joimax®
Endoscopic Spine Experts

Versicon®

Versatile Irrigation Control

User Manual

Irrigation pump for endoscopic spinal surgery and arthroscopy

Table of Content

1 Legal Notes

The manufacturer is grateful for information about any errors or inconsistencies in this document.

Due to continuous improvement of our products, we reserve the right to make technical changes that do not affect functionality and basic safety.

1.1 Liability

All procedures, notes and warnings described in this manual do not release the operator/user from his or her responsibilities regarding clinical judgment, experience and best clinical practice.

2 General Description

The joimax® Versicon® is a multi-range irrigation pump system, which was developed for use in minimally invasive spine surgery and arthroscopy. The pressure and flow range can be set to the requirements of the two methods. This enables irrigation for optimal endoscopic view without exposing the patient to the risk of excessive fluid pressure.

2.1 Clinical Benefits

Endoscopic spinal surgery and arthroscopy clearly profits from an irrigation system in terms of the following clinical benefits:

- Prevention of a collapse of the operation cavity with overpressure
- Constant irrigation of the operation cavity and reduction of infection risks
- Constant clear endoscopic view and reduction of surgical errors due to removal of loose particles and blood
- Constant cooling of the light emitting surface at the endoscope tip
- Constant cooling of the operation area during RF surgery
- Provision of conductive or non-conductive fluid for RF surgery

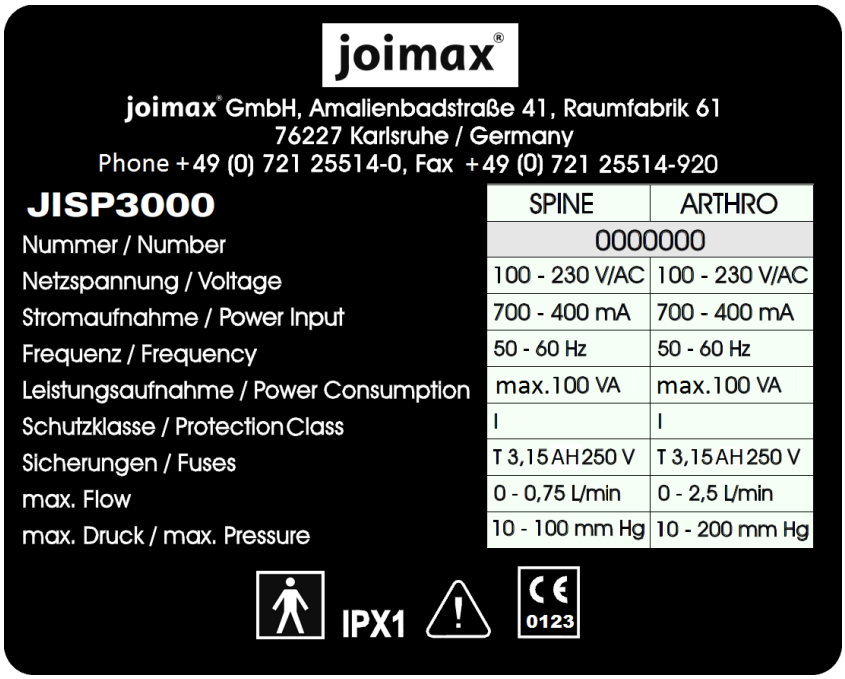
3 Signs and Symbols

3.1 Symbols on the Device and the Packaging

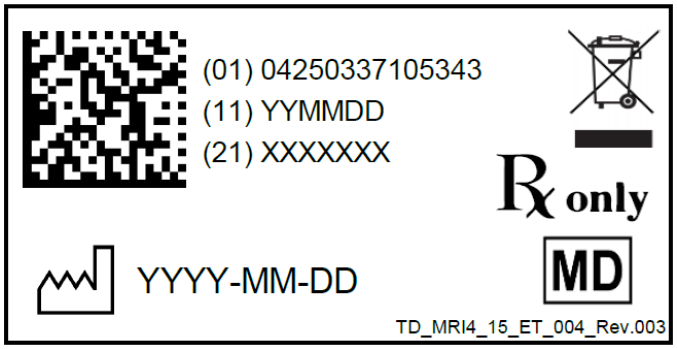
	Please note!
	Warning!
	Separate collection of electrical and electronic devices (in accordance with directive 2012/19/EU, WEEE)
	Applied part type BF
	CE mark of the manufacturer according to MDD 93/42/EEC
	Manufacturer
	Date of manufacture
	Follow Instructions for Use
REF	Item number
SN	Serial number
℞ only	Caution: U.S. federal law restricts this device to sale by or on the order of a physician.
IPX1	Ingress protection class according to IEC 60529 (protected against vertically falling water drops)
	Equipotential (potential equalization)
	Protective earth
	Warning; Electricity
	Foot switch connector
	Temperature limitiation
	Humidity limitation
	Atmospheric pressure limitation
	Keep away from rain

	Keep away from sunlight
	Medical Device

3.2 Device Label



Additional Label



4 Intended Purpose and Characteristics

Warning:
The device must be used only for its intended purpose described in this manual!

4.1 Intended Purpose

The joimax® Versicon® Irrigation Pump was developed for surgical use in endoscopic spinal surgery and arthroscopy. During the intended use a cavity is rinsed with sterile physiological infusion solution, in order to provide adequate visibility conditions during the endoscopic surgery.

Indications for Use

The device is designed to be used in combination with endoscopes in minimally invasive spine surgery and arthroscopy.

Contraindications

Use of the device is contraindicated if, in the opinion of an experienced physician or according to current professional literature, the use would endanger the patient, e.g. due to the general condition of the patient, or if any other contraindications exist.

Intended Patient Population

The Versicon® is intended to be used on adult patients of all genders with appropriate indications (except pregnant women). The use of the Versicon® is at the discretion of the respective user on the basis of his training and experience.

Intended Users

The Versicon® is designed for use by medical professionals (e.g. surgeons).
It must be operated under the supervision of qualified and authorized personnel. Users are required to be trained and familiar with the basic principles, application rules, and risks of the device in order to reliably avoid a risk to the patient, user, and others.

Intended Use Environment

The Versicon® is designed for use in operating rooms.
The control unit is positioned stationary outside of the patient environment, e.g. on a medical cart or table that is suitable in terms of tilting stability and weight of the device.

4.2 Characteristics

Performance Characteristics

The Versicon® provides two operating modes with adjustable irrigation flow from 0 to 750 ml/min in spine mode and 0 – 2500 ml/min in arthroscopy mode. Maximum fluid pressure is 100 mmHg and respectively 200 mmHg. Pressure accuracy is given at ± 5 % of the set value. Pressure is measured by two independent pressure sensors for high reliability and self control.

Principles of Operation

A pumping element employs the principle of a peristaltic roller wheel. A silicone tubing is stretched in a semi-circle around the roller wheel which in return regulates the flow of the saline solution inside the tubing as a function of the rotational frequency. Pump output is regulated to achieve a pressure in the cavity. The pressure in the tubing system is measured by two sensors (redundancy), which are located in the pressure measuring chamber. The applied pressure is compensated about the hydrostatic pressure, which depend on the vertical height difference between sensor and surgical cavity. For the static system (pump output = 0), the corrected pressure will be taken into account to derive the

cavity-pressure. While the roller wheel is rotating, a compensation is done about the value of the back pressure, in subject to the current pump output.

