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Flow Therme

Insufflation Gas Heating System

Flow Therme	7642
Heating Tube (Reusable)	7642HS
Heating Tube (Disposable)	7642HSE

User Manual

WISAP Medical Technology GmbH
Fichtenstraße 27
85649 Brunnthal-Hofolding
Germany

Tel.: +49 8104 / 8908-0
Fax: +49 8104 / 8908-90
mail: info@wisap.de
http://www.wisap.de

D

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WISAP would appreciate any comments from users regarding possible errors or unclear passages in this manual. Since the improvement of our products is an ongoing process, we reserve the right to make design changes without notice.

ES

WISAP agradece expresamente todo tipo de indicaciones que el usuario pueda darnos sobre eventuales errores o vaguedades contenidos en el presente manual. Dado que seguimos perfeccionando constantemente nuestros productos, nos reservamos el derecho a introducir modificaciones técnicas sin previo aviso.

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CE marking according to Directive (EU) 2017/745

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	WISAP Medical Technology GmbH Fichtenstraße 27 85649 Hofolding Germany Tel.: ++49 8104/8908-0 Fax: ++49 8104/8908-90 e-mail: info@wisap.de

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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 appearance and technical performance of the product through continued development of the product.

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

Your WISAP Team

1.2 SCOPE OF THIS USER MANUAL

This user manual covers the following products:

Flow Therme	**7642**
Heating Tube (Reusable)	**7642HS**
Heating Tube (Disposable)	**7642HSE**

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 with which the handling of the product can be made more efficient and easier.

1.4 ABBREVIATIONS IN THIS USER MANUAL

SRC	Safety-related Checks
LMC	Legal metrological Control

2 SAFTEY

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.

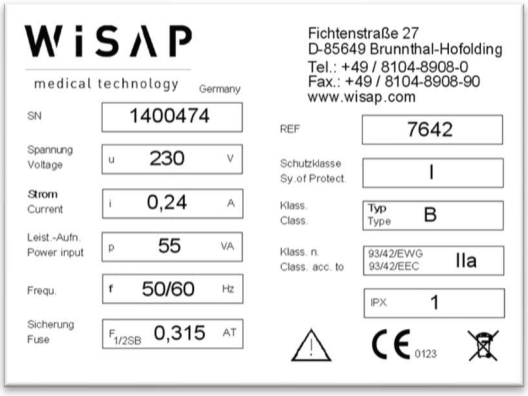


Figure 1: Type Label

Bildzeichen	Bedeutung
ON	Switch „OFF“ position
OFF	Switch „ON“ position
	Connection to the potential equalization
	Connection for Heating Tube
SN	Serial number of device
REF	Reference number
	Manufacturing date
	Manufacturer
	Accessory of type B
	Caution
	Consult instruction for use

Bildzeichen	Bedeutung
	Refer to the Manual!
IPX1	Protected against dripping water
IPX7	Protection agains the effects of temporary immersion in water
	The device must not be disposed of with normal hospital waste. For more information on disposal, please contact your authorized dealer or the manufacturer.
CE 0123	CE mark with identification number of the notified body. The product complies with the Essential Requirements of the Directive Regulation (EU) 2017/745 (MDR).

2.2 ICONS AND SYMBOLS ON THE PACKAGING

Bildzeichen	Bedeutung
	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!

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

DANGER!

The Flow Therme 7642 must be set up so that a separation of the electrical connector can be accomplished from the mains supply without difficulties!

DANGER!

To avoid the risk of electric shock, the Flow Therme 7642 may be connected only to a supply network with equipment grounding conductor!

DANGER!

Do not touch simultaneously the patient and the Flow Therme 7642 in order to avoid the risk of electric shock.

DANGER!

Only use sterilized accessories and heating tubes for each patient. Risk of infection!

DANGER!

Accessories that are designed for single use are not safe for a second application. The sterile single use parts are not designed for processing!

DANGER!

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

DANGER!

The WISAP Flow Therme 7642 is a precision device, which has solely to be operated with genuine WISAP accessories! The use of other than in the instructions specified accessories may result in increased electromagnetic emission, an increased effective radiated power or decreased immunity of the Flow Therme 7642.

DANGER!

