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1800VC

Virtual Colonoscopy Insufflator

User manual / Instructions for use

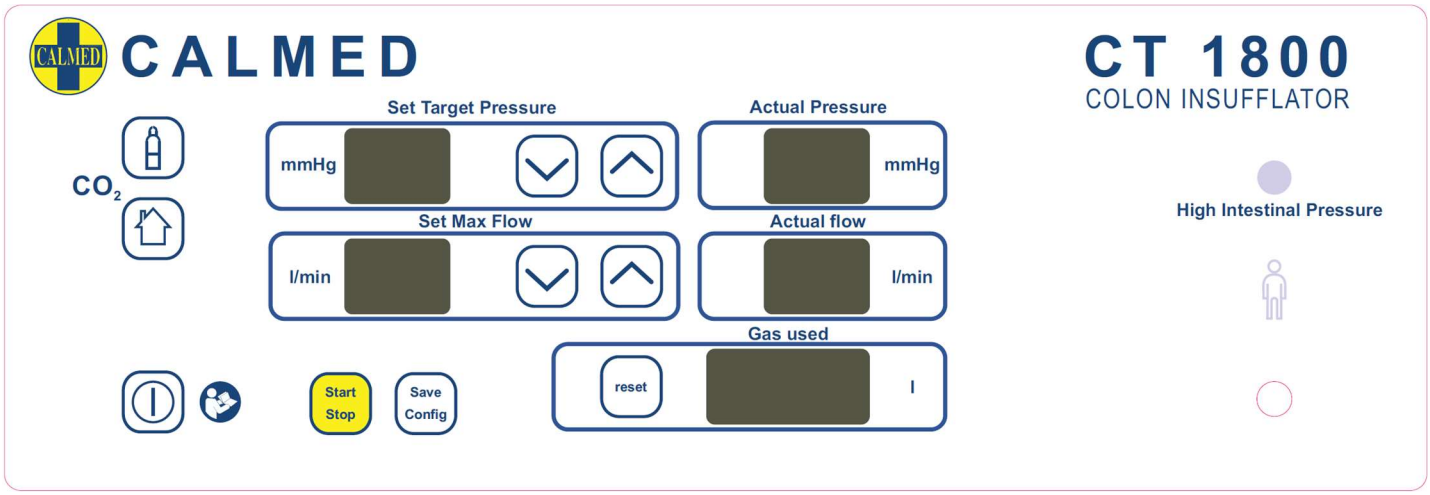

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Table of Contents

1 GENERAL INFORMATION

1.1 PREAMBLE

Dear customer,

Thank you for your confidence in WISAP Medical Technology GmbH. This product combines our longstanding experience and thorough workmanship. You have decided for reliable, high-quality WISAP device.

Please read these instructions carefully before you put your new unit into operation for the first time. This will prevent damage that can result from the wrong electrical connection or improper use.

Use the device only for the purposes described in these instructions. We will assume no liability for damage caused by using the unit for purposes other than those for which it was designed.

The high value and quality of our products, even beyond the warranty, can only be guaranteed if all the service work has been carried out by the company WISAP Medical Technology GmbH. This includes, inter alia, SRC / LMC Testing and comparative measurements, maintenance, and parts replacement.

The manufacturer reserves the right to modify the design and technical performance of the product through continued development of the product.

THIS MANUAL DOES NOT CONTAIN A DETAILED DESCRIPTION OF COLONOSCOPY AND IS NOT SUITABLE FOR INTRODUCING A BEGINNER TO THIS MEDICAL TECHNIQUE.

Your WISAP Team

1.2 SCOPE OF THIS USER MANUAL

This user manual covers the following products:

1800VC

1.3 ICONS IN THIS USER MANUAL

DANGER!

Failure to observe this warning leads to serious personal damage or injury.

WARNING!

Failure to observe this warning may lead to serious personal damage or injury.

CAUTION!

Failure to observe this warning may cause minor personal injury and may cause damage to the product.

NOTE!

A note contains valuable information or offers measures to make handling the product more efficient and easier.

1.4 ABBREVIATIONS IN THIS USER MANUAL

SRC	Safety-related Checks
LMC	Legal metrological Control

2 SAFETY

2.1 ICONS AND SYMBOLS ON THE MEDICAL PRODUCT

Icons are for user information and are provided by the type label on the back side of the device for example.

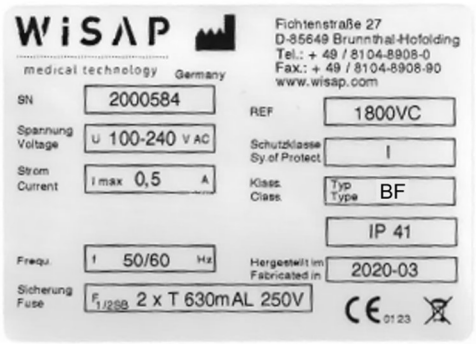


Figure 1: Type Label

Icon, Symbol	Descriptions
ON	Switch “On“-position
OFF	Switch “Off”- position
	Connection to the potential equalization
	Serial number
	Reference number
	Date of manufacture
	Manufacturer
	Spare parts of type BF
	Caution
	Consult instruction for use
	Refer to the Manual!
IPX1	Protected against dripping water
IPX7	Protection against the effects of temporary immersion in water

Icon, Symbol	Descriptions
	The device must not be disposed through the normal clinical disposal. For information on disposal, see the appropriate chapter.
CE 0123	CE-marking and identification number of the Notified Body. The product complies with the essential requirements of the Medical Device Directive 93 / 42 / EWG.

2.2 ICONS AND SYMBOLS ON THE PACKAGING

Icon, Symbol	Descriptions
	This side up
	Keep Dry
	Temperature Limitation
	Non-Sterile
	Do not Use if Package is damaged
	Atmospheric pressure Limitation
	Humidity Limitation
MD	Medical Device

2.3 DANGER

DANGER!

The use of this device is restricted to authorized personnel/physicians only.

DANGER!

This device may only be operated by appropriately qualified persons who have been trained in its use.

DANGER!

Only use sterile spare parts for each patient.

DANGER!

Spare parts that are designed for single use are not safe for a second application. Sterile single use spare parts are not designed for (re-)processing!

DANGER!

After each use, the device must be reprocessed before it is used again.

DANGER!

The device must never be operated with a defective power cord.

DANGER!

Switch off the device and disconnect the mains cable from the socket before replacing the fuse! Wait until the device has adjusted to the ambient temperature.

DANGER!

The device is an electrically operated medical device.

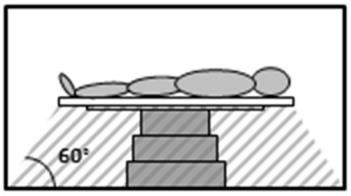
2.4 WARNINGS

WARNING!

The device is not destined for operation in explosive-endangered areas.

WARNING!

If explosive ANESTHETICS are in use, device and spare parts must not be operated in the highlighted zone.



WARNING!

The user is fully responsible for compliance with the applicable cleaning, disinfection, and sterilization regulations.
Faults resulting from non-compliance with the above-mentioned regulations are not the responsibility of the manufacturer and exclude any warranty claims and claims for damages.

WARNING!

It is important to ensure that before surgery, cleaning and disinfecting agents are thoroughly removed.

WARNING!

For your own safety and that of your patient, use only original spare parts.

2.5 CAUTIONS

CAUTION!

Observe all operating instructions and safety warnings listed in this user manual!
Read the instructions carefully before use.

CAUTION!

This device unit may only be installed by the manufacturer or by authorized personnel.

CAUTION!

The device may only be operated in medically utilized rooms which are set up in accordance with the guidelines of DIN VDE 0107.

CAUTION!

Before connecting the device to the mains, make sure the supply network follows the prescribed requirements (mains voltage, frequency and fuses).

CAUTION!

Make sure that the packaging of the device is intact. If the packaging is damaged upon arrival, WISAP can no longer guarantee the full functionality of the device. Therefore, please contact the manufacturer immediately.

CAUTION!

Opening of the housing (unit), repairs, modifications and calibrations may only be carried out by the manufacturer or by personnel expressly authorized by the manufacturer!

CAUTION!

Perform a visual inspection of the medical device before each use. When detecting damage set the unit aside immediately and do not perform any operation with it. Contact the manufacturer immediately.

CAUTION!

Fire hazard: only use rated fuses, see type plate.

CAUTION!

Check the device and all spare parts for proper operation before each use. In case of detected or suspected defects the product has not to be used.

CAUTION!

In case of detected or suspected malfunction of the medical device, switch it off and disconnect it from the power supply. Failure to do so could may have serious consequences!

CAUTION!

To ensure the safety of the medical device it must not be used in case of detected or suspected malfunction. The malfunctions must be rectified by the manufacturer or its authorized personnel immediately.

CAUTION!

The choice of the proposed intervention and the required instruments is the sole responsibility of the attending physician, regardless of the instructions contained in this manual.

CAUTION!

Place the device out of the patient’s reach!

