the remote control works correctly with the pump (refer to the chapter 2.3 part D)
- Check all connections between the pump and its accessories to ensure that connectors are functioning properly
- Check that the labeling information on all devices are still readable
- Check for any damage to devices receptacle (cracks, corrosion, buildup or damage to the receptacle)

EN

4.1 Installing the pump

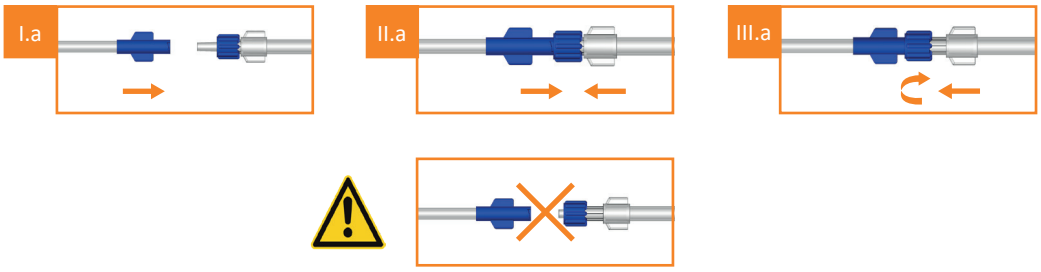
The pump has to be placed at the same level as the operating joint depending on patient position.

- Connect the power supply cable to an electrical socket.
- Press the "**POWER**" button: the LCD screen illuminates and displays "mmHg".

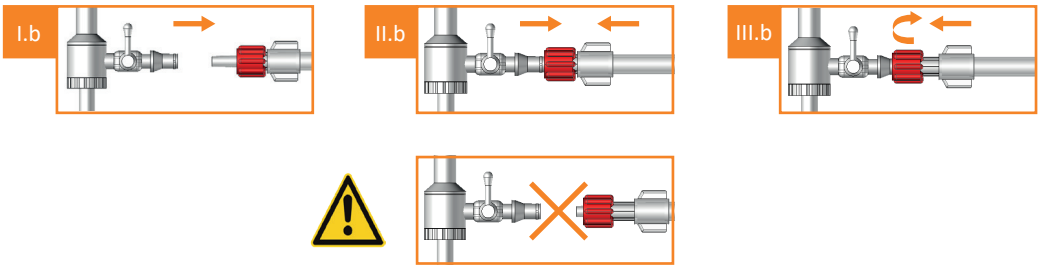
4.2 Connecting the tubing

- Use an aseptic method.
- The connections must be performed by circulating nurses or/and scrub nurse.
- The scrub nurse systematically manages all connections that must remain sterile.
- Turn on the pump by pressing the **"POWER"** button 13 before setting up tubing.
- Do not press on the "START/STOP" button 8 before setting all tubing (irrigation and suction parts).
- Make sure that the saline solution bags (NaCl 0.9%) are not within reach of electro medical devices before installing the tubing (not placed above or near devices)
- Replace the empty saline bags (0.9% of NaCl) before setting up tubing.
- Make sure all "Luer-Locks" are tight during all tubing connections.

Connection between the Day Tube Set and the Patient Tube Set



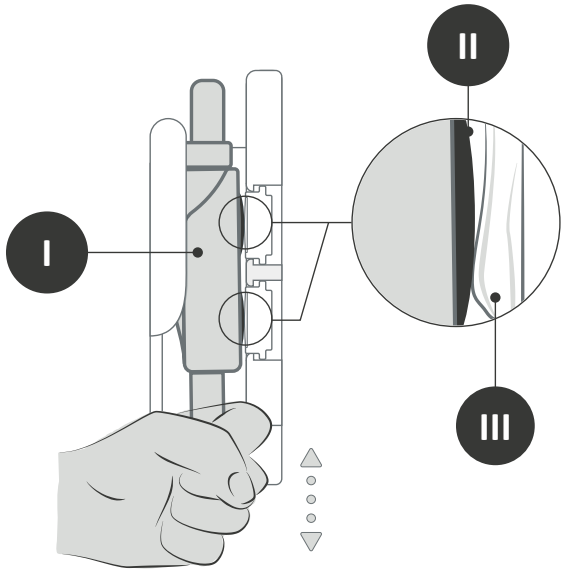
Connection between the tubing and the arthroscopic sheath / cannula



To properly connect the male Luer connector on the female Luer connector, the ring of the male Luer connector is moved backward (Fig. I.a and I.b); then the male cone of the male Luer connector is introduced into the female cone of the female Luer connector to the stop (Fig. II.a and II.b); then the ring is moved forward and screwed onto the screw thread of the female Luer connector (Fig. III.a and III.b).

EN

Precautions for the white silicone membranes situated on the retaining bracket for the irrigation tubing

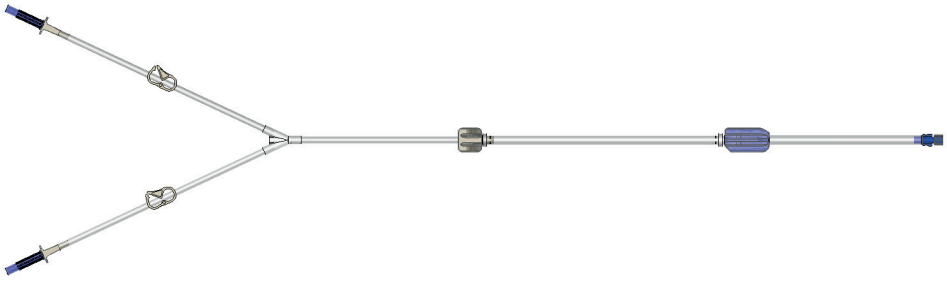


I. Blue connector from the Day Tube Set or Inflow Tube Set
II. Pressure sensor membranes pressurized
III. White silicone membrane deformed

Be careful when inserting or removing the blue connector: do not insert nor remove the blue connector with pressure inside to avoid to deform the white silicone membranes.

A- Day Tube Set

Description: the device for single day use delivers the irrigation fluid from the saline bag to the Patient Tube Set.