The Flow Therme 7642 may not be used arranged stacked next to or with other devices! When the operation close to or stacked with other equipment is required, the Flow Therme 7642 should be observed to verify their intended operation in this used arrangement.

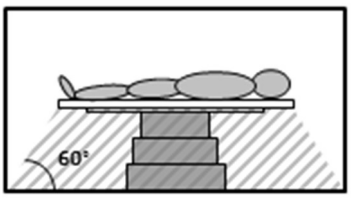
2.4 WARNINGS

WARNING!

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

WARNING!

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



WARNING!

The user is fully responsible for observing the applicable cleaning, disinfection and sterilization regulations. Errors caused by non-observance of the above regulations are not at the expense of the manufacturer and exclude any warranty and damage claims.

WARNING!

It is important to ensure that before surgery, cleaning and disinfecting agents are thoroughly removed. The approved residue limits must be observed.

WARNING!

Do not use this device as addition to the N2O-insufflator or to an Hysteroscopy insufflator.

WARNING!

The heating tube must not be squeezed, kinked or over-stretched, as this would lead to damage at the heating element and thus to failure of the gas heating system.

WARNING!

The device is only suitable for cold gas insufflation. The temperature of insufflation gas before insufflation must be < 26°C. There is overheating danger when the gas temperature is > 26°C.

WARNING!

For each operative intervention, we would recommend to have replacement heating tubes available.
Have a replacement Flow Therme 7642 available in the OR, which can be used in case of failure at the unit.

WARNING!

The Flow Therme 7642 device, including the accessories and cables, must be kept at least 30 cm away from the stationary transmitters (for example base stations of cellular and land mobile radios, amateur radio stations, AM and FM radio and television transmitters).

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 have been installed according to the guidelines of DIN VDE 0107.

CAUTION!

Before connecting this device to the mains power supply make sure the supply network is in compliance with the specified requirements (power voltage, frequency and fuses). Only then the device may be connected to the mains.

CAUTION!

Pay attention to the integrity of the packaging of the device. When the packaging is damaged upon arrival, WISAP can no longer guarantee the full functionality of the unit, please contact the manufacturer immediately.

CAUTION!

The controlling unit must not be sterilized!

CAUTION!

Heating tube and all further accessories used need to be exchanged after treatment of each patient!

CAUTION!

Run a visual inspection of this 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!

Check the appliance and all accessories for proper operation before each procedure. In case of detected or suspected defects the products is not to be used.

CAUTION!

The selection of the proposed intervention and the required instruments is the sole responsibility of the treating physician, regardless of the instructions given in this manual.

CAUTION!

Place the unit out of the reach of the patient!

CAUTION!

Please make sure that no liquid enters into the unit or that the controller unit does not get in touch with liquids.

CAUTION!

In order to ensure good dissipation of heat generated during an operation the control unit must not be covered with cloth.

CAUTION!

Opening of the housing (chassis, accessories), any repairs, modifications and calibrations may only be performed by the manufacturer or by personnel explicitly authorized by the manufacturer!

CAUTION!

Prior to opening the chassis, to exchange of fuse(s) or cleaning, please disconnect mains plug!

CAUTION!

Do not kink, squeeze, overstretch or overturn heating tube!
Damaged heating tube must be replaced by an intact!

CAUTION!

All processing operations must only be carried out in case of complete separation from the mains supply!

CAUTION!

Separate plugged instruments. Processing of the instruments is performed in this separate state.

CAUTION!

Only ever use a combined cleanser and disinfectant if no visible soiling is present.

CAUTION!

The heating tube should not be cleaned in disinfectant for more than 30 minutes. Silicone absorbs different disinfectants and would be damaged during subsequent steam sterilization!

CAUTION!

We suggest our customers to apply this device in standard OP room – the room temperature is between 22 and 26 °C. In situation that the room temperature is > 26°C, the gas temperature must be considered. There is overheating danger by gas temperature > 26°C.

2.6 NOTES

NOTE!

The user-manual have to be kept at a well-visible place nearby the unit.

NOTE!

Retain the instructions for use during the service life of power drive.

NOTE!

Give these instructions to any subsequent owner or user of the Flow Therme 7642.

NOTE!

Install the device onto a plane surface. It is recommended to secure the device against slipping.

NOTE!