CAUTION!

Please ensure that no liquid enters the device or that the control unit does not get in touch with liquids.

CAUTION!

Leaking accessories must be replaced immediately!

CAUTION!

The controll unit does not have to be sterilized! It can only be treated by wipe disinfection.

CAUTION!

To ensure good dissipation of the heat generated during operation, the device must not be covered.

CAUTION!

Do not pull on the cable to disconnect the plug. Risk of damage!

CAUTION!

The connection cables must not be bent, crushed, stretched or twisted!

CAUTION!

The 1800VC must only be used for virtual colonoscopy.

CAUTION!

Do not expose the device to liquids or a dirty environment.

CAUTION!

For safety reasons, always close the gas tap on the gas bottle or on the mains connection when the device is not in use.

CAUTION!

Caution when setting up and unpacking the device.

CAUTION!

Secure the device against slipping in case of possible excessive pulling on the device frame.

CAUTION!

Do not expose the device to excessive vibrations. Secure it sufficiently during transport. Do not drop the device. Do not expose the device to water/moisture. Do not expose the device to sudden temperature changes (above 10°C) due to condensation. Do not operate, store or transport the device in a dusty environment.

2.6 NOTES

NOTE!

The operating instructions/ instructions for use for use must be kept at a clearly visible place near the unit.

NOTE!

Retain the operating instructions during the service life of this medical device.

NOTE!

The instructions for use must be passed on to any subsequent owner or user of the 1800VC.

NOTE!

Place the unit on a level surface.

NOTE!

For the correct use of this medical device, it is important that the device adapts to the ambient conditions (room temperature). Please wait about 15 minutes after installation before using the device. This applies to the first use as well as in case the device is transported to another environment.

3 PRODUCT DESCRIPTION

3.1 INTENDED USE / PURPOSE

The 1800VC COLON INSUFFLATOR administers and regulates carbon dioxide as an expansion medium for the colon during CT colonography (CTC or Virtual Colonoscopy).

3.2 INDICATION/CONTRAINDICATION

The 1800VC COLON INSUFFLATOR should be used only when colon insufflation is indicated and should therefore not be used for any other treatments. It should only be used under the direct guidance of a physician experienced in colon insufflation. This device is contraindicated for hysteroscopic insufflation, i.e., it must not be used for intrauterine distention. This product should not be used in patients with known or suspected colonic perforation or toxic megacolon. It should not be used after a forceps, "hot" biopsy or loop polypectomy performed within six days. Do not use this product with a colostomy. Do not use this product following recent rectal surgery or low rectal anastomosis, or when proctitis or other rectal conditions such as inflammatory or neoplastic diseases are suspected.

3.3 USER GROUP

The medical device should only be operated by physicians who have prior experience in colonoscopy procedures.

DANGER!

The use of this device is restricted to authorized personnel/ physicians only.

3.4 PATIENT POPULATION

The patient population is defined as all adults over 18 years of age who are not contraindicated. There is neither a specific weight range nor a specific mental state of the patient.

3.5 OPERATING PRINCIPLE

The insufflator described in these instructions for use is state-of-the-art and offers the following insufflation modes available for the virtual colonoscopy insufflator.

- **LPS [Low Pressure Insufflation System]**

Advantages: The insufflation pressure is limited to the preselected body cavity pressure (*). This allows the user to determine and to know the level of maximum insufflation pressure (Max. insufflation pressure = preselected pressure + 4mmhg).

The maximum insufflation pressure can never exceed the maximum pressure determined by the hardware.

(*) Note: Despite the pressure limitation, a sudden interruption of a current gas flow may result in a pressure peak that exceed the pressure pre-setting.

WARNING!

In case of unfavourable conditions during the operating (high leakage rate, high gas flow, high volume of insufflation, long operation time), make sure that the patient does not suffer uncontrolled hypothermia, as insufflation draws heat from the body. Body temperature must be monitored during the entire insufflation. The risk of hypothermia can be significantly reduced by using gas preheated to body temperature.

WARNING!

If a high gas flow occurs during operation for no apparent reason, check the system for leaks immediately.

WARNING!

Leaks in the insufflation line (e.g. open hose connection) can endanger the patient!

WARNING!

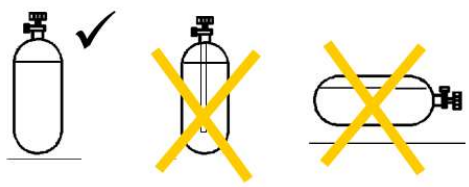
Position the patient nozzle of the insufflator and the associated hose as far as possible above the insufflation point so that any patient fluids (e.g. rinsing solutions) inadvertently entering the hose do not drain back into the insufflator due to gravity.

WARNING!

Please make sure that no liquid gas enters the unit!
This can lead to icing and thus to a significant reduction in the gas flow.

WARNING!

Always keep the CO2 tank in an upright position to avoid liquid CO2 penetrating into the unit.



NOTE!

The device has been tested and meets the requirements of DIN EN 60601-1-2.
(IEC 60601-1-2, EMC). Nevertheless, we recommend switching off unused devices in the immediate vicinity and disconnecting them from the mains.

3.6 VARIANTS OF THE MEDICAL PRODUCT

The medical device 1800VC for virtual colonoscopy is offered in one variant:

Type REF	Volume
1800VC	5 Liters

3.7 COMPONENTS OF THE MEDICAL PRODUCT

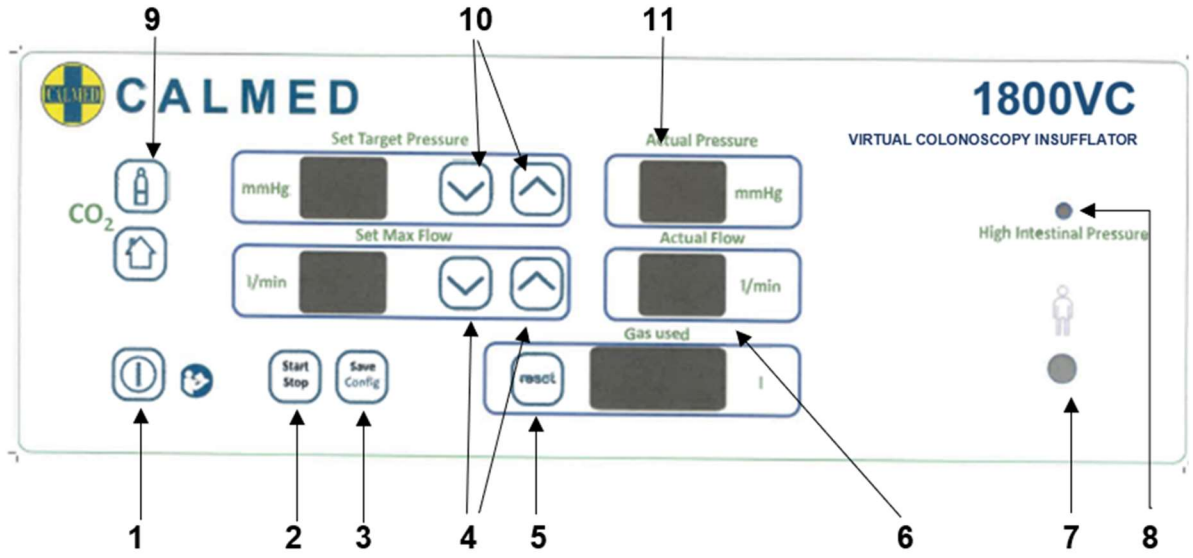
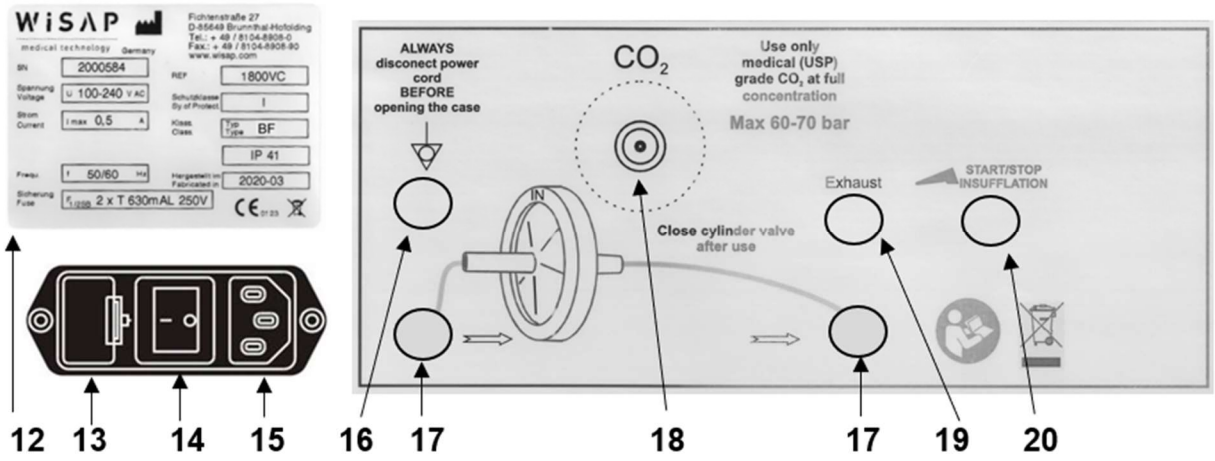