Key Components

Control Unit

The control unit contains the pump wheel with motor and motor control. It features a front with several buttons and displays for setting the desired fluid flow and pressure and display the current values. The device can be operated with AC line voltages of 100-230 V and a frequency of 50/60 Hz.

5 Scope of Delivery

After delivery of the joimax® Versicon® Irrigation Pump, the packaging must be checked for external damage. If any components are damaged or missing, please contact joimax® customer service.

Item number	Item description
JISP3000	joimax® Versicon® Spine Pump (including 1x Sensor Protection, 2x replacement fuses 2x T 3,15 AH 250 V, 2x Instructions for Use, 1x Device Quick Info)

6 Safety and Warning Notes

6.1 General Safety and Warning Notes

Warning:
This device must be used by trained professionals only!

Warning:
Installation of the device on a medical trolley with multiple socket-outlet leads to the establishment of a ME system and can lead to a reduced level of safety. The requirements regarding ME systems of IEC 60601-1 must always be observed.

Warning:
The device is not intended for use in explosive areas (e.g. in the presence of anaesthetic gas).

Warning:
Keep these instructions for use in a conspicuous place near the device!

Warning:
Read this manual carefully before first use. Protect yourself, patients, and third parties from damage by defective devices or improper operation!

Warning:
Mechanical stress, such as from falling, can damage or destroy the device!

Warning:
Never use the device with the housing open.

Warning:
Always make sure blood circulation is not impaired when positioning and sedating the patient.

The arthroscopy mode is currently not available for the U.S.

The type of rinsing fluid must be selected in accordance with the surgical procedure (e.g. saline solution for bipolar RF surgery).

6.2 Additional Notes regarding Electrosurgical Equipment

Warning:
If the device is used stacked in combination with electrosurgical devices, always position the device above the electrosurgical unit. Ensure that cables of active electrosurgical accessories are not positioned close to the control unit.

6.3 Additional Notes regarding MRI (Magnetic Resonance Imaging) and CT (Computer Tomography)

Warning:
Do not use the Versicon® during MRI or CT scans.
Due to energetic interactions of magnetic fields and X-rays with the material of the control unit, the electrical components of the Versicon® may be damaged. Unforeseeable side effects and visual disturbances may occur.

6.4 Residual Risks and Side -Effects

When using the product, residual risks exist and may lead to the following side effects for patient, user or third parties: transfer of pathogens, an abortion of the surgery or change of the technique.

7 Installation and Commissioning

Warning:
Examine the device, the accessories, and all electrical connections for function and damage prior to use! Defects in cables, connectors, housings or loose parts can impair performance and safety and must be rectified immediately!

Warning:
This device must be installed and commissioned by authorized personnel only. Improper installation could cause damage to the user, the patient, or others, and might damage the device or other medical equipment.

Warning:
Place the device in a way that allows easy disconnection from the mains.

Warning:
The ambient temperature must not exceed 35° C (95° F) during operation.

Warning:
Place the control unit on a clean, flat surface. Ensure that you keep sufficient space behind the device for efficient airflow. Make sure that a minimum distance of 15 cm (6”) is maintained between the back of the device and other objects. All ventilation openings must not be obstructed.

The device is recommended to be installed in the joimax® endoscopic trolley.

Keep the original packaging for possible shipment of the device!

The device and all accessories must be checked immediately upon receipt for completeness and obvious damage. Damages may be claimed only if the manufacturer is notified immediately (within a 24-hour period).

7.1 Connection of the Device

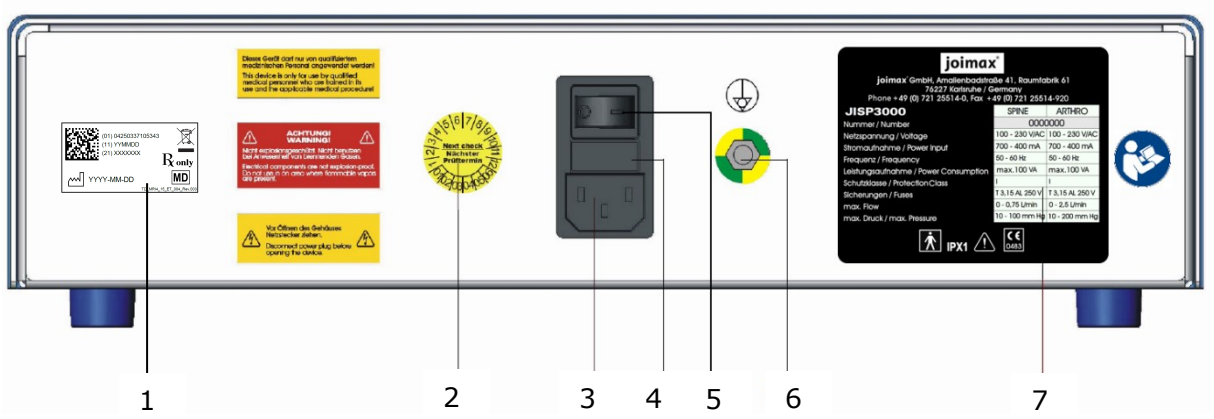
Warning:
To avoid the risk of electric shock, this equipment must always be connected to potential equalization and a power supply with protective earth!

Warning:
Only joimax® accessories (cables etc.) may be used for connection!

Warning:
Always keep cables out of passage areas in order to reduce the risk of stumbling.

Warning:
Before connecting and launching the system, all components must be visually inspected for integrity. Damaged parts must be replaced. This must be done by experts.

Rear Panel



1.	Additional label	5.	Power switch
2.	Service sticker	6.	Potential equalization connector
3.	Mains connection	7.	Device label
4.	Fuse holder		

Connecting the Control Unit to a Power Supply Network and Potential Equalization

Warning:
The device must always be connected to potential equalization and a supply network with protective earth.

Warning:
Always connect the device to a buffered power supply and make sure that the nominal voltage and power values are respected.
Check the power supply cable prior to use!

Respect the requirements of section 8.6.7 of IEC 60601-1 regarding medical electrical systems.

1. Switch off the power switch on the rear of the control unit (position "0").
2. Connect the potential equalization plug at the back of the control unit to grounding.
3. Connect the power inlet at the back of the control unit to a power outlet.
4. Set the power switch to position "I".