Method of use (to be performed by the circulating nurse):

- Open the outer package by using the opening tab
- Remove the tube set from the inner package and close the two clamps
- Remove all the caps on the spikes and connect the spikes to the bags of saline solution

EN

- Insert the blue connector from the tubing into the bracket with blue indicator (right opening) 3

Insert the blue connector only if the membranes are not pressurized

Do not touch the white silicone membranes.

- Place and center the tube around the irrigation pump head 1

Do not twist the tube

- Pull the tube tight through the left opening of the black bracket for the irrigation side (left opening) 3

- Insert the white connector from the tubing into the black bracket of the irrigation side (left opening) 3
- Connect the blue end (“Luer-Lock”) to the Patient Tube Set (refer to the below part B)
- Open one of the clamps connected to the bags of saline solution to be used in order to fill the irrigation tubing.

B- Patient Tube Set

Description: This device is intended to be used in conjunction with the pump and delivers the irrigation fluid from the Day Set Tube to the arthroscopy sheath / cannula during arthroscopy procedures.

Method of use (to be performed by the circulating nurse and the scrub nurse):

The circulating nurse:

- Open the outer package by using the opening tab

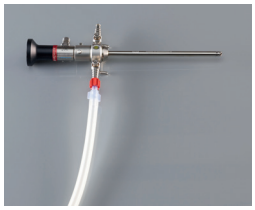
The scrub nurse:

- Remove the tube set from the inner package and ensure that the clamp is opened (otherwise, open the clamp)
- Ensure that all “Luer-Locks” are tight, then hand the blue cap to the circulating nurse

The circulating nurse:

- Remove the blue cap from the end of the Patient Tube Set and the Day Tube Set

- Connect the Patient Tube Set to the Day Tube Set and tigh the ring to lock both Luer connectors



The scrub nurse:

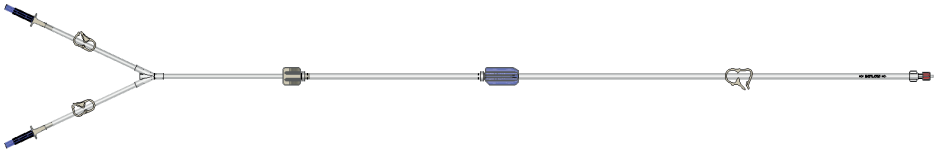
- Connect the red "Luer-Lock" of the Patient Tube Set to the arthroscopy sheath / cannula
- Open the arthroscopy sheath / cannula stopcock

The circulating nurse:

- Open one clamp of the Day Tube Set in order to fill the irrigation tubing
- Press on the **"START/STOP"** button 8 or 33: the pump is setting to **"START"** mode
- When the irrigation tubing has been purged of air, press again on the **"START/STOP"** button 8 or 33: the pump is setting to **"STOP"** mode

C- Inflow Tube Set

Description: This device for a single use delivers the irrigation fluid from the bag to the arthroscopy sheath / cannula during arthroscopy procedures.



Method of use (to be performed by the circulating nurse and the scrub nurse):

The circulating nurse:

- Open the outer package by using the opening tab

The scrub nurse:

- Remove the tube set from the inner package and ensure that the clamp close to the tube dedicated to the arthroscopy sheath / cannula is opened (otherwise, open the clamp)
- Keep the red end ("Luer-Lock") and hand the rest of the tubing with the two spikes to the circulating nurse

EN

The circulating nurse:

- Close the two clamps from the tubing
- Remove all the caps on the spikes and connect the spikes to the bags of saline solution
- Insert the blue connector of the tubing into the bracket with blue indicator (right opening) 3

Insert the blue connector only if the membranes are not pressurized
Maintain the blue connector vertically throughout insertion

- Place and center the tube around the irrigation pump head 1

Do not twist the tube

- Pull the tube tight through the left opening of the black bracket for the irrigation side (left opening) 3
- Insert the white connector from the tubing into the black bracket of the irrigation side (left opening) 3

The scrub nurse:

- Connect the red end ("Luer-Lock") to the arthroscopy sheath / cannula
- Open the arthroscopy sheath / cannula stopcock

The circulating nurse:

- Open one clamp of the Inflow Tube Set in order to fill the irrigation tubing
- Press on the **"START/STOP"** button 8 or 33 : the pump is setting to **"START"** mode
- When the irrigation tubing has been purged of air, press again on the **"START/STOP"** button 8 or 33: the pump is setting to **"STOP"** mode

D- Outflow Tube Set

Description: This device is intended to be used in conjunction with the pump during arthroscopy procedure. The outflow tube is used to remove the fluid in the joint via the cannula or a shaver.

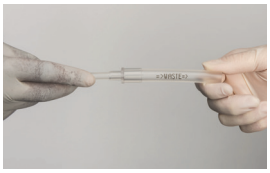
Method of use (to be performed by the circulating nurse and the scrub nurse):

The circulating nurse:

- Open the outer package by using the opening tab

The scrub nurse:

- Remove the tube set from the inner package and ensure that the clamp is opened (otherwise, open the clamp)
- Hand the tube end marked "WASTE" to the circulating nurse



EN

The circulating nurse:

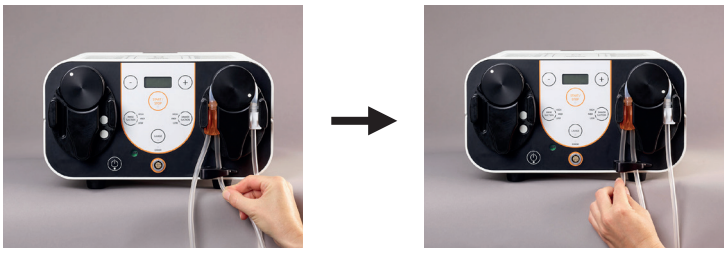
The pump fluid management has to be stopped. If the pump is set to **“START”** mode, press the **“START/STOP”** button 8 or 33.