For the correct use of this device it is important that the device adapts to the ambient conditions (room temperature). Please wait about 15 minutes after installation before you begin the application. This applies both to the first use and in the event that the device is transported to another environment.

NOTE!

Please consult the pertinent medical literature for techniques, complications and hazards.

3 PRODUCT DESCRIPTION

The WISAP Flow-Therme 7642 with the reuseable heating tube (REF 7642HS) or disposable heating tube (REF 7642HSE) serves – in conjunction with the CO2 cold gas insufflator – for preheating of insufflation gas to body temperature during diagnostic/ therapeutic Pelviscopies/Laparoscopies.

3.1 INTENDED USE / PURPOSE

The purpose or intended use of application for Flow Therme 7642 is:

Type of Device:	therapeutic device in the field of pelviscopy, laparoscopy
Application:	Insufflation of warm CO2 gas during endoscopic surgery
Application Field:	The Flow Therme is used in conjunction with the CO2 Insufflation Heating Tube to insufflate warm CO2 gas during endoscopic surgery. The body part that interacts indirectly with the airbag is the inner tissue. The application is intended only for patients with indicated surgery under general anesthesia.
Application Environment:	The Flow Therme is intended only for use in the operating room with the appropriate environmental conditions.

WARNING!

Do not use this device as addition to the N2O-insufflator or to a Hysteroscopy insufflator.

3.2 INDICATION/CONTRAINDICATION

The insufflation of cold gas leads to hypothermia of the abdominal cavity with a Peritoneal episode catarrh, which can be painful postoperatively. Especially for longer lasting therapeutic interventions associated with higher gas consumption, there is a significant cooling of the abdominal cavity.

After application of heated gas to body temperature of postoperative pain medication usage drops significantly, the subjective, postoperative patient comfort increases proven, many postoperative felt shoulder pain can be reduced.

The medical device is suitable for a patient population from a minimum of 5 years up to geriatric. A minimum weight of the patient is 30 kg.

Use of this device is contraindicated, whenever diagnostic/therapeutic Pelviscopy/ Laparoscopy is contraindicated.

3.3 INTENDED EFFECT / SIDE EFFECTS

By warming the CO2 gas during pelviscopic laparoscopic interventions a pain reduction in the area of the postoperative regeneration process is to be obtained. In addition, the occurrence of tachycardia and hypothermia during the course of the operation is reduced.

3.4 USER GROUP

The device may only be operated by surgeons with experience in endoscopic procedures during minimal invasive surgery and gynecology or from which authorized persons.

DANGER!

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

3.5 OPERATING PRINCIPLE

The basic performance of the Flow Therme 7642 is to provide a heating current for a heating tube with the parameters:

- Heating voltage: 20 VDC ± 10%,
- Heating current: 1 A ± 10%.

The heating coil in the disposable heating tube or the heating coil mesh in the reusable heating tube is heated by electrical energy. The insufflation gas flowing through the heating tube is added with thermal energy through the heating coil or the heating coil mesh and thus the cold insufflation gas (< 26°C) is heated to 37 ± 3°C.

The worst possible error with this device is the overheating due to higher voltage. In this case, the device is switched off by the built-in heating circuit fuse and has no function. The insufflation is thus carried out without heated gas - there is no immediate danger to patients or users.

NOTE!

Flow rate can directly affect the result of heating. From 5 l/m, the gas is heated in the appropriate temperature range (37 ± 3 ° C). Below 5 l/m, the temperature of the gas is greatly reduced with flow rate.

3.6 VARIANTS OF THE MEDICAL PRODUCT

The device can be provided for different operation currents and voltages. Further variants are not available.

3.7 LITERATURE

[1] Schmerzreduzierung nach pelvi-/laparoskopischen Eingriffen durch Einblasen von körperwarmem CO2Gas (Flow-Therme); K. Semm, W.-D.Arp, M. Trappe, D. Kube; Geburtsh. u. Frauenheilk. 54 (1994) 300304; Georg Thieme Verlag Stuttgart - New York

[2] Laparo-endosk. chir. 1, 21-22 (1992) Hans Marseille Verlag GmbH München

(Selection)