Figure 2: Operating elements of unit's front side

No.	Component / Element / Function
1	Pushbutton for STAND-BY
2	Pushbutton to "START / STOP" of insufflation. (Insufflation mode "**LPS** ")
3	When the user enters the SYSTEM CONFIGURATION, this button is used to save the modifications
4	Pushbuttons for preselection of gas flow rate
5	RESET Pushbutton for resetting the gas consumption display
6	Display for showing the current gas flow rate (unit: liters / minute)
7	Patient nozzle (according to ISO 5356-1:1987)
8	When the target pressure is equal to or above 20 mmHg, this signal indicates the high-pressure condition
9	CO_2 pressure supply indicator CO2 Display of the pressure supply - of high-pressure CO_2 tank - of clinical wall socket supply
10	Pressure preselection buttons
11	Display to show the current colon pressure (unit: mmHg)



No.	Component / Element / Function
12	Type label
13	Fuses (2x fine-wire fuses according to IEC 127)
14	Mains switch
15	Connection to power supply
16	DIN 42801 socket connector for potential equalization line
17	Studs for the connection of external filter hoses
18	High pressure connection stud according to US-Standard (UNF 7/16“20G).
19	Exhaust pipe for exsufflation
20	Connection of foot switch (not applicable for 1800VC)

WARNING!

This product must not be modified without permission of the manufacturer!

WARNING!

The use of hydrophobic filter is strongly recommended to prevent cross-contamination of the patient!
When using a hydrophobic filter, a reduced flow capacity should be considered. Replace a contaminated filter immediately to ensure unobstructed gas flow. Use a new and sterile filter for each patient.

CAUTION!

Fire hazard! Only use suitable fuses, see type plate.

CAUTION!

Do not pull the cable to disconnect the plug! Risk of damage!

Push-button for Stand-By

Illuminated in GREEN when unit is in stand-by mode. Gets brighter when the unit is switched on.

Push button for stand-by

Lights GREEN when the unit is in stand -by mode. Becomes brighter when the device is switched on.

The unit performs a self-test after being switched on (can be seen on all switched-on displays).

The last saved working parameters are used as default settings.

WARNING!

The stand-by key does not disconnect the device from the power supply. To disconnect the device from the mains, pull out the mains plug at the rear of the instrument.

Display power supply

Lights in GREEN when power supply is correct.

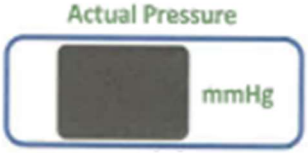
Lights in RED when power supply is inaccurate.

CO_2 – tank pressure display.

- Pressure values above 18000 mmHg (25 bar) are displayed in GREEN.
- Pressure values below 18000 mmHg (25 bar) are displayed in RED.

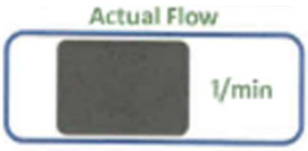
Change the gas cylinder if the amount of gas remaining in the tank (see equation) is less than the amount of gas estimated to complete the procedure:

Equation: CO2 cylinder contents (kg) x 20 liters.

	**Clinical CO_2 – pressure supply display** Monitoring of the pressure supply is deactivated! (Lights up when a clinical supply has been selected. The alarm is triggered when the gas supply fails completely).
	**Pushbutton to START / STOP the insufflation** Illuminates brighter when activated.
	**Pushbutton to save the configuration** When the user enters the SYSTEM CONFIGURATION (see 5.1), the changes are saved with this button.
	**Display for pressure presetting and pushbuttons for presetting the target pressure** Presettable pressure range from 5 – 25 mmHg, increased in increments of 1. (SET flashes GREEN when cavity pressure is preset). The Display for the pre-setting pressure switches between preselected pressure and “H” if pressure preset **> 19 mmHg**. Arrow down reduces the preset pressure. Arrow up increases the preset pressure.
	**Display for showing the current pressure (green)**

WARNING!

Reducing the pressure presetting to a value below the actual body cavity pressure does not immediately result in gas being released from the body cavity! Gas release by the insufflator is only initiated when the cavity pressure exceeds the preset pressure by more than 5 mmHg. To release the pressure quickly, allow the gas to escape from any opening in the body cavity (e.g., by opening a stopcock).

	**Display to show presetting of maximum gas flow rate and pressure buttons to preset target flow rate.** Presettable pressure range of 1–5 liter/minute which is increased/decreased in increment of 1. (SET flashes GREEN if pre-setting flow rate)
	**Display of the current gas flow rate** The current gas flow rate is automatically pre-set by the insufflator according to demand.
	**Display of the gas consumed since the last RESET**
	**Patient symbol and warning light** Illuminates RED when the unit's safety system has detected a malfunction that may result in danger to the patient or staff.
	When the target pressure is equal or above 20 mmHg this signal indicates the high-pressure condition.

WARNING!

Do not use the device if there is any suspicion of possible contamination, if faults or malfunctions are present or suspected, or if the device is obviously damaged.

WARNING!

Have the unit repaired by authorized service personnel only.

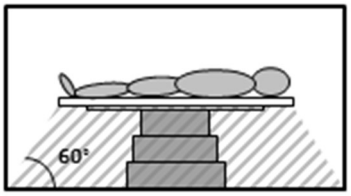
4 COMMISSIONING

WARNING!

The device is not intended for operation in potentially explosive areas.

WARNING!

When using explosive flammable anaesthetics, do not operate the unit and spare parts in the designated area.



CAUTION!

The device may only be operated in in rooms used for medical purposes which are equipped in accordance with the guidelines of DIN VDE 0107.

NOTE!

Retain the instructions for use during the entire service life of this medical device.

4.1 METHOD OF DELIVERY

4.1.1 PACKAGING

The device is carefully packed with various protective materials. Take the Insufflator 1800VC out of the packaging.

DANGER!

Sterilized spare parts (e.g. tubes) are to be used only once for each patient.

CAUTION!

Observe all operating and safety instructions listed in this user manual! Read the instructions carefully before use.

CAUTION!

Ensure that the packaging of the device is intact. If the packaging is damaged upon arrival, WISAP can no longer guarantee the full functionality of the device, please contact the manufacturer immediately.

4.1.2 INCOMING INSPECTION

Check the unit and spare parts (if applicable) immediately after receipt for obvious damage or missing parts.
Claims for damages can only be accepted if the supplier is notified immediately (within 24 hours).

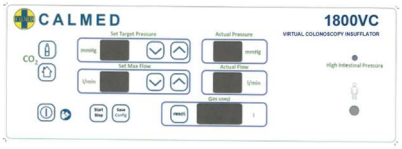
Always use the original packaging if you must return the unit or spare parts.

Describe the fault or malfunction and name a person who we may contact in the event of any questions.

	NOTE! Place the device on a level surface.

4.2 SCOPE OF DELIVERY

The standard delivery of the insufflator 1800VC includes:

Image	Description	Article Number
	Control Unit	1800VC
	Power-Cord	1110ND2
	User Manual	

4.3 CONDITIONS FOR OPERATION

Temperature	+10°C bis +40°C
Air pressure	70 to 106 kPa
Humidity	30% to 70% relative humidity

4.4 INSTALLATION OF THE DEVICE / INITIAL START-UP

Place the unit on a clean and level surface. The ambient temperature and humidity should be within the range specified in the technical data sheet (see chapter 10).

Before commissioning, the device must be connected to a potential equalization system via a suitable potential equalization cable. The connection for the potential equalization (according to IEC 417-5021) is located on the rear of the device.

The unit and the components connected to it must be connected to the potential equalization of the treatment room via a suitable grounding cable before coming into contact with the patient. The Insufflator is equipped with a rear socket which complies with DIN 42801. Use this socket to ground the unit in accordance with local safety regulations.

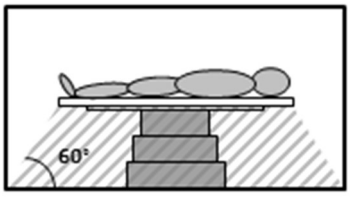
The mains connection must have a ground contact. Please use the mains cable supplied with the device or an equivalent cable.

NOTE!

Place the device on a level surface.

WARNING!

When using explosive flammable anaesthetics, do not operate the unit and spare parts in the designated zone.



WARNING!

Check BEFORE initial start-up whether the voltage at the location matches the voltage range specified on the type plate. Incorrect voltage can cause errors and malfunction and destroy the device. A connection to the mains supply must be carried out in accordance with the regulations.

WARNING!