- Insert the “WASTE” end into the waste collection system
- Insert the orange connector of the tubing into the bracket with the orange indicator (left opening) 4
- Place and center the tube around the suction pump head 2

Do not twist the tube

- Pull the tube tight through the right opening of the black bracket for the suction side (right opening) 4
- Insert the white connector from the tubing into the black bracket of the suction side (right opening) 4

- Insert the “OUTFLOW CANNULA” tube into the right side of the “Pinch Valve”
- Insert the “SHAVER” tube part into the left side of the “Pinch valve”



Make sure the DOUBLEFLO pump is positioned such that the “OUTFLOW CANNULA” tube and “SHAVER” tube hang vertically and the shelf does not interfere.

EN

The scrub nurse:

- When the cannula is used: insert the “OUTFLOW CANNULA” tube into the cannula
- When the cannula is not used: close the clamp on the “OUTFLOW CANNULA” tube
- Insert the “SHAVER” tube into the outflow spigot of the shaver handpiece

The circulating nurse:

The pump fluid management has to be launched by pressing on the **“START/STOP”** button 8 or 33.

4.3 Connecting the footswitch

Connect the footswitch cable to the PEDAL connector of the pump 14.

Do not disconnect the footswitch during the operation.

4.4 Communication with the remote control

Please, ensure that the batteries of the remote control are functional.

- Use an aseptic method
- Put the remote control into the sterile protective bag (not provided by Hemodia)

When the pump is switched on (via the “**POWER**” button 13), the remote control is immediatly connected with the pump.

EN

4.5 Connecting the Hand Control Interfaces (HCI)

PRECAUTIONS

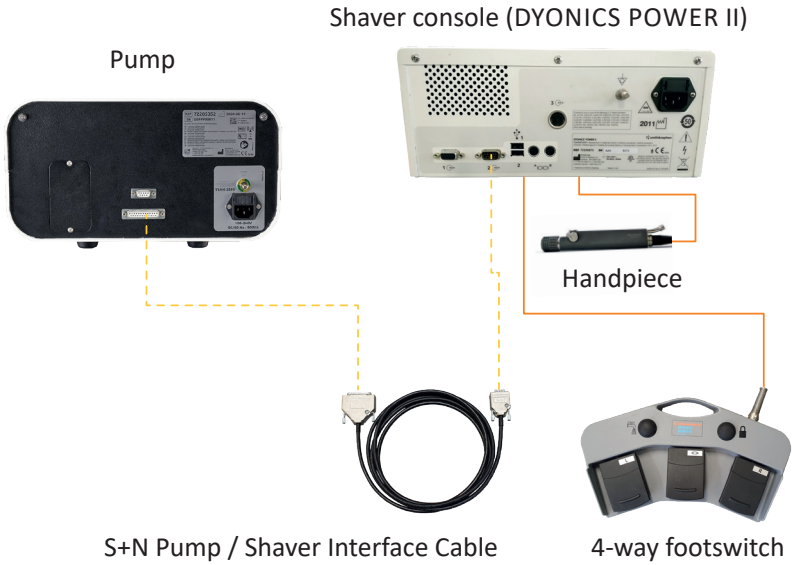
Before plugging and unplugging the Hand Control Interface, turn off both electromedical devices. Prior to use, inspect the product and do not use if damaged.

Control the Hand Control Interface connectors and ensure that cleaned cable connectors are completely dry prior to connecting the electromedical devices.

Do not disconnect the Hand Control Interface during the operation.

Make sure the 25 and 9 pin connectors are tight during connection.

A- S+N Pump / Shaver Interface Cable



INSTRUCTIONS FOR USE

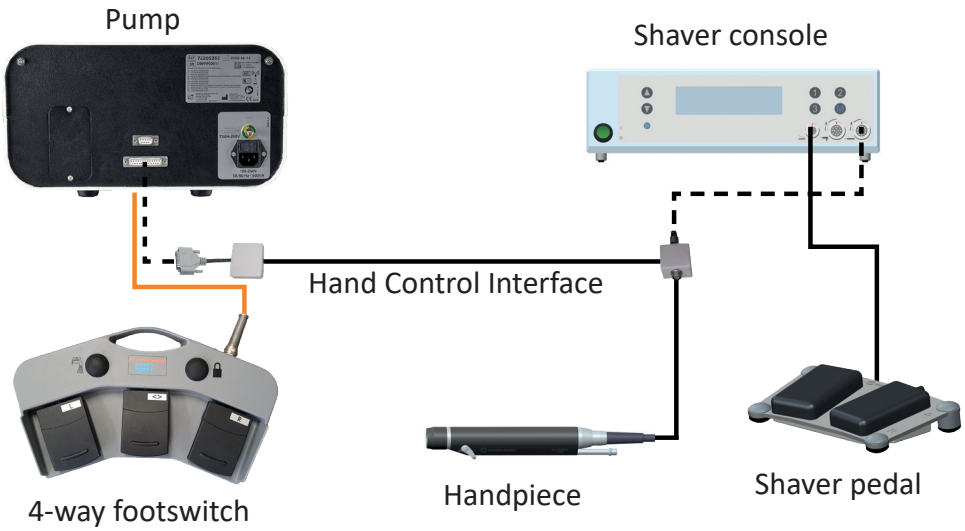
- Connect the 25 pin connector of the S+N Pump / Shaver Interface Cable cable to the dedicated connector at the back (22) of the pump.
- Connect the 9 pin connector of the S+N Pump / Shaver Interface Cable cable to the dedicated connector at the back of the DYONICS POWER II shaver console.

Compatibilities associated to the S+N Pump / Shaver Interface Cable						
Manufacturer	Shaver console		Handpiece		Footswitch of the shaver console	
	Item	Reference	Item	Reference	Item	Reference
SMITH+NEPHEW/ DYONICS	POWER II Control System	72200873	POWERMINI	72201503	DYONICS POWER II Footswitch	72201092
			POWERMAX	7210542		
			POWERMAX ELITE	72200617		

NOTE : When using the S+N Interface Cable, all functions of the DOUBLEFLO footswitch can be activated by the DYONICS POWER II footswitch. The DOUBLEFLO footswitch becomes optional.