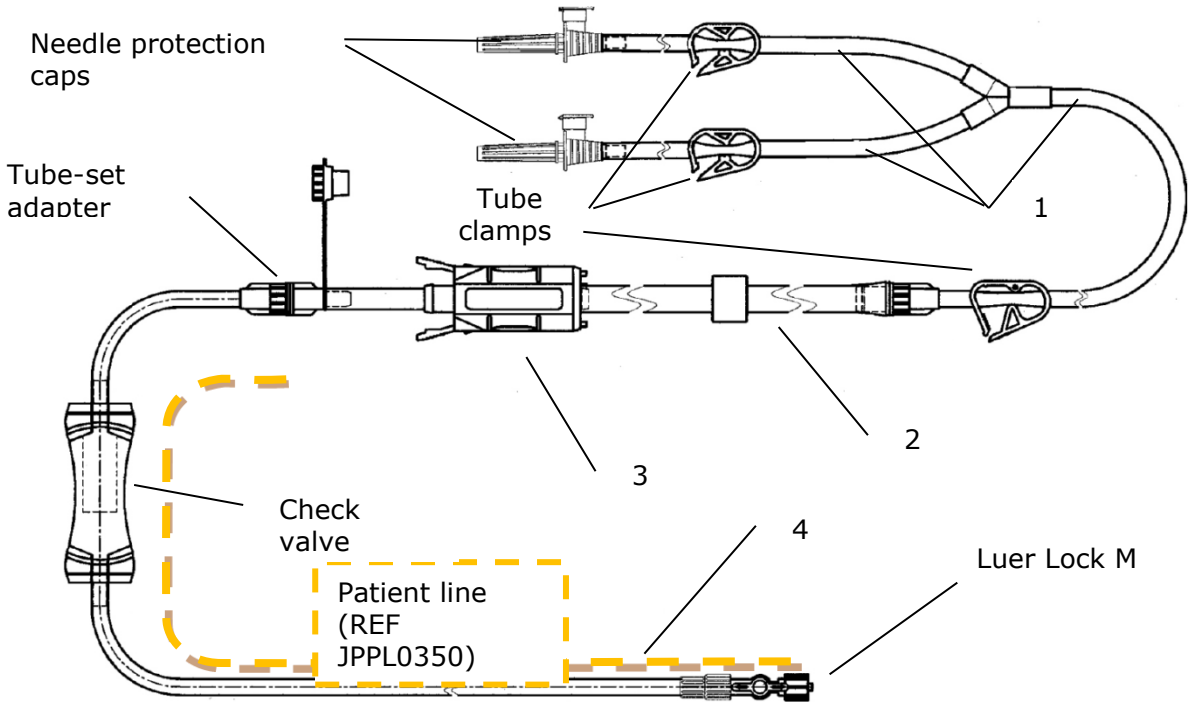
Connecting the Foot Switch

Optional: Connect the foot switch to the FLUSH CONTROL connection at the front of the control unit.

Only connect the foot switch after successful self-testing.

7.2 Insertion of the single-use tubing set

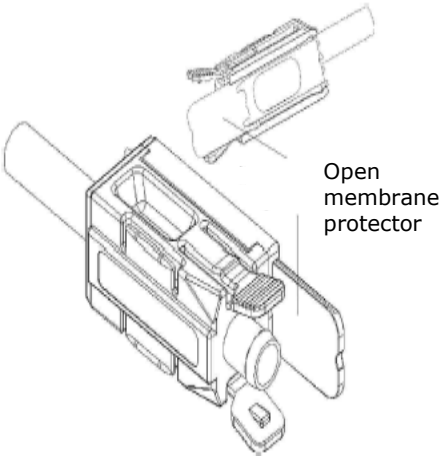
joimax® Single-use Tubing Set



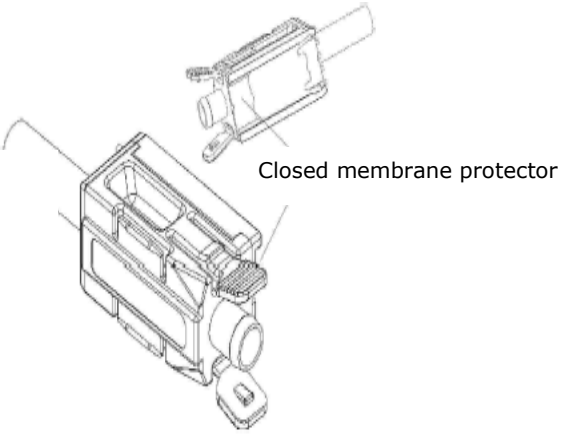
1	Supply tube with connection for reservoir to sterile infusion solution
2	Pump segment with tube stopper
3	Pressure metering chamber
4	Patient-sided tube section with LL M connection for instrument (length 3.5m / 137.8 in)

Pressure metering chamber with membrane protector

The pressure metering chamber has been provided with a membrane protector in order to prevent damage to the sensor's membrane, during transport, storage or handling.
The membrane protector opens and closes automatically when the pressure metering chamber is inserted or removed.



In open condition - Membrane protector opens when the pressure metering chamber is inserted into the metering chamber guide

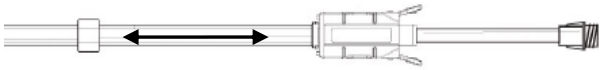


In closed condition - Membrane protector before and after removal of the pressure metering chamber from the metering chamber guide.

Warning:
Do not touch the pressure sensors in the tube bracket with the metering chamber guide! Keep sharp or pointy objects away from the pressure sensors, as these may damage the pressure sensors.

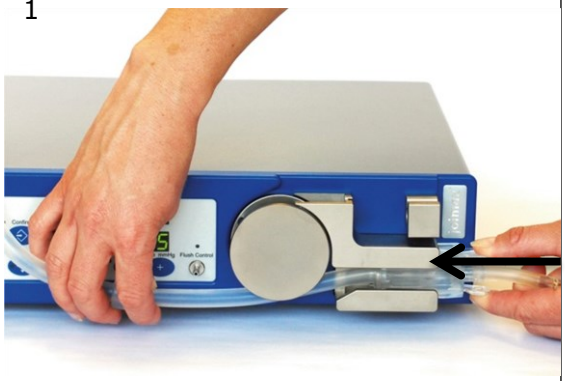
Warning:
The check valve of the tubing set must not be compressed when handling it.

Before inserting the tubing set stretch the flexible part a few times.



Only insert the tubing set after successful self-testing.

1



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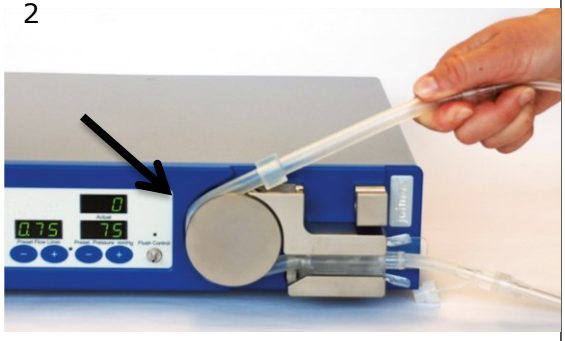

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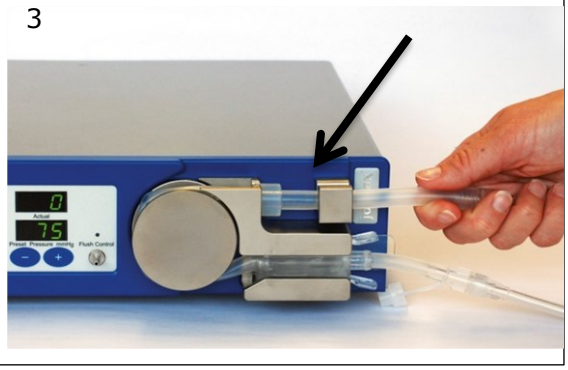


1. Insert the pressure metering chamber until it locks and the middle segments of the display turn off.
   If the middle segments do not turn off, the metering chamber might be damaged or not completely locked.