Position the patient nozzle of the insufflator and the associated hose as far as possible above the insufflation site so that patient fluids (e.g., rinsing solutions) that accidentally enter the hose do not flow back into the insufflator due to gravity.

WARNING!

To prevent electrical shock, do not open the device. Leave maintenance and calibration to be qualified service personnel.

CAUTION!

To avoid the risk of electric shock, connect this device only to a power supply with ground wire.

CAUTION!

The device may only be operated in rooms used for medical purposes which are set up in accordance with the guidelines of DIN VDE 0107.

CAUTION!

The unit may only be installed by the manufacturer or by AUTHORIZED PERSONNEL.

CAUTION!

Place the device out of the patient's reach!

CAUTION!

Please make sure that no liquid enters the control unit and that the unit does not come into contact with liquids.

CAUTION!

To ensure good dissipation of the heat generated during operation, do not cover the control unit with a cloth.

NOTE!

For the correct use of this device, it is important that the device adapts to the ambient conditions (room temperature). Please wait approximately 15 minutes after installation before you start using the application. This will help to remove any condensation from the electronic circuits.

This applies both to first-time use and to the case that the device is transported to another environment.

DANGER!

The device must never be operated with a defective power cord.

CAUTION!

This control unit may only be installed by the manufacturer or by authorized personnel.

CAUTION!

Before connecting the medical device to the mains, make sure the mains supply complies with the prescribed requirements (mains voltage, frequency, and fuses).

CAUTION!

Check the device and all spare parts for proper functioning before each use. If defects are found or suspected, the product must not be used.

CAUTION!

To ensure safety, the device and its spare parts must not be used in the event of a detected or suspected malfunction. The malfunctions must be serviced immediately by the manufacturer or his authorized personnel.

CAUTION!

The connection cable to the medical device must not be kinked, crushed, stretched, or twisted!

NOTE!

Place the device on a level surface.

CAUTION!

Ensure that the packaging of the medical device is intact. If the packaging is damaged upon arrival, WISAP can no longer guarantee the full functionality of the device, please contact the manufacturer immediately.

4.4.1 GAS SUPPLY

A standard US bolt (UNF 7/16" 20G) is located on the rear of the unit to allow connection of a suitable high pressure hose (original equipment) to a CO2 gas supply (max. inlet pressure 16 MPa).

Various high-pressure hoses are available. Check with your local distributor to determine which system is required to connect the unit to your country`s standard gas supply.

WARNING!

For your own safety, and the safety of your patient, use only original spare parts.

4.4.2 GAS FILTERING

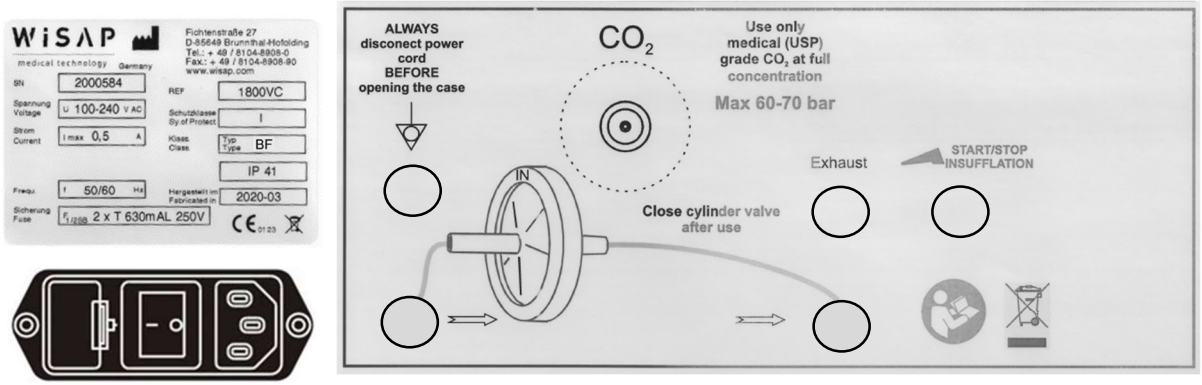
It is strongly recommended to use only CO_2 of medical (USP) quality and full concentration (no gas mixtures).

To ensure the purity of the insufflation gas, a gas filter (Art.-No. 7085FE) must be installed in the gas supply path.
As this filter element becomes less resistant over time due to contamination, it must be replaced regularly to maintain the maximum flow rate.

WISAP recommends:

- Connection to a gas cylinder: with each bottle exchange
- Connection to a house connection: after 10 OPs (approx..3000 liters)

For this purpose, the unit is equipped with a plug-in connection for smooth 6x4 polyurethane hoses on the back. These are used to connect the CO2 filter at the back of the unit.



Connecting the plastic hose
Cut the plastic tube straight.

Insert it into the screw connection as far as it will go. The tube and the fitting are now sealed and the tube is secured against being pulled out.

Disconnecting the plastic hose
Press in the release ring on both sides.
The tube can now be easily removed.

4.4.3 CONNECTION OF THE DEVICE TO THE PATIENT

The connection of the 1800VC insufflator to the tubing (patient) is made via the technically standardized Luer-Lock, whereby it can be assumed that any physician familiar with colonoscopy knows how to connect a appropriate tube to such an interface. Only medical tubing approved for the use of CO_2 with an integrated filter may be used.

The company WISAP is not a seller or manufacturer of such tubes currently. WISAP is not currently a seller or manufacturer of such tubing.

4.5 FUNCTIONAL TEST

The performance of the functional test is prescribed by the IEC 60601-1 standards. It must be carried out before each operation. The function test is used to check the device in connection with its spare parts and to ensure that the device is ready for operation.

The following steps should be performed before each clinical application:

- Connect unit to power supply and switch on power switch (situated at the rear panel). Connect the instrument to the power supply and turn on the power switch (see rear panel).
    - The STAND-BY button lights up
    - All displays are deactivated

- Switch on the device by pressing the STAND-BY button once.
    - The display shows the default print pre-setting
    - The display shows the present gas flow rate
    - The display shows the current cavity pressure ("0 mmHg" if the patient connector is not connected)
    - The display shows a flow rate of “0.0“
    - The display lights up green (patient symbol)
    - The display does not show an error message "E – X X"

- Start insufflation
    - The display must show a flow rate of "0.0" l/min.
    - An acoustic and visual alarm is triggered by the bottle monitoring system.

- After opening the cylinder valve, the pressure indicator should light up GREEN (only when the tank is full!).

- Check the connected high-pressure hose to ensure that it is in a stable and firm position and also that it is not leaking (no hissing should be heard)

- Start the insufflation in LPS mode.

    - After a short delay of approx. 3 seconds, the unit starts to supply a rapidly increasing gas flow.
    - The rising gas consumption is displayed.

- Close the gas outlet of the device slowly with your thumb until the gas flow stops.

    - The reading should return to “0.0“. The measured value should be "0.0" again.
    - The indicated pressure must correspond to the pre-setting (±3 mmHg) The displayed pressure must match the default setting (±3 mmHg).

- Start insufflation by pressing the Start/Stop button.

    - When the outlet of the device is open, the displayed gas flow must reach the value specified in the operating instructions (±1 l/min).

- Pressing the pushbutton again (Start/Stop) stops the insufflation (toggle mode).

Needle according to Veress

- Connect the insufflation needle to the insufflator via an insufflation tube and start insufflation (LPS mode).

    - An undamaged needle should allow a gas flow of at least 1.5 l/min at a preset pressure of 14mmHg. (This test is for control and evaluation purpose only).
    - Should a mechanical malfunction or blockage occur (e.g. due to sterile deposits/sediments), the resulting flow rate will not reach the expected value.

WARNING!

Do not use the device if there is any suspicion of possible contamination, if faults or malfunctions are present or suspected, or if the device is obviously damaged.

WARNING!

Have the unit repaired by authorized service personnel.

DANGER!

The device must never be operated with a defective power cord.

NOTE!

In the start-up phase after each switching-on of the device, the control unit increases the speed to the maximum value within the first 2 seconds.

5 OPERATION

WARNING!

Always work only with sterile substances, sterile fluids and sterile spare parts.

CAUTION!

To prevent symptoms of fatigue, ensure that the work area is supplied with sufficient fresh air, as an increasing CO_2 content in the air can lead to signs of fatigue among medical personnel.

CAUTION!

Always have a filled CO_2 cylinder ready for replacement. This prevents interruption of the operation due to lack of gas for insufflation.

CAUTION!

Perform a visual inspection of the medical device before each use. When detecting damage, set the unit aside immediately and do not perform any operation with it. Contact the manufacturer immediately.

NOTE!