EN

B- HCI compatible with CONMED, ARTHREX and STRYKER shaver consoles



INSTRUCTIONS FOR USE

This style of interface is used for Hand Control Interface CMD.

This style of interface is used for Hand Control Interface ARTX and Hand Control Interface SYK.

The Hand Control Interface CMD, Hand Control Interface ARTX and Hand Control Interface SYK are compatible with following shaver systems:

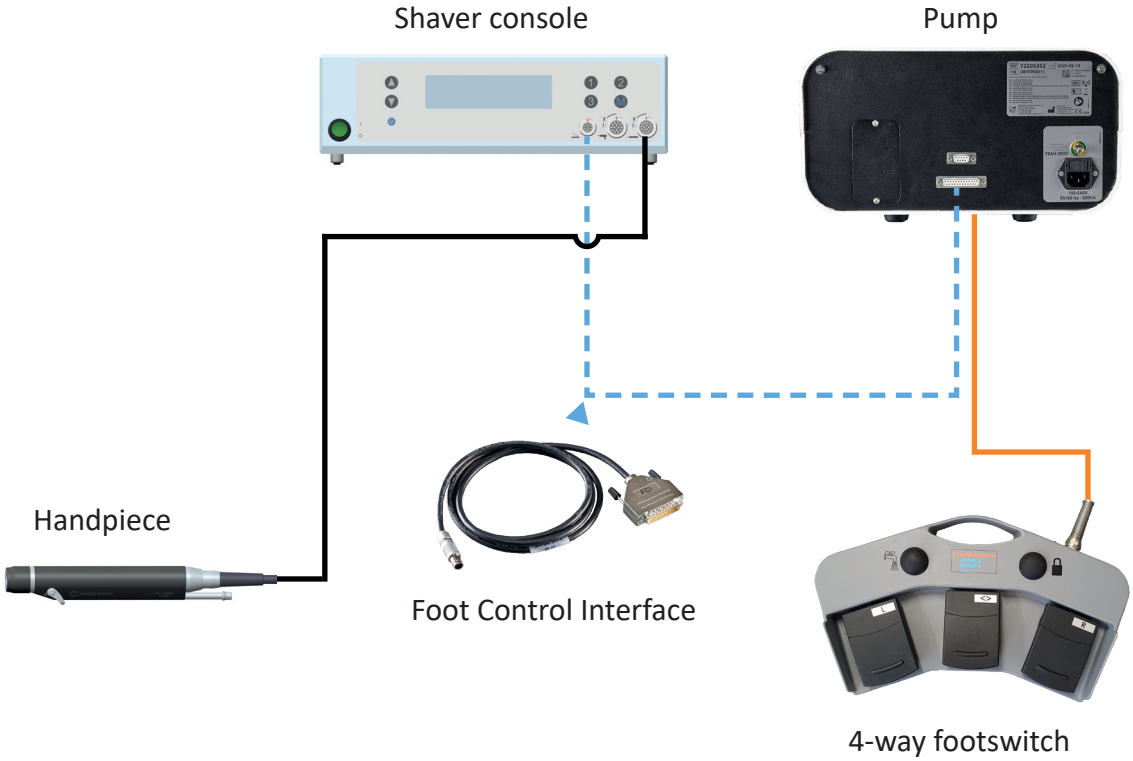
Designation of HCI	Manufacturer	Shaver console		Handpiece	
		Item	Reference	Item	Reference
Hand Control Interface CMD	CONMED/LINVATEC	D4000	D4000	Advantage Turbo	D9924
		D4000A	D4000A		
Hand Control Interface ARTX	ARTHREX	SYNERGY	AR-8305	APS II	AR-8325H, AR-8325F, AR-8330H
Hand Control Interface SYK	STRYKER	CROSSFIRE II	475100000	FORMULA 180	375-708-500
				FORMULA SHAVER HANDPIECE	375-701-500, 375-704-500

EN

4.6 Connecting the Foot Control Interfaces (FCI)

PRECAUTIONS

Before plugging and unplugging the FCI, turn off both electromedical devices. Prior to use, inspect the product and do not use if damaged.
Check the FCI connectors and ensure that cleaned cable connectors are completely dry prior to connecting the electromedical devices.
Do not disconnect the Foot Control Interface during the operation.
Make sure the 25 pin connector is tight during connection.



INSTRUCTIONS FOR USE

- Connect fully the Foot Control Interface cable into the connector FCI of the pump 14
- Then, from the pump, connect the FCI cable into the foot connector of the adapted shaver console F

EN

A- Foot control interface CONMED shaver consoles

The Foot Control Interface CMD is used during arthroscopy procedure to activate a **CONMED** handpiece of a **CONMED** shaver console by using the 4-way footswitch connected to the pump. This FCI is compatible with the following shaver systems:

Manufacturer	Shaver console		Footswitch of the shaver console	
	Item	Reference	Item	Reference
CONMED/LINVATEC	D4000	D4000	3 Pedal Footswitch	C9863
			MicroChoice Footswitch	5020-053
	D4000A	D4000A	3 Pedal Footswitch	C9863
			MicroChoice Footswitch	5020-053

It is recommended before using the foot control interface to read the instructions of the **CONMED** shaver console user manual for the warnings and precautions associated with those devices.

When using the **CONMED** shaver console, the activation of the pump and handpiece can be made from the 4-way footswitch connected to the pump.

INSTRUCTIONS FOR USE

Before each operating mode **(FOWARD/REVERSE/OSCILLATION)**, verify outside the joint that the system is functioning properly before using it.

CHOOSING THE MODE:

Press momentarily the **REVERSE** 25 control from the 4-way footswitch to choose rotation mode (FORWARD/REVERSE/OSCILLATION) on **CONMED** shaver console.