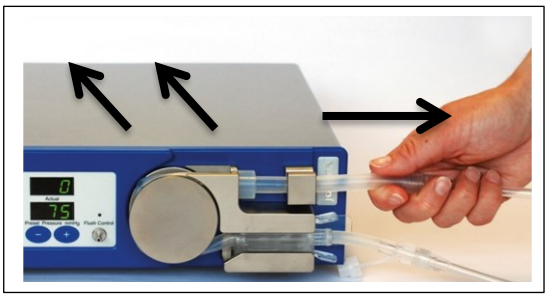
2. Guide the pump segment around the roller wheel and on through the upper tube bracket. Ensure that the tube stopper is correctly seated in its designated anchoring. If the pump segment is not or incorrectly inserted, the error message "E 5.3 / ItB" will appear on the "FLOW" and "PRESSURE" indicators after the device has been started.

3. Insert the pump segment into the tube guide.

4. Connect the supply tube to the reservoir and the patient-sided tube section to the instrument.

   The supply tube can be used several times. If this is the case, connect a new patient-sided tube section (patient line) to the tubing set and to the instrument.

7.3 Removal of the single-use tubing set

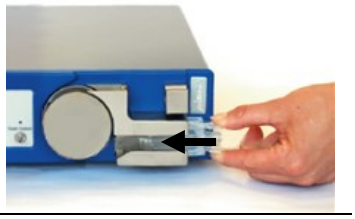


1. Remove the connections at the reservoir and then at the instrument before detaching the tubing set from the device.

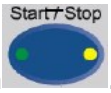
2. Remove the pump segment from the tube guide and tube bracket. Press both detention springs together to remove the pressure metering chamber. Then slowly pull the pressure metering chamber from the metering chamber guide.

3. Re-insert the sensor protection into the metering chamber guide.

The sensor protection provides protection for the pressure sensors against accidental mechanical damage. It should always be re-installed whenever the device is not in use.



7.4 Functional Tests

1. The pump is activated via the START/STOP button 

. The START LED lights up.

2. Liquids are now conveyed. The tubing set must be ventilated until liquid is discharged from the end of the instrument. Ventilation is complete once there are no recognizable air bubbles in the tubing set.

3. The function check is completed. Stop the pump using the START/STOP button. The STOP LED lights up.

7.4.1 Behavior in the Event of Malfunctions

In the event of malfunction of the device or changes in its performance that may affect safety (e.g. deviations from the permissible operating conditions) have the faults corrected immediately.

The Versicon® can be switched off at any time by using the power switch as an emergency stop switch.

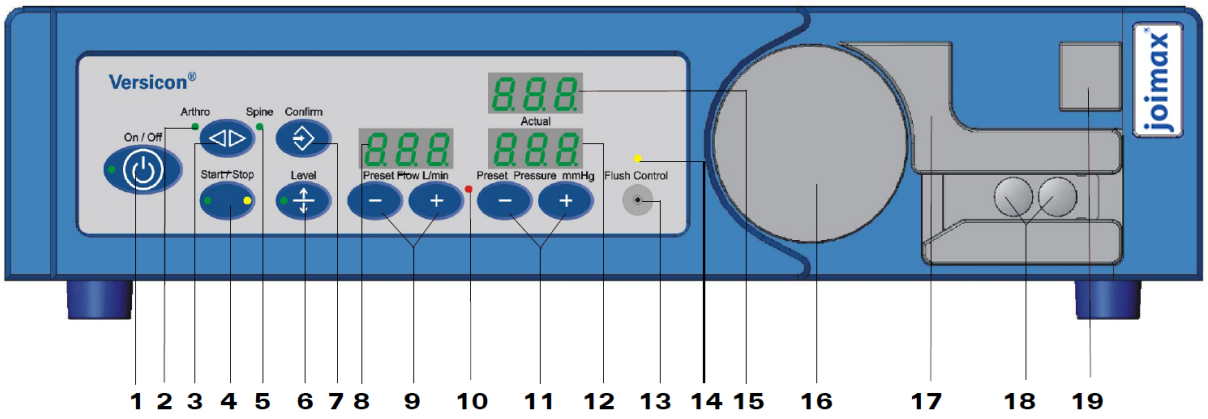
Proceed as follows in case of malfunctions:

1. Inspect the Versicon® and perform a functional test.
2. Contact the joimax® technical support.
3. Report any serious incident to joimax® GmbH and the competent authority having jurisdiction in your locale, see Chapter 0.

8 Operation

8.1 Control elements

Front Panel



1	ON/OFF button	11	+/- PRESET PRESSURE button
2	ARTHRO LED indicator	12	PRESSURE indicator
3	ARTHRO/SPINE (Mode) selection button	13	FLUSH CONTROL connection for foot switch
4	START/STOP pump button	14	FLUSH CONTROL LED indicator
5	SPINE LED indicator	15	ACTUAL (current pressure) indicator
6	LEVEL selection button	16	Roller wheel
7	CONFIRM button	17	Tube bracket with metering chamber guide
8	FLOW indicator	18	Pressure sensors
9	+/- PRESET FLOW button	19	Tube guide
10	FLOW LIMIT LED indicator		

8.2 Starting the device

Warning:
Make sure that the device is turned on only after checking the power connector and after ensuring that the device is completely wired.

Only insert the tubing set and connect the foot switch after successful self-testing.

After connecting the joimax® Versicon® in accordance with the connection diagram (chapter 7.1), the system start **must** be carried out in the following order:

1. Remove the sensor protection block from the metering chamber guide and store it in a safe place.

2. Activate the control unit via the ON/OFF button  .
   A short beep sounds and the ON/OFF LED lights up.

3. The self-test is performed (refer to chapter 8.2.1), the operational readiness and the end of the self-test are signaled by a 3-fold beep.

4. Insert the single-use tubing set (refer to chapter 7.2).

5. The ARTHRO/SPINE LED flashes. Select the desired application using the ARTHRO/SPINE (Mode) selection button 

   .
   Confirm with the CONFIRM key  .

6. If the middle segments light up in all displays, this indicates that no tubing set has been inserted. If the tubing set is inserted, the displays goes out again.

7. The LEVEL LED  flashes.

   This indicates that the level (height difference between pump pressure sensor and patient) is to be entered. By pressing the buttons PRESSURE +/- the level setting is executed, the level value is displayed in the display field PRESSURE indicator during the setting process. Once the setting has been made, confirm the setting value by pressing the LEVEL selection button and the process is completed.
   The detailed procedure is described in chapter 8.4.1.