3.8 COMPONENTS OF THE MEDICAL PRODUCT

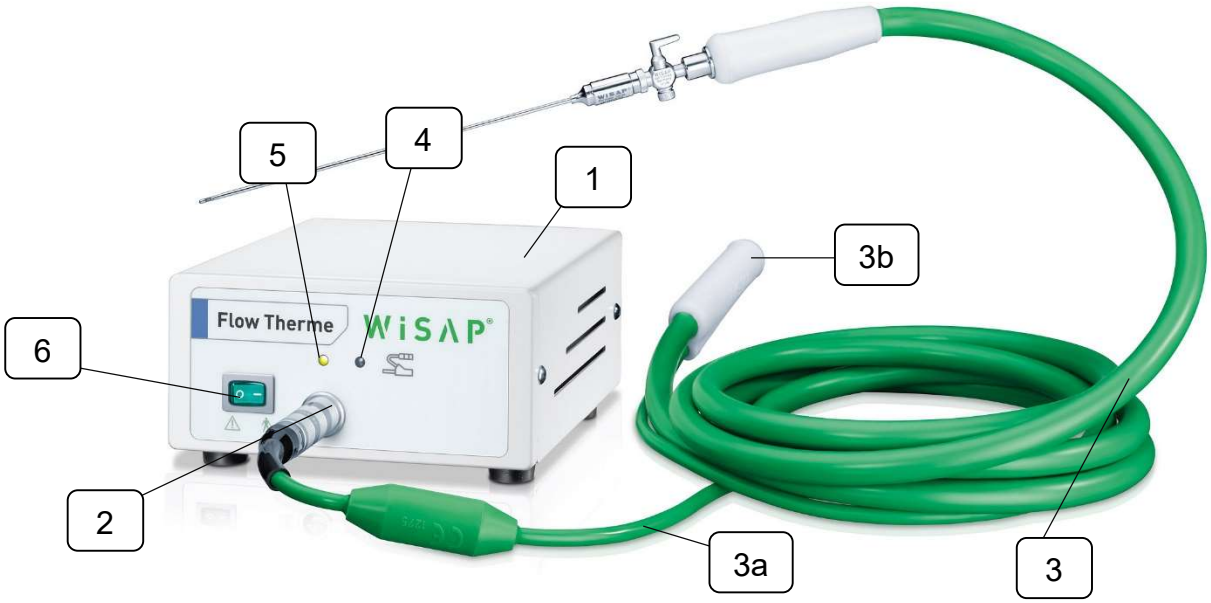


Figure 2: Front Side

Figure 3: Front Side

No.	Component /Element	Function
1	Control unit Flow Therme 7642	The control unit Flow Therme 7642 provides the necessary supply voltage for the intended use of the heated hose.
2	Connection socket for heating tube cable	To this socket, the plug of heating tube cable **3a** is attached.
3	Heating tube	The heating tube cable is attached to receptacle **2** of the unit. The heating tube preheats insufflation gas to body temperature; needs to be replaced after each operative intervention.
3a	Heating tube cable with plug	About the Heating tube the insufflation gas is preheated to body temperature.
3b	Connection cap for insufflation unit	With the connection cap, the heating tube is attached to the insufflator.
4	LED “Control of heating voltage”	Green LED „Control of heating voltage“ lights up, if supply voltage for the heating tube is available inside the unit. 🟢
5	LED “Interrupted heat circuit”	Red LED flashes, the green LED is illuminated, if heating circuit is interrupted or the heating current is to low, i. e. • Heating tube is not connected • Heating tube is defective • Circuit breaker at the rear of the unit has released. 🟢 🔴

6	Mains switch	Mains switch for turning the unit Flow Therme 7642 on and off, ON = I, OFF = 0. Green rocker switch illuminates, if unit is ON.

The device is only separated from the mains with all poles, if mains plug is disconnected. Only turn device on, when all connections are established.

7	Circuit breaker	Circuit breaker releases, if heating tube **3** or connection cable **3a** are overstressed, for instance by squeezing, kinking or overturning. Released fuse can be reset by depressing the black fuse knob.
8	Grounding connection	The potential equalization connector allows connection of other active devices on the same ground potential or is used for redundant connection to the protective earth. The potential equalization connector complies with the requirements of the standard IEC 60601-1.

CAUTION: Adequate grounding is only guaranteed, if a connection between the pin at the unit and the stationary potential equalization bar has been established.