ACTIVATING THE MODE:

Press and keep pressed the **FORWARD** 27 control from the 4-way footswitch to activate the handpiece

B- Foot control interface for ARTHREX shaver console

The Foot Control Interface ARTX is used during arthroscopy procedure to activate an **ARTHREX** handpiece of an **ARTHREX** shaver console by using the 4-way footswitch connected to the pump. This FCI is compatible with following shaver system:

Manufacturer	Shaver console		Footswitch of the shaver console	
	Item	Reference	Item	Reference
ARTHREX	SYNERGY	AR-8305	APS II Footswitch, Standard	AR-8310

It is recommended before using the foot control interface to read the instructions of the **ARTHREX** shaver console user manual for the warnings and precautions associated with those devices.

When using the **ARTHREX** shaver console, the activation of the pump and handpiece can be made from the 4-way footswitch connected to the pump.

INSTRUCTIONS FOR USE

Before each operating mode **(FOWARD/REVERSE/OSCILLATION)**, verify outside the joint that the system is functioning properly before using it.

FORWARD MODE:

Press and keep pressed the **FORWARD** 27 control from the 4-way footswitch to activate the handpiece in **FORWARD** mode.

REVERSE MODE:

Press and keep pressed the **REVERSE** 25 control from the 4-way footswitch to activate the handpiece in **REVERSE** mode.

OSCILLATION MODE:

Press and keep pressed the **OSCILLATE** 26 control from the 4-way footswitch to activate the handpiece in the **OSCILLATION** mode.

EN

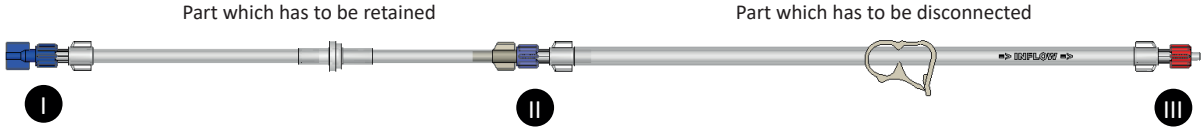
5.1 During the operating day: after surgery

A- Day Tube Set

Leave the Day Tube Set in place when another operation is scheduled on the same day

B- Patient Tube Set disconnection

Flush the irrigation system after each patient procedure prior to disconnection
After flush, switch off the fluid management by pressing on the “START/STOP” button 8 or 33.



The circulating nurse:

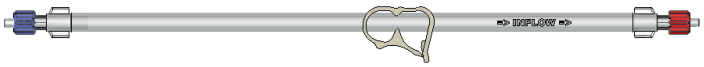
- Close the opened clamp of the Day Tube Set

The scrub nurse:

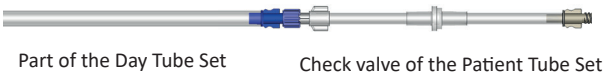
- Close the clamp of the Patient Tube Set
- Disconnect the red “Luer Lock” III from the Patient Tube Set to the arthroscopy sheath / cannula

The circulating nurse:

- Leave in place the “Luer Lock” connected to the Day Tube Set I, disconnect the blue “Luer Lock” under the check valve II and discard this tubing (part of the Patient Tube Set)



The check valve will remain connected to the Day Tube Set until the next arthroscopic case.



C- Inflow Tube Set disconnection

The scrub nurse:

- Disconnect the tubing from the arthroscopy sheath / cannula

The circulating nurse:

- Close the all clamps of the tubing
- Remove the spikes from the saline solution bags
- Disconnect the blue connector from the bracket with blue indicator of the irrigation side (right opening) 3

Do not remove the blue connector with pressure inside
Do not touch the blue connector while removing the tubing
Pull on the tubing to remove the blue connector

- Disconnect the white connector from the black bracket of the irrigation side (left opening)
- Dispose the irrigation tubing in a dedicated site

D- Outflow Tube Set disconnection

The circulating nurse:

Switch on the fluid management by pressing on the **"START/STOP"** button 8 or 33

The scrub nurse:

- Press and keep pressed the **"LAVAGE/RINSE"** control of the footswitch 25 in order to drain the joint and the suction tubing on the cannula side
- Press and keep pressed the **FORWARD** 27 or **REVERSE** 25 or **OSCILLATE** 26 control in order to drain the shaver tube
- Disconnect the cannula and the shaver handpiece from the suction tubing

The circulating nurse:

- Disconnect the white connector from the black bracket of the suction side (right opening)
- Remove the "outflow cannula" and "shaver" tubes from the "Pinch Valve"
- Disconnect the orange connector from the bracket with orange indicator of the suction side (left opening)
- Dispose of the suction tubing in a dedicated site

5.2 Connection of a new Patient Tube Set for the next operation

The circulating nurse:

- Use an aseptic method
- Disconnect the blue "Luer Lock" to the Day Tube Set I and dispose of the tube with check valve in a dedicated site

Must take off gloves and wear new ones before connecting the new Patient Tube Set.

- Refer to the chapter 4.2 part B for the connection between the Patient Tube Set and the Day Tube Set

The scrub nurse:

- Refer to the chapter 4.2 part B

The circulating nurse:

- Refer to the chapter 4.2 part B to purge of air the irrigation tubing

5.3 End of operating day

- Remove all tubing (refer to the chapter 5.1 except for the Day Tube Set)
- Remove the Day Tube Set (refer to the chapter 5.1 part C: steps performed by the circulating nurse in chapter 5.1 part C)
- Remove all accessories
- Switch off the fluid management by pressing the **"START/STOP"** button 8 or 33
- Switch off the pump by pushing the "**POWER**" button 13
- Clean the devices (pump and accessories) after each day of use (refer to the Chapter 7.1)

EN

6.1 Starting the pump

Press the "**POWER**" button 13 to switch on the pump.

You must set up all tubing (irrigation and suction part) before launching the fluid management with the "**START/STOP**" button 8 or 33.

6.2 Pressure setting adjustment

A- Adjustment

Press once on the pressure adjustment buttons (+ or -) 5 6 or 28 29 to adjust pressure setting. The pressure is viewable on the LCD screen of the pump 7.
The preset pressure is 50 mmHg.
It is recommended to start the operation with the lowest possible pressure setting, so as to obtain the desired expansion in the joint. The intra-articular pressure can then be increased.