8. Optional: Connect the foot switch to the FLUSH CONTROL connection at the front of the control unit.

9. Perform the functional tests (refer to chapter 7.4).

The ARTHRO/SPINE (Mode) selection must always be confirmed by pressing the CONFIRM button, otherwise the device cannot be started. 

The LEVEL selection must always be confirmed by pressing the LEVEL selection button, otherwise the device cannot be started. 

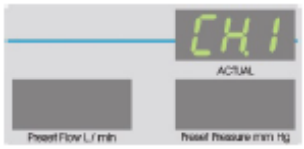
8.2.1 Self-test

Only insert the tubing set and connect the foot switch after successful self-testing.

1 All LEDs light up for 2 seconds and then go out again.

2 

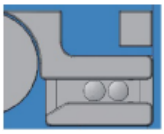
The FLOW and PRESSURE indicators display the current program version of the control and display boards for 1 second and then go out again

3 

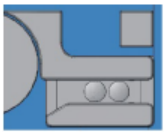
CHECK 1 (CH.1 lights up on the ACTUAL indicator) - Testing, no metering chamber inserted.

If the self-test stops at this stage, a beep will sound and the FLOW and PRESSURE indicators display the error messages "E1.1. / CHb". Check whether the metering chamber is correctly seated in the guide. If this is the case, remove the tubing set completely and restart the device (off/on).

4 


CHECK2 (CH.2)
Testing of 1st pressure sensor in the tube bracket with the metering chamber guide.

5 


CHECK3 (CH.3)
Testing of 2nd pressure sensor in the tube bracket with the metering chamber guide

6 

CHECK4 (CH.4)
Checking the pressure sensor for the foot switch.

7 

CHECK5 (CH.5)
Checking the motor.

8 The self-test is completed. Functionality is indicated with a 3-fold beep.The single-use tubing set can be inserted and the optional foot switch can be connected.

8.3 Shutting down the device

For full disconnection from the power supply, the mains switch at the rear of the device must be switched to position "0".

Once a work process was terminated with the START/STOP 

button, the system is shut down by pressing the ON/OFF  button.

8.4 System Settings

8.4.1 Hydrostatic Pressure Compensation (LEVEL)

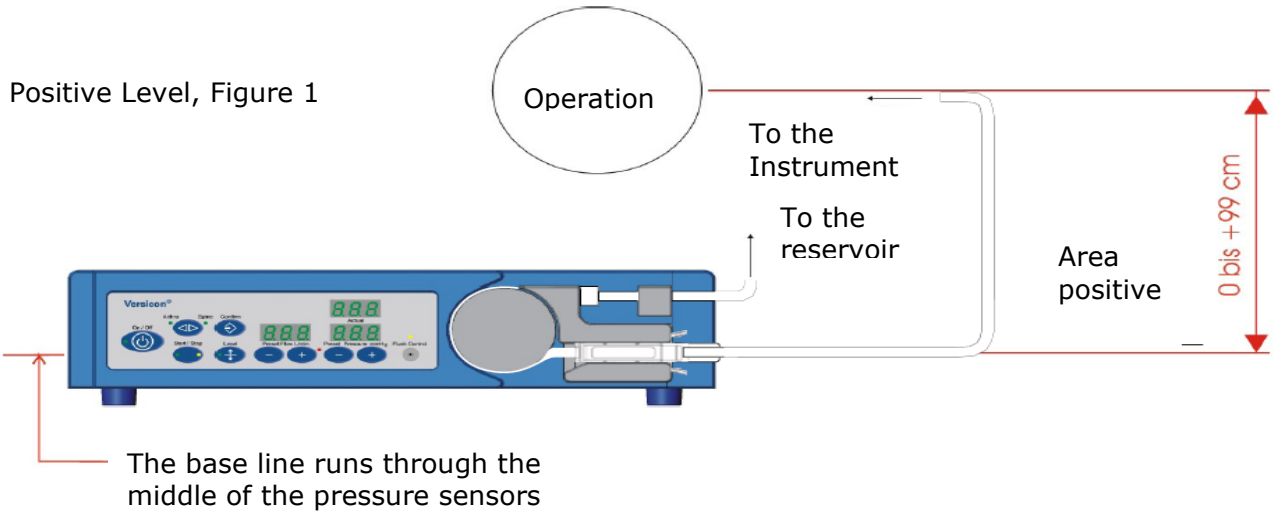
The LEVEL function is used to set the relative position of the patient's area of application at pressure sensor level and to activate hydrostatic pressure compensation. Only this enables reliable pressure measurement at the device. This function is automatically called up after every device activation and successful self-test. It can however also be carried out during surgery.

During hydrostatic pressure compensation, a distinction is made between:

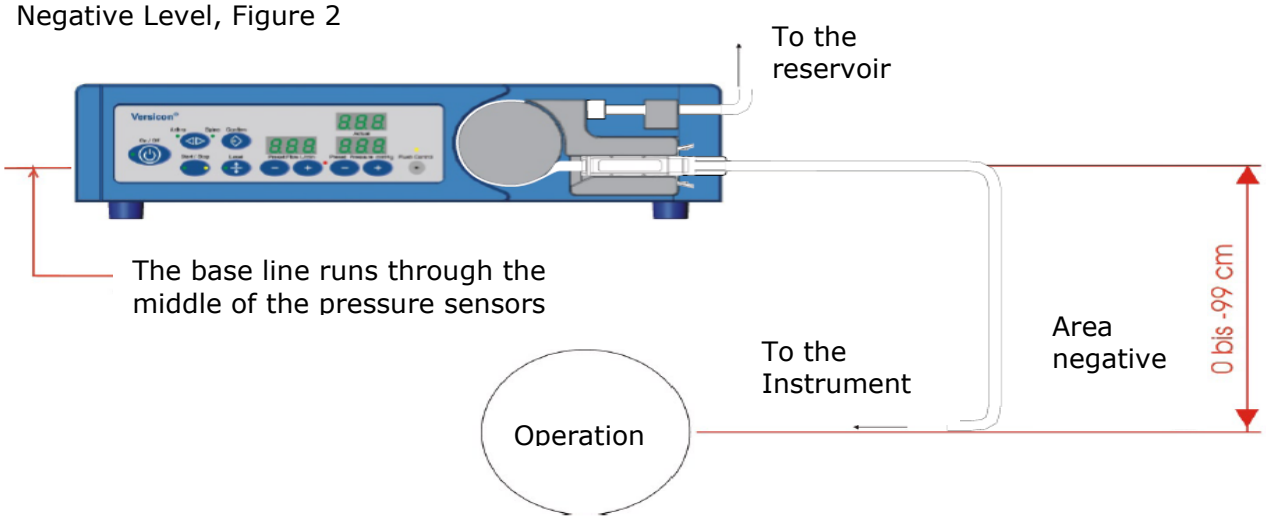
- the "Positive Level" range, see Figure 1
  - patient's area of application is located above the pressure sensor level at the device
  - value ranges from 0 to +99 cm / 0 to +38.98 in
    (Conversion inches to centimeters: 1in = 2.54cm)

- and the "Negative Level" range, see Figure 2
  - patient's area of application is located below the pressure sensor level at the device
  - value ranges from 0 to -99 cm / -38.98 in
    (Conversion inches to centimeters: 1in = 2.54cm)

Positive Level, Figure 1



Negative Level, Figure 2



If the device's installation height was modified or the surgical table was raised or lowered during or after surgery, the height difference between the pressure sensor level and the patient must be determined manually again:

1. Use the +/- PRESET PRESSURE buttons to set the determined height difference.
2. Confirm with the LEVEL button.

If no modifications were performed, confirm the displayed current value (height difference) with the LEVEL button and the LEVEL LED extinguishes.