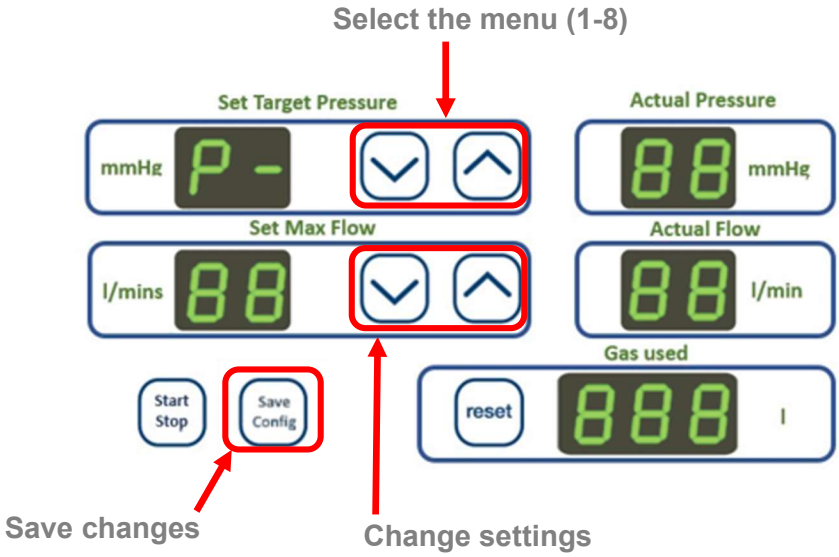
The device has been tested and meets the requirements of DIN EN 60601-1-2 (IEC 60601-1-2, EMC). Nevertheless, we recommend switching off unused devices in the immediate vicinity and disconnecting them from the mains.

5.1 SYSTEM CONFIGURATION

The unit can be configured/optimized according to the individual needs of the user.

To enter the configurations menu, the RESET button must be pressed while the device is switched on.

You will find the following display:



The device is now in the configuration menu.

You can select the various menu steps with the "increase pressure" or "decrease pressure" key.

With the "increase gas flow" or "decrease gas flow" key, you can change the settings in the menu steps.

See the following table:

<table>
<tr><th colspan="3">Menu Step 1 Selection of Gas Supply</th></tr>
<tr><td>Indicator Pressure Step 1

Indicator Gas Flow Setting 0</td><td> 
</td><td>CO_2 high pressure tank is selected
Graphic of CO_2 tank is illuminated
(factory setting)
 
co2
- A pressure level above 25 bars is displayed in GREEN.
- A pressure level below 25 bar is displayed in RED</td></tr>
<tr><td>Indicator Pressure Step 1

Indicator Gas Flow Setting 1</td><td> 
</td><td>Clinical gas supply is selected
Graphic of the house is illuminated
 
co2
This may be required if the unit is connected to a clinical gas supply system to deactivate the pressure monitoring of the CO2 tank. Otherwise, a permanent (false) pressure supply alarm will occur.</td></tr>
</table>

CAUTION!

The monitoring of the CO_2 tank must not be switched “OFF“ if the clinical gas supply system itself is not monitored.

NOTE!

Please note that when this device is used by multiple users, changing the default setting may lead to misunderstandings.

Menu Step 2 Acoustic Signal “on/off” at insufflation start		
Indicator Pressure Step 2 Indicator Gas Flow Setting 0		**Acoustic signal OFF** No acoustic signal is activated at the start of insufflation.
Indicator Pressure Step 2 Indicator Gas Flow Setting 1		**Acoustic signal ON** Activation of an acoustic signal (several beeps) at the start of insufflation. *(factory setting)*

Menu Step 3 Predefine pressure value		
Indicator Pressure Step 3 Indicator Gas Flow Setting 0		**Memory of last used Pressure setting** The unit always starts with the last preselected pressure value if this does not exceed 15 mmHg. In case of a pressure >15mmHg, the value is limited to 15mmHg. This value can be increased if necessary. *(factory setting)*
Indicator Pressure Step 3 Indicator Gas Flow Setting 5 … **10** … 25		**Predefined pressure setting** The pressure preset value can be set, which is displayed when the device is switched on. The values can be set from 5-25 mmHg. The set value can be changed at any time during operation of the keypad.

Menu Step 4 Predefined mass flow		
Indicator Pressure Step 4 Indicator Gas Flow Setting 0		**Saving the last flow setting used** The unit always starts with the last preselected mass flow value. *(factory setting)*
Indicator Pressure Step 4 Indicator Gas Flow Setting 3		**Preset flow setting** In step 6, you can set the preset mass flow rate value that is displayed when the instrument is in LPS mode. The values are adjustable from 1–5 l/min. The set value can be changed at any time during the operation of the keypad.

Menu Step 5 Delay time of the safety valve		
Indicator Pressure Step 5 Indicator Gas Flow Settings		In Step 7, the delay of the drain valve can be set. The drain valve is actuated with a delay in the event of overpressure. The values can be set from 1-10 seconds. The device is delivered with a time delay of 5 seconds. *(factory setting)*

Menu Step 6 Restore factory settings		
Indicator Pressure Step 6 Indicator Gas Flow Setting 0		Enter step 6 und switch to setting 1 to reset the system to the factory settings.
Indicator Pressure Step 6 Indicator Gas Flow Setting 1		After pressing the Save Config button, the factory settings are restored. The display returns to the step 1 menu.

Menu Step 7		
		***For service only***

Menu Step 8		
		***For service only***

Safe the selected configuration:

Every “STEP” must be saved separately by pressing the "Save Config" key.

If the corresponding menu is left without pressing the “Save Config” key, all changes in the menu will be lost.

To return to the **standard mode**, press the Start/Stop key.

5.2 APPLICATION/NOTES

5.2.1 Procedure

Colonoscopy procedures, including the use of insufflators, are well documented in the relevant literature.

The following instructions are provided only as a general guide and to assist in performing the procedure.

- Flush the system with the insufflation gas before each procedure to remove any air that has entered the insufflation system. Replace the device with a clean one if you notice any signs of fluid contamination.

- If possible, only start the operation with a full CO2 cylinder. Always have a full CO2 cylinder ready for replacement.

- CO_2 condenses at a pressure of 60 bars and at a (room) temperature of approx. 20°C. If any condensed CO_2 remains in the bottle, the pressure does not change. For this reason, the amount of gas in the bottle cannot be determined based solely on the basis of the pressure in the bottle!

- The use of a **hydrophobic filter** is strongly recommended to prevent cross-contamination of patients. Use a new and sterile filter for each patient. When using a hydrophobic filter, a reduced flow capacity should be considered. Replace a dirty filter immediately to ensure unobstructed gas flow.

WARNING!

The use of a sterile hydrophobic insufflation filter is mandatory to meet the requirements of safety protection class BF!

WARNING!

Position the patient nozzle of the insufflator and the associated tubing as far as possible above the insufflation site so that patient fluids which accidentally enter the tubing do not flow back into the insufflator due to gravity.

- When the colon is filled, reducing the preselected pressure in the colon will not immediately reduce the actual pressure in the intestine. To quickly reduce the colon pressure, first reduce the pressure preset. Then create a large leakage, e.g., by disconnecting the tube connection.

- In the following cases, disconnect the patient hose or close it with a stopcock or roller clamp:
  When the CO_2 cylinder is exhausted, during replacement and before the power switch or flow selector is switched on.

- Make sure that the connection to the patient is disconnected before the insufflator is switched off.

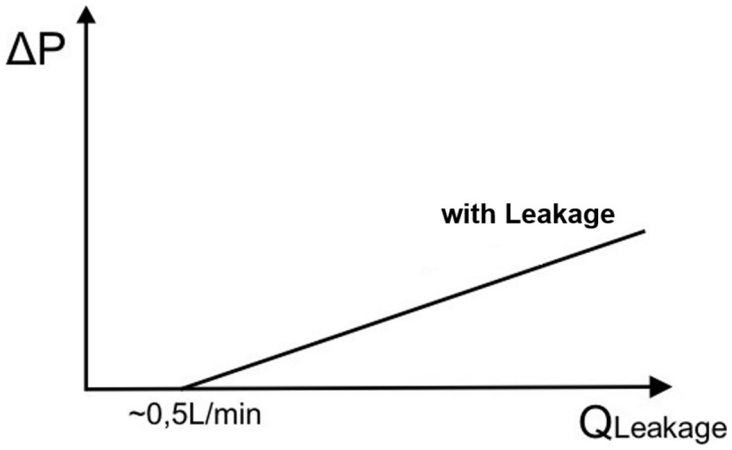
- Remove the insufflation hose from the patient nozzle of the insufflator before switching off the unit.

- Close valve of CO_2 tank before removing/disconnecting the high-pressure hose from the insufflator.
- CO_2 vanishes rapidly from the insufflation system. If the adapted insufflation line is not open, the resulting negative pressure may cause severe damage to the electronic system.

Leakage effects
In case of an insufflation system with a significant leakage flow (starting with 0,5 l/min), the device does not reach the desired target pressure due to the physical correlation between inflow and outflow of the colon.