Reminder:

- Press the + or - buttons allows to increase or decrease the pressure setting by increments/ decrements of 5 mmHg. Minimum level: 20 mmHg / Maximum level: 150 mmHg

B- Adjustment of Cannula and Shaver flow rates

Three cannula suction levels (LOW, MED, HIGH) can be set on the Pump. Press on the "**RINSE SUCTION**" 9 or 31 button to adjust the cannula suction flow rate. Three Shaver suction levels (LOW, MED, HIGH) can be set on the Pump. Press on the "**SHAVER SUCTION**" 10 or 30 button to adjust the shaver suction flow rate.

C- Recommended pressure and flow rate level

Joint	Pressure setting with tourniquet	Pressure setting without tourniquet	RINSE SUCTION	SHAVER SUCTION
	mmHg	mmHg	/	/
Shoulder joint	/	60	Low or Med	Low or Med
Acromioplasty	/	60	Low or Med	Med or High
Knee scope	30 50-60	65 50-60	Low or Med Low or Med	Low or Med Med or High
Wrist	30	65	Low or Med	Low or Med
Elbow, ankle	40	65	Low or Med	Low or Med
Hip	/	65	Low or Med	Low or Med

D- Errors

When an error is detected, the error indicator light illuminates and the error code flashes on the LCD screen. When the error indicator lights up without an error code on the pump screen, this means that there is an overpressure, this is why the fluid management automatically switches to STOP (and restart automatically).
Refer to part 2.6.

6.3 LAVAGE mode

The **“LAVAGE”** mode is used to limit bleeding when the visualization is hampered by blood or debris. Press momentarily the “**LAVAGE/RINSE**” control 24 from the footswitch to activate **“LAVAGE”** mode. The “**LAVAGE**” indicator light on the pump 11 remains illuminated throughout the LAVAGE cycle. The pressure increases to 50% from the pressure setting for 60 seconds. Press again momentarily the “**LAVAGE/RINSE**” control 24 from the footswitch to deactivate the **“LAVAGE”** mode.

6.4 RINSE mode

The “**RINSE**” mode is used to activate the suction through the cannula at the flow rate selected by the user (LOW, MED or HIGH). Press and keep pressed the “**LAVAGE/RINSE**” control 24 from the footswitch to activate “**RINSE**” mode. Release the “**LAVAGE/RINSE**” control 24 from the footswitch to deactivate the “**RINSE**” mode.

6.5 Using the equipotential terminal

The equipotential terminal allows connection of the pump to another device via a connecting cable in order to equalize the potentials and avoid any risk to the patient in case of a fault in the electrical installations. The connecting cable is not supplied.

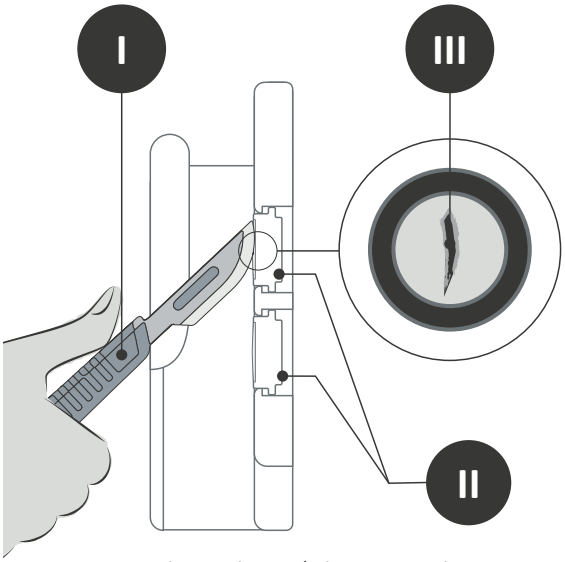
EN

7.1 Cleaning

Switch off the pump (**"POWER"** button 13) at the end of a operating day. To avoid electric shock, disconnect the power supply before cleaning the pump. Disconnect each accessory from the pump and remove the used tubing. Clean all the surfaces of the pump using a cloth moistened with a neutral pH detergent. Wipe the device afterwards with a cloth soaked in distilled water. If needed, dry the equipment with lint free cloth to remove any access water. Clean all the surfaces of accessories with a neutral pH detergent.

- Avoid any contacts with the white silicone membranes
- If cleaning the white silicone membranes (e.g: blood, moisture, etc.) is required, clean this area with high precaution to avoid damage to the white silicone membranes
- Do not use abrasive tools or sharp objects (like knives, scalpels,...) to avoid to tear the white silicone membranes

Precautions during the cleaning of the retaining bracket for the irrigation tubing



I. Sharp object / abrasive tool
II. White silicone membranes
III. Torned white silicone membrane

- Do not immerse the pump, the interfaces and the electrical connectors of the footswitch during cleaning
- Observe the cleaning procedures
- Do not autoclave the pump and its accessories
- Do not fold the footswitch cable and interface when stowing away
- The electrical connections must remain dry
- Do not fold the mains cable during storage
- Do not clean the pump and its accessories with abrasive cleaning or disinfectant compounds, solvents, or other materials that could scratch or damage the device
- Always comply with the instructions issued by the manucfacturer of cleaning disinfectant regarding concentration, exposure times, temperature, and material compatibility
- If there is dust or moisture on the receptacles, remove with dry compressed air

EN

8.1 Legal manufacturer

HEMODIA SAS
85 rue du Chêne vert
31670 Labège - France
+44 20 34 45 51 79

First affixing of the CE marking: January, 2021

8.2 Warranty

The warranty period for the pump is 18 months. Within this period, errors resulting from faulty material and/or inadequate workmanship will be remedied by the manufacturer free of charge. The pump shelf life is 18 months and tubing expiration date is 3 years.

The manufacturer is not liable for direct or consequential damages, and the warranty becomes null and void if:

- the device and/or the accessories are improperly used, prepared, or maintained;
- the instructions and rules in the instructions for use are not adhered to;
- unauthorized persons perform repairs, adjustments, or alterations on the device or accessories;
- unauthorized persons open the device;
- the prescribed inspection and maintenance schedule is not adhered to.