The LEVEL function can also be activated at any time during operation:

1. Keep the LEVEL button pressed for 3 seconds. The roller wheel stops and the new determined height difference between the patient and the pressure sensor level at the device must be set.
2. Press the LEVEL button again to confirm the entered value; the LEVEL LED extinguishes.
3. Restart the device with the START/STOP button and the START LED will light up.

Always ensure that the LEVEL is confirmed with the LEVEL button, as otherwise the device will not start (all buttons are then deactivated; if these buttons are pressed, a two-fold beep will sound).

8.4.2 Flow and Pressure Values

Warning:
Make sure the device is set up in a way to generate sufficient flow. Insufficient flow may impair the endoscopic view.

Flow and pressure values are set with the +/- PRESET PRESSURE buttons.

If the specified flow is insufficient to create the preselected pressure, a pulsating beep will sound and the FLOW LIMIT LED flashes. In order to reach the previously set pressure, the flow must be increased accordingly by pressing the + PRESET FLOW button. Leakage limitation is ensured in the case of a preselected maximum flow.
The pulsating beep can be deactivated with the LEVEL button. Only the FLOW LIMIT LED flashes.

8.4.3 Arthro or Spine Mode

If the area of application needs to be changed between Arthro and Spine, stop the device with the START/STOP button; the STOP LED lights up. Keep the ARTHRO/SPINE button pressed for 3 seconds; the ARTHRO or SPINE LED flashes. Now you can select the Arthro or Spine area of application.
Press CONFIRM to confirm the area of application. The LED of the selected area of application lights up. The LEVEL LED flashes. Now set the LEVEL.

8.4.4 Flush Function

The Flush function can be activated at any time during operation and is triggered by the foot switch.

The flushing process is limited to 2 seconds and the waiting period between flushing processes is 2 seconds. Pressure monitoring is deactivated during the Flush function, i.e. the device will create maximum pressure for a short period of time. Pressure monitoring is resumed once the 2 seconds have passed.

9 Processing

Warning:
The Versicon® Control Unit must be cleaned and disinfected before first use.

Warning:
The Versicon® Control Unit is not suitable for sterilization!

Warning:
Check the device and all accessories after processing and prior to every use for damage and for proper operation.

Warning:
Do not touch the pressure sensors with sharp objects.

Always respect locally applicable regulations and hygiene procedures of the hospital.

9.1 Cleaning and Disinfection of the Control Unit and Foot Switch

Warning:
Ensure no liquid enters the Versicon® Control Unit and the foot switch during cleaning and disinfection.

Warning:
Before cleaning or disinfection, turn off the device and disconnect all components from the Versicon® Control Unit and disconnect the control unit from its power source.

Warning:
In case of severe soiling, the front panel of the control unit can be carefully cleaned with a cotton swab soaked in alcohol. Do not use any sharp objects for cleaning!

For effective wipe disinfection of the Versicon®, use of Mikrozid® sensitive wipes (Schülke & Mayr) is recommended by joimax® GmbH.

The surfaces of the Versicon® Control Unit and the foot switch can be cleaned and disinfected with a suitable mild varnish- and plastic-friendly cleaning and disinfectant detergent using the following procedure:

1. Turn off the device.
2. Disconnect all components from the control unit and disconnect the control unit from the power supply.
3. Wipe the surfaces of the control unit and the foot switch with a clean, soft cloth, moistened with a suitable detergent or disinfectant.
4. Wipe the surfaces again with a sponge or a soft cloth, moistened with clean water.
5. Dry the surfaces with a clean and lint-free cloth.

10 Technical Data

IEC 60601-1 Safety classification		
Protection class / applied part	I / Type BF	
MDD 93/42/EEC Classification		
Risk class	II a	
Electrical data		
Mains voltage	100-230 V / AC	
Power input	700-400 mA	
Mains frequency	50 / 60 Hz	
Mains fuse	2x T 3,15 AH 250 V (5x20 mm / 0.2x0.79 in)	
Power consumption	Max. 100 VA	
Possible EM or other disturbances		
Emitted interference	Group 1, Class B, in accordance with EN 55011 not life-sustaining. Device in accordance with IEC 60601-1-2	
Operating conditions		
Operating temperature	+10 to +35°C / +50 to +95°F	
Relative humidity	30 – 70 % , non condensing	
Atmospheric pressure	70 – 106 kPa	
Storage and transport conditions		
Temperature	-40 to +70°C / -40 to +158°F	
Relative humidity	10 – 90 % , non condensing	
Atmospheric pressure	70 – 106 kPa	
Ranges, accuracy and precision of measured values	**SPINE**	**ARTHRO**
Adjustable range of flow rate	0 – 0,75 L/min 0 – 0.198 US gpm	0 – 2,5 L/min 0 – 0.66 US gpm
Accuracy at max. flow rate	0,75 L/min ± 15 % 0.198 US gpm ± 15 %	1,1 L/min ± 15 % 0.291 US gpm ± 15 %
Adjustable range of pressure	10 – 100 mmHg	10 – 200 mmHg
Accuracy at max. pressure	100 mmHg ± 5 %	200 mmHg ± 5 %
Weight and dimensions		
joimax® Versicon® Control Unit	10,0 kg / 22 lb; 380x95x320 mm / 14.96x3.74x12.6 in	
Foot switch (optional)	0,8 kg / 1.76 lb; 105x61x167 mm / 4.13x2.4x6.57 in	
Ingress protection	IPX1	
The system is completely closed for access by the user during intended use. The Versicon® software is embedded into the control unit and the system does not provide any network functionality. Therefore no requirements concerning hardware or special IT security measures are necessary to run the software as intended.		

11 EMC Notes

Warning:
The Versicon® mandates special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided.

Warning:
Use of accessories and cables other than those specified or provided by the manufacturer of this equipment may result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning:
Use of this device adjacent to or stacked with other devices should be avoided, because it might result in improper operation. If the device must be used in a stacked configuration or adjacent with other electronic devices, this device and the other devices must be observed to ensure normal operation.

Warning:
This product may emit radio frequency energy and, if not installed and used according to the instructions, may cause harmful interferences to other devices in the vicinity. If this product interferes with other devices, the user is encouraged to try the following in order to correct the interference:

- *Increase the distance between interfering components.*
- *Consult the manufacturer of the other device for help.*

Warning:
Portable RF communications equipment should be used no closer than 30 cm (12”) to any part of the Versicon®. Otherwise, the performance of this equipment might be impaired.