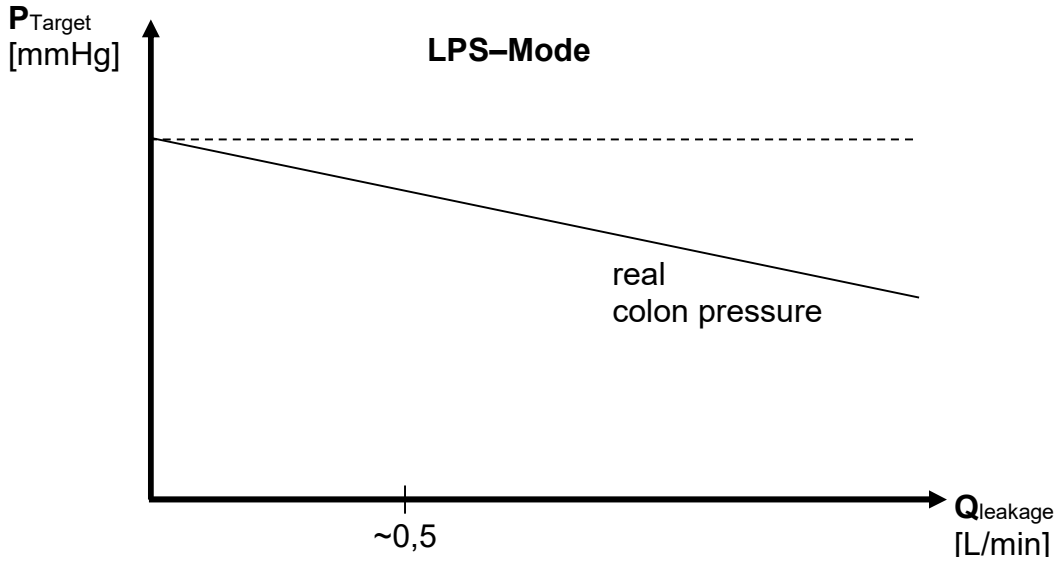
The pressure difference ΔP between preselected pressure and actual pressure depends on the size of leakage volume and on the preselected pressure (see diagram below).

The deviation ΔP could reach a value up to 10 % of the preselected abdominal pressure.



Example: If the set pressure is equal to the impact pressure (e.g. 14mmHg) and a leakage flow is present (e.g. 2 l/min), the device cannot determine the set value.

The following diagram shows the typical relationship between an increasing leakage flow and the deviation value of the set pressure:



5.2.2 Safety features

General
The unit is equipped with an acoustic signal generator that can emit audible alarms and provide audible signals to the user to confirm that a key has been pressed or to indicate a stored value.
A graphical warning light (symbol of a person) on the front of the device lights RED when a visual signal is needed. The corresponding indicator flashes to inform the user for what reason the alarm has occurred.

Pressure alarm
If the colon pressure exceeds the preselected value by more than 5 mmHg, the unit will give an intermittent warning signal as long as the condition persists. The pressure display flashes simultaneously. The patient symbol lights up red.

Monitoring of the CO_2 tank
If the filling pressure of the connected CO_2 tank falls below a pressure level of 25 bar, a visual and an audible warning is activated with the red illuminated symbol of a CO_2 tank on the front of the unit.

Occlusion test
(Monitoring of the insufflation line)
If there is no gas flow for a period of 15 seconds despite insufflation being switched ON, the device checks whether the insufflation line is blocked (e.g. insufflation hose kinked, stopcock closed, etc.) or whether the colon has just filled with gas according to the pre-settings.

Diagnostic System
The instrument is equipped with a self-test and diagnostic system that monitors the sensor functions and other important components.
If the error message "E-X X" appears, stop operation immediately and contact the service personnel. All explanations of the error codes that occur can be found in Chapter 7.

External filter
To protect both the patient and the sensors from coarse contamination, the unit is equipped with a removable external gas filter. This is easily accessible and located on the rear panel and protects the insufflator from contamination as well as liquids (e.g. oil).

Since the filter element loses its effectiveness over time, it should be replaced regularly to ensure maximum flow rate.

WISAP recommends:
- Connected to gas cylinders: every time the cylinder is replaced.
- Connected to house: after the use of about 3000 litres CO_2 gas

5.2.3 **Known side effects**

- Pain, discomfort and bloating may occur after and during surgery.

- Hemodynamic changes
Hemodynamic changes occur during contrast-enhanced CT immediately after CT colonography with carbon dioxide insufflation and should be considered when interpreting the images.

- Nausea and vomiting may be a consequence of CO_2 gas insufflation in individual cases.

- Hematochezia may be a consequence of virtual colonoscopy in isolated cases. However, virtual colonoscopy can also be used to determine the cause of hematochezia.

- Colonic ischemia:
Colonoscopy-related colonic ischemia is a very rare complication to consider after colonoscopy in the differential diagnosis of abdominal pain. This is especially true in elderly, frail, and comorbid patients.

- Idiosyncratic reactions
Patients with sickle cell-anemia or pulmonary insufficiency are at increased risk of metabolic imbalance associated with excessive CO2 intake.

6 HYGIENIC MEASURES

To maintain effectiveness of the device, maintenance and storage must be carried out carefully. Spare parts that come into contact with human tissue must be sterilized to prevent infection of the patient.

The following procedures must be performed after each use of the unit and its spare parts:

- Disposable filters, disposable tubing sets and/or instruments are intended for single use and must be disposed of in accordance with the appropriate regulations.

DANGER!

Spare parts intended for single use are not safe for a second application. Sterile single-use spare parts are not intended for (re)processing!

DANGER!

After each use, multi-use devices must be reprocessed before they are used again. For example, the control unit must be wipe-disinfected before it is used again on another patient.

WARNING!

The user is fully responsible for compliance with the applicable cleaning, disinfection, and sterilization regulations. Faults resulting from non-observance of the above-mentioned regulations are not the responsibility of the manufacturer and exclude any warranty and damage compensation claims.

WARNING!

It is important that cleaning agents and disinfectants are thoroughly removed before examining the patient.

Please refer to the tabular overview in Chapter 6.1 for further information on cleaning, disinfection and sterilisation.

6.1 CLEANING AND DISINFECTION

6.1.1 CONTROL UNIT

After use, the device must be switched off and the connection and the power cord must be removed. The power cord must also be disconnected from the mains. An aqueous disinfectant is suitable for cleaning the external surfaces of the unit. Please observe the solution concentration specified by the manufacturer of the disinfectant. Wipe the surface of the unit with a cloth moistened with disinfectant. The penetration of liquid into the device must be avoided at all costs.
The outer surface may be treated with a cleaning agent or disinfectant that will not damage the paint.

CAUTION!

Unplug the unit from the power supply before cleaning.

CAUTION!

Avoid using flammable or explosive substances.
If you must use such a substance, wait until it has completely evaporated before switching the unit on again.

CAUTION!

Make sure that no cleaning agents get into the interior of the device.

CAUTION!

The control unit must not be sterilized!

6.1.2 SPARE PARTS

Metal instruments should be cleaned of coarse impurities and then rinsed with clean water and carefully dried inside and out. Cleaning and disinfection instructions for your metal instruments can be found in the respective manufacturer's operating instructions.

6.2 STERILIZATION

CAUTION!

The control unit must not be sterilized!

Metal instruments can be sterilized after they have been cleaned of coarse impurities, then rinsed in clean water and carefully dried inside and out. The sterilization instructions for your metal instruments can be found in the respective manufacturer's operating instructions.

7 TROUBLE SHOOTING

The unit has an internal microprocessor-controlled diagnostic system that enables the user to quickly identify faults that are not immediately apparent.

Error messages “E – X X“ are shown in the pressure pre-setting display, current cavity pressure display and gas consumption display.

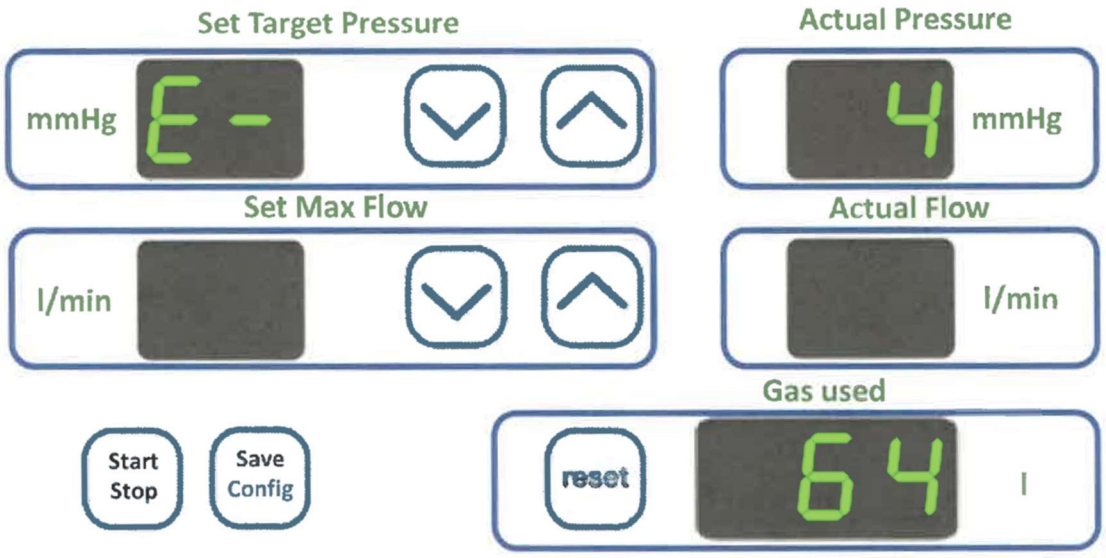


Figure 3: Sample for E - 4 64

Fatal errors requiring immediate abort (e.g. code check error):