Only certified service providers are allowed to perform repairs or alterations to the device or accessories.

EN

9.1 Physical dimensions (pump)

Dimensions
Height: 7.7 in (195 mm)
Width: 13.2 in (336 mm)
Depth: 14.5 in (367mm)
Weight: 28.7 lbs (12,8 kg)

9.2 Storage conditions (pump and accessories)

Temperature range: from 14°F to 113°F (-10°C to +45°C)
Relative humidity range: between 35% and 90%

9.3 Operating conditions (pump and accessories)

Temperature range: 50°F to 95°F (10 °C to 35 °C)
Relative humidity range: between 35% and 75%
Atmospheric pressure range: 600 hPa to 1060 hPa (450 mmHg to 795 mmHg)

9.4 Performance specifications (pump)

Pressure setting
Preset: 50 mmHg
Minimum: 20 mmHg
Maximum: 150 mmHg
Step: 5 by 5 mmHg

Inflow rate
Minimum: 0 mL/min
Maximum: 1100 mL/min ± 100 mL/min

Cannula flow rate
Default (Resting): 100 mL/min ± 20 mL/min
Low: 200 mL/min ± 40 mL/min
Med: 400 mL/min ± 40 mL/min
High: 600 mL/min ± 60 mL/min

Shaver flow rate
Low: 200 mL/min ± 40 mL/min
Med: 500 mL/min ± 50 mL/min
High: 800 mL/min ± 80 mL/min

Suction levels
Default RINSE SUCTION: LOW
Default SHAVER SUCTION: LOW

Software security
The software security is activated if the sensor pressure is greater than 250 ± 10 mmHg for at least 2 seconds.

Hardware security
The hardware security is activated if the sensor pressure is greater than 280 ± 10 mmHg (opening of the motor power circuit via safety relay).

9.5 EMC compliance matrix

Electromagnetic immunity - Enclosure port, AC input power port, DC input power port, patient coupling port and input/output signal ports
Professional healthcare facility environment

The DOUBLEFLO pump is designed for use in the electromagnetic environment specified below. The client or user of the DOUBLEFLO pump should ensure that it is used in such an environment.

Basic EMC phenomenon/ standard or test method	Test levels	Compliance level	Type of port
Electrostatic discharges (ESD)/IEC 61000-4-2	± 8 kV → contact ± 2 kV, ± 4 kV, ± 6 kV, ± 8 kV, ± 15 kV → air	Indirect ± 8 kV (vertical) Indirect ± 8 kV (horizontal) Direct ± 8 kV Air ± 2 kV Air ± 4 kV Air ± 8 kV Air ± 15 kV	- Enclosure port - Patient coupling port - Input/output signal ports
Radiated RF electromagnetic fields/ IEC 61000-4-3	3 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz	80 MHz - 1 GHz → 3 V/m (80% AM, 1kHz) on 4 sides in vertical and horizontal polarity 1 GHz - 2.7 GHz → 3 V/m (80% AM, 1kHz) on 4 sides in vertical and horizontal polarity	- Enclosure port
Proximity fields emitted by wireless RF communication devices/ IEC 61000-4-3	9 V/m 704 MHz - 787 MHz and 5.1 GHz - 5.8 GHz PM ext. 217 Hz 27 V/m 380 MHz - 390 MHz PM ext. 18 Hz 28 V/m 430 MHz - 470 MHz FM deviation +5 kHz sinus. 1 kHz 28 V/m 800 MHz - 960 MHz PM ext. 18 Hz 28 V/m 1.7 GHz - 1.99 GHz and 2.4 GHz - 2.57 GHz PM ext. 217 Hz	9 V/m 710 MHz, 745 MHz, 780 MHz and 5,24 GHz, 5,5 GHz, 5,785 GHz 27 V/m 385 MHz 28 V/m 450 MHz 28 V/m 810 MHz, 870 MHz, 930 MHz 28 V/m 1,72 GHz, 1,845 GHz, 1,97 GHz and 2,45 GHz	- Enclosure port
Surges between phase and neutral/IEC 61000-4-5	± 0.5 kV, ± 1 kV	AC power supply with dephasing of 0°, 90°, 180°, 270° ± 0.5 kV (level 2) ± 1 kV (level 3)	- AC input power port - DC input power port

EN

Electromagnetic immunity - Enclosure port, AC input power port, DC input power port, patient coupling port and input/output signal ports Professional healthcare facility enviro			
The DOUBLEFLO pump is designed for use in the electromagnetic environment specified below. The client or user of the DOUBLEFLO pump should ensure that it is used in such an environment.			
Basic EMC phenomenon/ standard or test method	**Test levels**	**Compliance level**	**Type of port**
Surges between phase and earth and then between neutral and earth/IEC 61000-4-5	± 0.5 kV, ± 1 kV, ± 2 kV	AC power supply with dephasing of 0°, 90°, 180°, 270° ± 0.5 kV (level 1) ± 1 kV (level 2) ± 2 kV (level 3)	- AC input power port - DC input power port - Input/output signal ports
Conducted disturbances, induced by RF fields/IEC 61000-4-6	3 V 0.15 MHz - 80 MHz 6 V in ISM bands and bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	AC power supply 230Vac/50Hz Pedal cable (Pedal side) Pedal cable (Pump side) 3V on the band between 0.15 MHz and 80 MHz 6V on the frequency bands: 6.765 MHz - 6.795 MHz; 13.553 MHz - 13.567 MHz; 26.957 MHz - 27.283 MHz; 40.66 MHz - 40.70 MHz.	- AC input power port - DC input power port - Input/output signal ports - Patient coupling port
Magnetic fields at the designated industrial frequency/IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	Applicable Pedal sensors sensitive to magnetic fields	- Enclosure port
Voltage dips/IEC 61000-4-11	0% UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1 single-phase cycle: at 0° 70% UT; 25/30 single-phase cycle: at 0°	AC power supply at: - 0% UT (0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°) for 10 ms - 0% UT (0°) for 20 ms - 70% UT (0°) for 500 ms	- AC input power port
Voltage interruptions/IEC 61000-4-11	0 % UT; 250/300 cycle	AC power supply at 0% UT (0°) for 5 sec.	- AC input power port
Transient electrical disturbances by conduction along supply lines only/ISO 7637-2	Not applicable	Not applicable	- DC input power port