This equipment has been tested and found to comply with the requirements regarding electromagnetic compatibility (EMC) according to IEC 60601-1-2:2014 (Ed.4). The customer or user of the Versicon® has to ensure that it is operated in such environments.

The Versicon® is suitable to be used in combination with RF surgical equipment. The device was tested according to IEC 60601-2-2, BB.4 and can withstand the emissions produced by such equipment.

The Versicon® is suitable for use in professional healthcare facility environments according to IEC 60601-1-2:2014 (Ed.4).

Emitted interference measurements	**Compliance**	**Electromagnetic environment - guidelines**
HF emissions in accordance with CISPR 11	Group 1	The joimax® Versicon® uses HF energy for its internal function only. For this reason, HF radiation is very low, and it is unlikely that neighboring electrical devices are disturbed.
	Class B	The joimax® Versicon ® is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power network, which also supplies buildings used for domestic purposes.
Emission of harmonics in accordance with IEC 61000-3-2	Class A	
Emission of voltage fluctuations/flicker in accordance with IEC 61000-3-3	Compliant	

Phenomenon	Basic EMC standard or test method	Immunity Test Levels	Compliance Levels	Electromagnetic environment - guidelines
Enclosure Port				
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should consist of wood or concrete or have ceramic tiles. If the floor has synthetic material applied to it, relative humidity must be at least 30%.
Radiated RF EM fields	IEC 61000-4-3	3 V/m 80 MHz - 2,7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz - 2,7 GHz 80 % AM at 1 kHz	Portable and mobile radios must be switched off or should be operated at a distance from the joimax® Versicon ® that does not fall below the calculated protection distance for the transmission frequency. Recommended protection distance: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz with P as the nominal power of the transmitter in watts (W) as specified by the transmitter manufacturer and as the recommended safety distance in meters (m). The field strength of stationary radio transmitters at all frequencies should be lower than the compliance level.. In the vicinity of devices bearing the following symbol, interference is possible: 
Proximity fields from RF wireless communication equipment	IEC 61000-4-3	See table "Enclosure port immunity to RF wireless communication equipment" below		Minimum distances between the joimax® Versicon ® and wireless communication equipment as specified in table "Enclosure port immunity to RF wireless communication equipment", must not be fallen below.
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz	30 A/m 50 Hz	Mains frequency magnetic fields must meet the typical values found in the business and hospital environment.
Input AC Power Port				
Electrical fast transients / bursts	IEC 61000-4-4	±2 kV 100 kHz repetition frequency	±2 kV 100 kHz repetition frequency	The quality of the supply voltage must be that of a typical business or hospital environment.
Surges Line-to-line	IEC 61000-4-5	±0,5 kV, ±1 kV	±0,5 kV, ±1 kV	
Surges Line-to-ground	IEC 61000-4-5	±0,5 kV, ±1 kV, ±2kV	±0,5 kV, ±1 kV, ±2kV	

Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	Portable and mobile radios must be switched off or should be operated at a distance from the joimax® Versicon ® that does not fall below the calculated protection distance for the transmission frequency. Recommended protection distance: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz with P as the nominal power of the transmitter in watts (W) as specified by the transmitter manufacturer and as the recommended safety distance in meters (m). The field strength of stationary radio transmitters at all frequencies should be lower than the compliance level.. In the vicinity of devices bearing the following symbol, interference is possible: 
Voltage dips	IEC 61000-4-11	0 % U T ; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0 % U T ; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	The quality of the supply voltage must be that of a typical business or hospital environment. If the user of the joimax® Versicon ® requires continued operation even in the event of power interruptions, it is recommended to power the joimax® Versicon ® from an uninterruptible power supply or a battery.
Voltage interruptions	IEC 61000-4-11	0 % U T ; 250/300 cycle	0 % U T ; 250/300 cycle	

Phenomenon	Basic EMC standard or test method	Immunity Test Levels	Compliance Levels	Electromagnetic environment - guidelines
Signal Input/Output Parts Port				
Electrostatic discharge	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should consist of wood or concrete or have ceramic tiles. If the floor has synthetic material applied to it, relative humidity must be at least 30%.
Electrical fast trasients / bursts	IEC 61000-4-4	±1 kV 100 kHz repetition frequency	±1 kV 100 kHz repetition frequency	The quality of the supply voltage must be that of a typical business or hospital environment.
Surges Line-to-ground	IEC 61000-4-5	±2 kV	±2 kV	
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0,15 MHz - 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz - 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	Portable and mobile radios must be switched off or should be operated at a distance from the joimax® Versicon ® that does not fall below the calculated protection distance for the transmission frequency. Recommended protection distance: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz with P as the nominal power of the transmitter in watts (W) as specified by the transmitter manufacturer and as the recommended safety distance in meters (m). The field strength of stationary radio transmitters at all frequencies should be lower than the compliance level. In the vicinity of devices bearing the following symbol, interference is possible: 

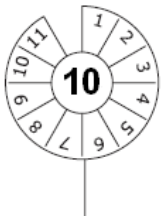
Enclosure Port Immunity to RF Wireless Communication Equipment							
Test Frequency (MHz)	**Band**	**Service**	**Modulation**	**Max. Power** (W)	**Distance** (m)	**Immunity Test Level** (V/m)	**Com-pliance Level** (V/m)
385	380 - 390	TETRA 400	Pulse modulation 18 Hz	1,8	0,3	27	27
450	430 - 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0,3	28	28
710	704 - 787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0,3	9	9
745							
780							
810	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0,3	28	28
870							
930							
1720	1700 - 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0,3	28	28
1845							
1970							
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0,3	28	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0,3	9	9
5500							
5785							

12 Service / Maintenance

Warning:
Do not use the device during service activities.

joimax® GmbH recommends performing a function and safety inspection at regular intervals according to EN 62353 or to other corresponding country-specific regulation.

The Versicon® is low maintenance. Regardless of the Versicon® being low maintenance, regular service can contribute to early detection of defects and faults and, thus, extend the operating life of the devices.



Next inspection

An operating life of 8 years is specified for the Versicon®. Any use beyond this depends on the results of the safety inspections.
joimax® GmbH recommends an inspection to be performed at least once a year. The inspection should be documented with an inspection-label on the device.

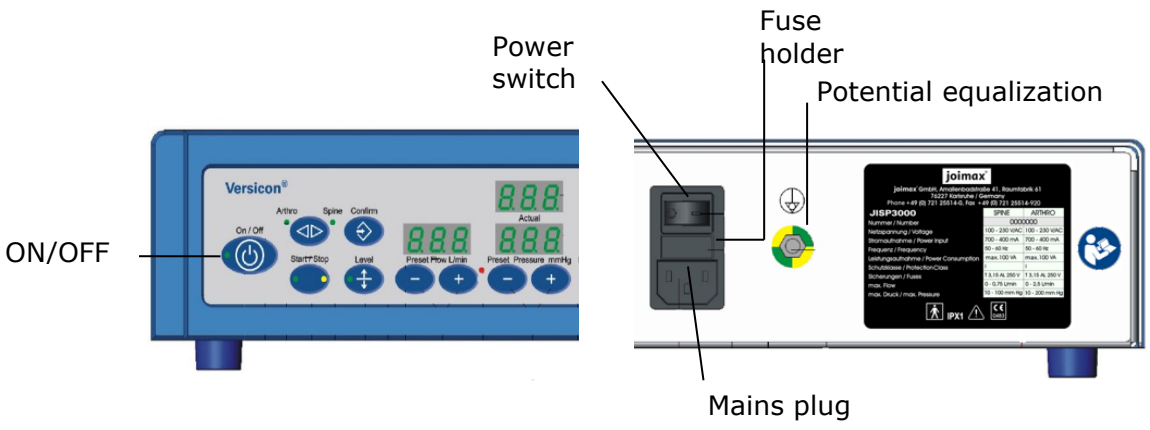
12.1 Replacing the Fuse

Warning:
Always observe the specifications on the device label and follow the instructions below when replacing the fuse. Non-observance may result in malfunction of the device and possible injury.