Error	*Display pressure preset*	*Display current cavity pressure*	*Display gas con-sumption*	*Description*
ERROR_CODE_CHECKSUM	E	1	1	Program code checksum (CRC32) error
ERROR_LOCAL_CODE_CHECKSUM	E	1	2	Not used

Major errors, serious errors which require a process stop:

Error	*Display pressure pre-setting*	*Display current cavity pressure*	*Display gas con-sumption*	*Description*
ERROR_INT_VOLTAGE_REF	E	2	1	Internal voltage reference
ERROR_EXT_VOLTAGE_REF	E	2	2	Extern voltage reference
ERROR_POWER_P5V_M12V	E	2	4	Power supply +5V, -12V out of range
ERROR_PRESSURE_TRANS	E	2	8	Pressure transducer 1,2
	E	2	16	Not used
ERROR_MASS_FLOW_TRANS	E	2	32	Mass flow transducer 1
	E	2	64	Not used

	E	2	128	Not used
ERROR_DEVICE_ID	E	2	256	Mismatch between HICON and external EEPROM
ERROR_ANALOG_VALVE	E	2	512	Mismatch between voltage of the analogue valve and the relation of the system pressure and control variable
ERROR_LEAKAGE_FLOW_EXCEEDED	E	2	1024	Leakage gas flow (>0,25L/min) of the analog valve or more than 5s

Minor errors: non-serious errors that require notification to the user within a specified period. Upon completion of the current operation, a review by authorized personnel is required:

Error	*Display pressure pre-setting*	*Display current cavity pressure*	*Display gas consumption*	*Description*
ERROR_EXT_OSCILLATOR	E	4	1	External oscillator error
ERROR_TABLE_PRESSURE_TRANS	E	4	2	Pressure transducer table load error
ERROR_TABLE_MASS_FLOW_TRANS	E	4	4	Mass flow transducer table load error
ERROR_INIT_CAN_CONTROLLER	E	4	8	CAN Controller initialization (baud Rate) error (not for 1800VC)
ERROR_CAN_BUS_OVERLOAD	E	4	16	CAN Bus overload executions (not for 1800VC)
ERROR_CPU_TEMPERATURE	E	4	32	CPU temperature out of range
	E	4	64	Not used
	E	4	128	Not used
ERROR_INITIALIZE_NEONATAL	E	4	256	Can't initialize neonatal mode (Hardware error, not for 1800VC)
ERROR_READ_DEVICE_CLASS	E	4	512	Can't read device class (5L, 16L, 20L, 25L, 30L, 45L), see ADC1 conversion time
ERROR_LEAKAGE_FLOW	E	4	1024	Leakage gas flow (>0,05L/min) of the analog valve or more than 5s

WARNING!

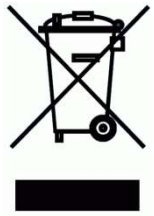
Do not use the device if there is any suspicion of possible contamination, if faults or malfunctions are present or suspected, or if the device is obviously damaged.

WARNING!

Have the unit repaired by authorized service personnel.

8 DISPOSAL

At the end of the product's service life, all components of this device should be disposed of properly. Make sure that the materials are carefully separated. The materials used do not contain any hazardous substances. The housing material is recyclable. The electronic boards should be disposed of via a suitable recycling process.



This symbol on the product and/or accompanying documents means that the product must not be disposed of with general household waste., If you wish to dispose of this product, please contact your dealer or supplier for further information.
This symbol applies only to the countries in the EEA (*).

(*) EEA = European Economic Area, which comprises the EU Member States plus Norway, Iceland and Liechtenstein

9 LIST OF SPARE PARTS

The following spare parts can be obtained from WISAP customer service:

Item No.	Description
7085FE	External gas filter for gas supply (backside)
1110ND2	Power cable / Mains cable
7090ES	Set of open-ended wrenches

WARNING!

For your own safety and that of your patient, use only original spare parts.

10 TECHNICAL DATA

- Line voltage:	100 ... 240 Vac	
- Maximum power consumption:	55 VA	
- Mains fuses:	2 x 0,65 AT (SB)	
- Frequency:	50 / 60 Hz	
- Protection class:	1	
- Protection symbol:	BF 	
- Classification as per REGULATION (EU) 2017/745	IIa	
- Weight:	approx. 8.0 kg	
- Operating environment:	10^{o} – 40^{o} C 30% - 70% 70 bis 106 kPa	Ambient temperature relative humidity barometric pressure
- Storage and transportation environment:	– 40^{0} C ... +70^{0}C 10% ... 90% 50 bis 106 kPa	Ambient temperature relative humidity barometric pressure
- Noise emission	< 40 dB (A)	
- Insufflation medium:	CO_2	medical grade (USP)
- Maximum gas flow :	1 - 5 l/min	Type: 1800VC with 5 l/min
- Pressure setting range:	5 - 25 mmHg	
- Tolerances:		
Display for		
- Colon pressure:	± 3 mmHg	
- Gas flow:	± 0.5 l/min	
- Consumption:	± 15 %	
- Manufactured and tested according to:	IEC 60601-1:2013-12 2017/745/EC	

The nameplate contains technical data such as the model and serial number of your unit, which must always be provided when ordering spare parts or marking other inquiries.

11 OVERVIEW OF ELECTROMAGNETIC COMPATIBILITY (EMC)

Manufacturer's Declaration for Electromagnetic Compatibility
Acc. to IEC 60601-1-2
For the WISAP insufflator 1800VC

Guidance and Manufacturer Declaration - Electromagnetic Emissions		
The 1800VC is designed to operate in an environment as specified below. The customer or operator of the device must ensure that it is operated in such an environment.		
Interference emission/ emission test	**Compliance**	**Electromagnetic Environment -Guideline**
RF emissions CISPR 11	Group 1	The level of unintentionally generated RF emissions is very low and is unlikely that neighbouring electronic equipment will be disturbed by them. The device is suitable for use in all establishments, including residential areas, and in establishments directly connected to a public power supply that is also used for residential purposes. (1*) The power consumption of the control unit is less than 100W.
RF emissions CISPR 11	Class B	
Harmonic emissons IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies (1*)	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The 1800VC is designed to operate in an environment as specified below. The customer or the operator of the system must ensure that it is operated in such an environment.			
Interference immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	**± 8 kV** Contact discharge **± 15 kV** Air discharge	**± 8 kV** Contact discharge **± 15 kV** Air discharge	Floors should be made of wood or concrete or covered ceramic tiles. For floors made of synthetic materials, the relative humidity must be at least 30%.
Electrical fast transients (bursts) IEC 61000-4-4	**± 2 kV** Mains cabling **± 1 kV** Input and output cabling	**± 2 kV** **± 1 kV**	The quality of the supply voltage should correspond to that of a typical commercial or hospital environment.
Overvoltage IEC 61000-4-5	**± 1 kV** Differential mode **± 2 kV** Common mode	**± 1 kV** Differential mode **± 2 kV** Common mode	The quality of the supply voltage should correspond to that of a typical commercial or hospital environment.
Voltage dips and overvoltage fluctuations according to IEC 61000-4-11	0 % U_T (**100 %** dip in U_T/) for 0,5 cycle 0 % U_T (**100 %** dip in U_T/) for 1 cycle 70 % U_T (**30 %** dip in U_T/) for 25 cycles < 0 % U_T (**> 100 %** dip in U_T/) for 5 s	0 % U_T (**100 %** dip in U_T/) for 0,5 cycle 0 % U_T (**100 %** dip in U_T/) for 1 cycle 70 % U_T (**30 %** dip in U_T/) for 25 cycles < 0 % U_T (**> 100 %** dip in U_T/) for 5 s	The quality of the supply voltage should correspond to that of a typical commercial or hospital environment. If the user of the 1800VC wishes to continue operation during power supply interruptions, it is recommended that the 1800VC be powered from an uninterruptible power supply or a battery.
Magnetic field at mains frequency (50/60) Hz IEC 61000-4-8	**30** A/m	**30** A/m	Magnetic fields at the power frequency should be that typically expected in a business or hospital environment.
U_T = Mains AC voltage before applying the test level			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The 1800VC is designed to operate in an environment as specified below. The customer or operator of the system must ensure that it is operated in such an environment.			
Test of immunity	**IEC 60601 test level**	**Level of compliance**	**Electromagnetic Environment - Guideline**
			Portable and mobile radios should not be used in the vicinity of the device system, including its wiring, if the recommended protective distance is not maintained.
Conducted RF disturbances IEC 61000-4-6	6 $V_{effective\ value}$ 150 kHz to 80 MHz	6 $V_{effective\ value}$	d = 1,17 $\sqrt{P}$
Radiated RF disturbances IEC 61000-4-3	3 V/m 80 MHz to 2,7 GHz	3 V/m	d = 1,17 $\sqrt{P}$ für 80 MHz bis 800 MHz d = 2,33 $\sqrt{P}$ für 800 MHz bis 2,7 GHz
Proximity fields ~~from~~ of RF wireless Communication equipment IEC 61000-4-3	According to IEC 60601-1-2, Table 9 (Chapter 8.10)	According to IEC 60601-1-2, Table 9 (Chapter 8.10)	
			Where P is the nominal power of the transmitter in watts (W) and E is the immunity test value according to the transmitter manufacturer's specification and d is recommended separation distance in meters (m). The field strength of fixed radio transmitters should be below the limit value b at all frequencies, which can be verified by on-site testing: 
Note 1: For 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not be applicable in all cases. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people			