Electromagnetic emission Professional healthcare facility environment		
The DOUBLEFLO pump is designed for use in the electromagnetic environment specified below. The client or user of the DOUBLEFLO pump should ensure that it is used in such an environment.		
Phenomenon	**Basic standard**	**Compliance level**
Conducted and RF radiated voltage emissions	CISPR 11	Conducted emissions - Power supply 230Vac/50Hz (Phase and neutral between 150 kHz and 30 MHz) 100Vac/50Hz (Phase and neutral between 150 kHz and 30 MHz) 100Vac/60Hz (Phase and neutral between 150 kHz and 30 MHz) 220vac/50Hz (Phase and neutral between 150 kHz and 30 MHz) 220Vac/60Hz (Phase and neutral between 150 kHz and 30 MHz) 120Vac/60Hz (Phase and neutral between 150 kHz and 30 MHz) RF radiated voltage emissions (vertical and horizontal polarities; frequency between 30 MHz and 1 GHz) Measurement performed at 360° Group 1 Class A
Harmonic distortion	IEC 61000-3-2	AC power supply Class A
Voltage fluctuation and flicker	IEC 61000-3-3	AC power supply

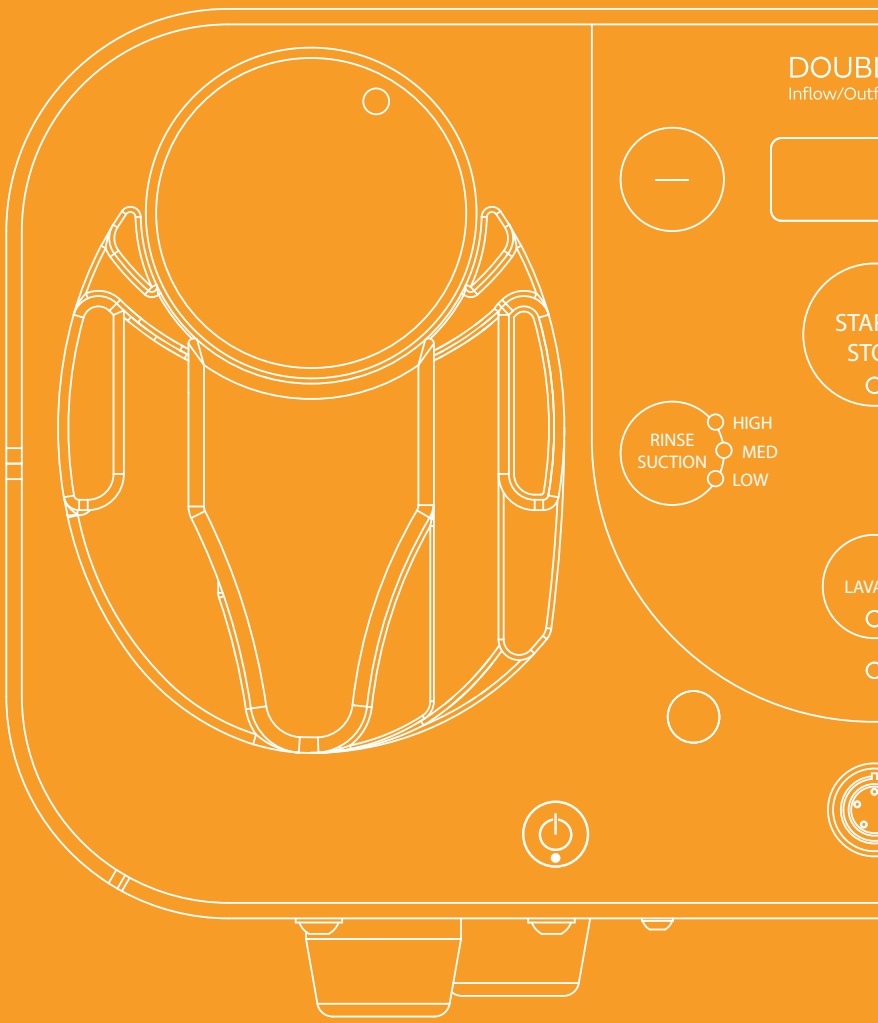
The essential performance of the DOUBLEFLO pump is to control the intra-articular pressure until 300 mmHg regardless of the outflow, in order to avoid overpressure superior to 300 mmHg in the patient's joint.

EN

PUMP AND ACCESSORIES	
Product ref.	Designation
72205352	PUMP
72205357	FOOTSWITCH - WIRED
72205359	REMOTE
72205360	SMITH + NEPHEW PUMP/SHAVER INTERFACE CABLE
72205361	HAND CONTROL INTERFACE ARTX
72205362	FOOT CONTROL INTERFACE ARTX
72205363	HAND CONTROL INTERFACE SYK
72205364	HAND CONTROL INTERFACE CMD
72205365	FOOT CONTROL INTERFACE CMD

TUBES SETS	
Product ref.	Designation
72205353	DAY TUBE SET
72205354	PATIENT TUBE SET
72205355	INFLOW TUBE SET
72205356	OUTFLOW TUBE SET

POWER CORDS	
Product ref.	Designation
104270	POWER CORD FOR US
103822	POWER CORD FOR UK
103373	POWER CORD FOR EU
104383	POWER CORD FOR ANZ
104380	POWER CORD FOR JAPAN
103899	POWER CORD FOR SWITZERLAND
103773	POWER CORD FOR SOUTH AFRICA
103773	POWER CORD FOR BRAZIL
103773	POWER CORD FOR CHILE
104384	POWER CORD FOR CHINA
103822	POWER CORD FOR MALAYSIA
104381	POWER CORD FOR INDIA



DOUBLEFLO

Inflow/Outflow Pump