Warning:
Always disconnect the device from the power supply when performing service activities.

The replacement of the mains fuse may be carried out by the local expert staff as specified below:

1. Turn off the device via the power switch at the backside of the control unit.
2. Disconnect the mains plug and potential equalization from the device.
3. Remove the mains fuse holder with a slotted screwdriver or other suitable tool from the mains fuse box.
4. Check the type of replacement fuse on the device label and replace the defective fuses.
5. Insert the mains fuse holder in the mains fuse box.
6. Connect mains plug and potential equalization.
7. Turn on the device via the power switch at the backside, press the button “ON/OFF” at the device front and check the function of the device.
8. If the fuses fail again, please contact joimax® customer service.



13 Troubleshooting

Problem/Error Message	Possible cause	Solution
- Complete failure of the device - No function - On/Off switch light off	- Power supply failure - Mains fuse missing	- Check power supply - Check mains fuse - Continue irrigation by gravity (Caution, keep low pressure!) - Contact joimax® customer service
A pulsating beep sounds	Overpressure is registered by the device	Decrease the FLOW setting immediately
All center segment indicators light up	No tubing set inserted	Insert tubing set
Insufficient flow/pressure	- Wrong level - Electronic defect - Wear and tear (preventive maintenance recommended)	- Check and potentially adjust level setting to true level measurement - Check and adjust flow/pressure settings - Contact joimax® customer service
Error message: E1.1 CHb	Premature insertion of the metering chamber with tubing set before onset of self-test	Remove metering chamber, deactivate device and restart after 15 seconds, if the attempt fails again, inform the joimax® customer service
Error message: E5.3 ItB	Incorrect insertion of the pump segment with tubing set around the roller wheel	Remove pump segment with tubing set and replace around the roller wheel; if the error message persists, remove pump segment with tubing set, deactivate the device and restart device after 15 seconds; if the attempt fails again, inform the joimax® customer service
Error message: E1.2 Led	Diode defect on user pad	Contact joimax® customer service
Error message: E1.5 UIC	Defect at display board	Contact joimax® customer service
Error message: E2.1 xxx	Defective 1st pressure sensor (left)	Contact joimax® customer service
Error message: E2.5 SnS	Maximum pressure sensor deviation	Contact joimax® customer service
Error message: E3.1 xxx	Defective 2nd pressure sensor (right)	Contact joimax® customer service
Error message: E4.1 LFS	Defective connection to foot switch	Contact joimax® customer service
Error message: E4.2 xxx	Defective foot switch sensor	Contact joimax® customer service
Error message: E5.1 Irr	Defective motor	Contact joimax® customer service
Error message: E5.6 tBE	Blocked roller wheel	Contact joimax® customer service

14 Warranty

Warning:
Do not open the Versicon®. Unauthorized opening, repair, or modification of the device releases joimax® GmbH from any liability for the operating safety of the device and results in any claims becoming void, even during the warranty period.

Warning:
In case of return of equipment or accessories, original packaging material must always be used!

Warning:
To protect your staff and the joimax® GmbH employees, please clean the unit and its accessories and disinfect it before sending it.
Should this be impossible due to temporal constraints, please prepare the unit as much as possible and label it accordingly.

The warranty period for the Versicon® depends on the legal regulations of the specific country. Failure due to faulty material and/or poor processing must be rectified by the manufacturer free of charge within this period.
Transport costs and shipment risks are excluded hereof.
In addition, the details in our general terms and conditions apply.

To facilitate quick processing of service requests and repairs, we ask you to send the product with the following information:

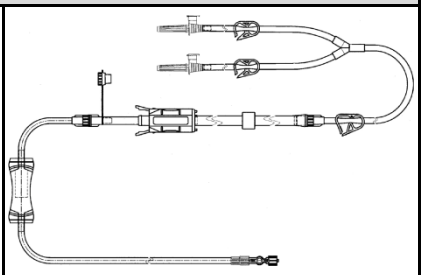
- Model/Item number (REF)
- Serial number (SN)
- A description of the error as accurate as possible
- Invoice of the device if available
- Contact person for questions

15 Consumables / Accessories

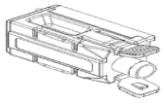
Warning:
Only the consumables/accessories from joimax® GmbH listed below are to be used with the Versicon®. Use of consumables/accessories and cables other than those specified or provided by the manufacturer may result in improper operation.

Consumables

All consumables are provided by joimax® GmbH. Replacements for all consumables can be ordered from joimax® GmbH or via the respective local joimax® distributor.

Item number	Item description	
JTSB350D	joimax® Single-use Tubing Set for joimax® Versicon Spinal-Pump JISP3000, sterile packaged	
JPPL0350	joimax® Disposable Patient Line for joimax® Versicon® (length 3,5m)	

Accessories

Item number	Item description	
JIFS0001	joimax® Versicon® Foot Switch	
JISPSEN01	joimax® Sensor Protection for joimax® Versicon JISP3000	

16 Compatibility

Only the tubing sets provided by joimax® GmbH listed in chapter 15 are compatible for use with the Versicon®. Compatibility is ensured via mechanical coding of the pressure chamber.

For further information and new products directly contact the joimax® customer service or your joimax® representative.

17 Disposal of the Device

Warning:
This symbol indicates that medical devices must be disposed of separately from household waste. Dispose of electrical waste in accordance with the applicable national and local regulations.

Warning:
This symbol must be affixed to the waste container or the device when discarding it.

Dispose of packing material, unless it is contaminated, in accordance with national and local regulations.

According to the implementation of European law into national laws and regulations, you are obliged to properly dispose of medical devices.

Discard used and contaminated medical devices at a collection point of an appropriate disposal carrier. "Medical waste" is classified according to dangerous goods law (for transportation) by UN number UN 3291.

18 Incidents Reporting

Any serious incident that has occurred in relation to the device should be reported to joimax® GmbH and the competent authority having jurisdiction in your locale.

Please notify us at the following telephone number:

For the US	**+1 949-859-3472**	**(24-hour availability)**
For all other countries	**+49 (0)721 25514 – 999**	**(24-hour availability)**

Thank you for your support!

CE 0123

REF IFUVERSEN

Document-ID: TD_VERS_15_GA_002

joined minimal access

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