a: The field strength from stationary transmitters, e.g. base stations of cellular and land mobile radios, amateur radio stations, AM and FM radio and television transmitters cannot be accurately predicted. To avoid the electromagnetic interference from the stationary transmitter, the 1800VC including spare parts and cables must be at least 30 cm away from the stationary transmitters.
b: In the frequency range from 150 kHz to 80 MHz, the field strengths should be less than 3 V/m.

Recommended distance between portable and mobile RF communications equipment and the device

The 1800VC is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device. As recommended below, according to the maximum output power of the communications devices.

Maximum rated output power from transmitter in watts	**Separation distance depending on the frequency of the transmitter in meters**		
	150 kHz bis 80 MHz $d = 1{,}17\sqrt{P}$	**80 MHz bis 800 MHz** $d = 1{,}17\sqrt{P}$	**800 MHz – 2,7 GHz** $d = 2{,}33\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,37	0,37	0,74
1	1,17	1,17	2,33
10	3,70	3,70	7,37
100	11,70	11,70	23,30

For transmitters with a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power of the transmitter in watts (W) as specified by the transmitter manufacturer.

Note 1:
For 80 MHz and 800 MHz, the higher frequency range applies.

Note 2:
These guidelines may not be applicable in all cases. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

12 TECHNICAL SERVICE AND MAINTENANCE

12.1 FREQUENCY OF MAINTENANCE

In order to avoid accidents due to aging or normal wear and tear, the unit including spare parts must be subjected to a functional and safety check in accordance with IEC 60601-1 at regular intervals. **Annual maintenance is therefore required.**

CAUTION!

Opening of the housing, possible repairs, modifications and calibrations may only be carried by the manufacturer or by personnel expressly authorized by the manufacturer!

CAUTION!

Modifications of the mechanical condition or the use of foreign spare parts/components are not allowed, because they can change the important EMC properties of the device including the used spare parts-!

12.2 TESTING BEFORE FIRST INTENDED USE, AFTER MODIFICATION AND MAINTENANCE

Testing prior the first intended use, after each modification and after maintenance is carried out in accordance with DIN EN 62353 ("Medical electrical equipment – repeat testing and testing after repair of medical electrical equipment").

The following tests must be performed at regular intervals:

- Change the fuses if necessary
- Check the mechanical condition of the device including the spare parts
- Check the tight fit of all electrical equipment including the protective conductor connection
- Check the legibility of all functionally important inscriptions and the type plate
- Check that all necessary documents (instructions for use) are available
- Check the function of all operating elements, sockets, and lights on the device
- Check the protective conductor resistance according to DIN EN 62353
- Check the tightness according to DIN EN 62353

If the test does not reveal any change in the mechanical condition or the use of non-approved components, no measures need to be taken with regard to EMC. Otherwise, the device must be returned to the manufacturer for repair.

12.3 SAFETY INSPECTION (REPEATED TESTS)

The safety checks are carried out according to DIN EN 62353 ("Medical electrical equipment- loop test and test after repair of medical electrical equipment"). The safety check is the responsibility of the operator but should be carried out regularly (12-month interval) by the manufacturer or a person authorized by him.

The individual test points can be found in chapter 12.

12.4 REPLACING THE FUSES

DANGER!

Switch off the device before replacing the fuse and disconnect the power cord from the socket! Wait until the device has adjusted to the ambient temperature.

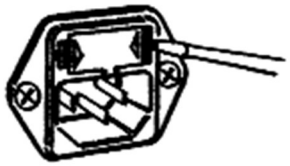
Switch OFF the device by pressing the OFF switch on the front of the device.

Disconnect the power cord from the mains by pulling the power plug of the power cord out of the socket.

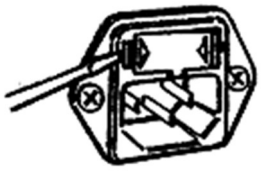
Unplug the power cord from the medical device power connector and store it near the device.

The fuses are located above the mains socket.

Insert a suitable tool (screwdriver) into the recess on the right and press the latch to the left so that the fuse box comes out easily.

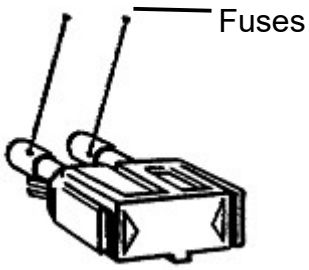


Insert a suitable tool (screwdriver) into the left recess and press the latch to the right so that the fuse box comes out completely.



Pull out the fuse box.

Remove the fuse and insert the new fuse(s). Only use fuses with the correct electrical values (specification see chapter 0)



Insert the fuse. Correct installation on both sides is indicated by an audible "click".

12.5 SERVICE / REPAIR / MODIFICATION

All services, such as regular maintenance, inspection, repair, modification, calibration, et cetera, must be carried out by the manufacturer or by persons expressly authorized by the manufacturer, taking into account the special safety regulations for medical equipment.

The services provided are listed in the table in section 12.7.

12.6 PRODUCT SERVICE LIFE

If all maintenance and service work is carried out, a minimum service life of 10 years can be expected.

12.7 SERVICE TABLE

Date	Description	Signature

12.8 REPAIR AND RETURNS

If a repair is necessary, please contact us or inform your local dealer. In order to process your repair as quickly as possible, please request an **RMA NUMBER**.

Pack the cleaned (not contaminated *) device only in the original packaging and send it back to us free of charge. Describe corresponding faults or malfunctions and indicate a person we can contact in case of queries.

*When returning a used product, for whatever reason, we are required to assume that the returned product may be contaminated in order to protect our employees. Contaminated products pose a potential health hazard to anyone who comes into contact with the returned product due to the presence of infectious agents and pathogens.

A decontamination certificate must be included in each package and must be visible immediately after opening the package.

If this is not possible, the contaminated product must be clearly wrapped in a security foil with a notice of the contamination.
The manufacturer may refuse to repair contaminated products.

13 INSTRUCTIONS

The unit with serial number: _____ was released to the customer on

_____.

Training was provided by Mr./Ms.: _____

The following person(s) was trained:

_____ Function: _____

_____ Function: _____

14 WARRANTY / LIABILITY

The manufacturer guarantees that the unit and spare parts have been carefully checked before leaving the factory. The manufacturer is only liable for the safety-related properties within the scope of the legal regulations if all work on the product is carried out by factory-authorized service personnel and the equipment and spare parts are used exclusively for the intended purpose. Authorized service personnel may only be trained and certified by the manufacturer.

14.1 WARRANTY

WISAP Medical Technology GmbH granted a 12-month warranty on product and material defects. Faults or defects caused by improper handling are excluded from the warranty.

In case of unauthorized opening, modifications and/or repairs, we do not assume any liability for the proper and safe function of the device. All warranty claims are hereby voided.

- The unit is handled improperly
- Incorrect operation leads to damage to the unit
- Non-compliance with the operating instructions
- Implementation of changes to the device (modifications, alterations extensions etc.) without written permission, carrying out modifications to the unit (conversions, extensions, etc.) without written authorization
- Opening of the housing by unauthorized persons
- Use of non-original spare parts
- Force majeure (e.g. lightning strike)
- Transport damage resulting from improper packaging when returning; to avoid transport damages, we advise you to pack the device including all components safe for transport damage due to improper packaging when returning the device; to avoid transport damage, we advise you to pack the device including all components in a transport-safe manner
- In case of defective packaging, repair costs will be charged. Also, during the warranty period any warranty expires

If the complaint is unlawful, we are entitled to charge a reasonable fee for the inspection and delivery of the unit.

14.2 LIABILITY

We, as the manufacturer of this device, are liable for the safety, reliability and performance of the equipment only if:

- Maintenance, installation, extensions, readjustments, modifications or repairs have been carried out by our service personnel or by personnel authorized by us.
- The electrical installation of the respective room complies with the standards of the VDE 0107
- The instructions in the operating manual are/were followed exactly when operating the device.

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