9	Mains connection with fuse drawer	Mains connection with fuse drawer. Only operate device with the voltage and the fuses indicated on type plate.
	Type plate	On the type plate, technical data, as well as type and serial number of our unit can be found, which need to be indicated when ordering spare parts or asking any questions.

4 PUTTING INTO OPERATION

4.1 KIND OF DELIVERY

The device and its accessories are carefully packed with different protecting materials. Remove the Power Drive and all its accessories from the packaging.

DANGER!

Only use sterilized accessories for each patient.

CAUTION!

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

CAUTION!

Pay attention to the integrity of the packaging of the device. When the packaging is damaged upon arrival, WISAP can no longer guarantee the full functionality of the unit, please contact the manufacturer immediately.

NOTE!

Install the device onto a plane surface. It is recommended to secure the device against slipping.

Pay attention to the integrity of the packaging! If the packaging is damaged, a permissible use can no longer be guaranteed. Contact immediately the manufacturer!

If the packaging of the heating 7642 HSE1 damaged, it can’t longer be guaranteed a sterile condition of the disposable heating tube and the heating tube must not be used!

4.2 SCOPE OF DELIVERY

The standard delivery of this device includes:

Image	Definition	Article Number
	Controller-unit	7642
	Power-Cord	
	User Manual	

4.3 CONDITIONS FOR OPERATION

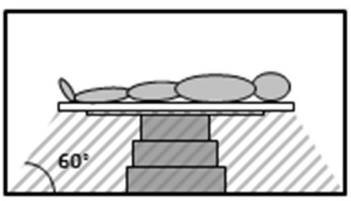
Operation	+10°C bis + 35°C
Storage and transport	- 10°C bis + 60°C
Humidity	max. 85 %

WARNING!

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

WARNING!

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



4.4 ASSEMBLING

4.4.1 Location

Install the device onto a plane surface. It is recommended to secure the device against slipping.

4.4.2 Connection to the Heating Tube

Insert the plug connector of the used heating cable into the socket of the control unit Flow Therme 7642.

Pay attention to the coding of the connector: The arrow on the connector must point to the mark on the sleeve!

4.4.3 Connection to the Insufflator

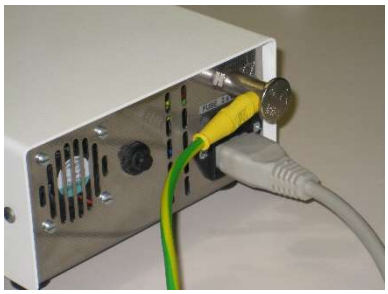
Connect the connector cap of the used heating tube to the insufflation device.

Pay attention to tightness of the connector!

4.4.4 Connection to the Grounding

Connect the potential equalization connector on the rear of the Flow Therme 7642 with a green-yellow potential equalization cable and connect it to the hospital's own potential equalization rail or when mounting the unit in an equipment trolley with its potential equalization connection.

4.4.5 Connection to the mains



Attach mains cable to receptacle at the rear of the Flow Therme 7642.

CAUTION!

Before connecting this device to the mains power supply make sure the supply network is in compliance with the specified requirements (power voltage, frequency and fuses). Only then the device may be connected to the mains.

CAUTION!

Prior to opening the chassis, to exchange of fuse(s) or cleaning, please disconnect mains plug!

NOTE!

For the correct use of this device it is important that the device adapts to the ambient conditions (room temperature). Please wait about 15 minutes after installation before you begin the application. This applies both to the first use and in the event that the device is transported to another environment.

4.4.6 Connection with the needle acc. Veress

Connect the needle acc. Veress with help of the Luer-Lock at the heating tube.

4.5 FIRST PUTTING INTO OPERATION

CAUTION!

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

CAUTION!

Run a visual inspection of this 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!

Do not kink, squeeze, overstretch or overturn heating tube!
Damaged heating tube must be replaced by an intact!

CAUTION!

The device may only be operated in medically utilized rooms, which have been installed according to the guidelines of DIN VDE 0107.

CAUTION!

Place the unit out of the reach of the patient!

CAUTION!

Please make sure that no liquid enters into the Controller unit or that the unit does not get in touch with liquids.

CAUTION!

In order to ensure good dissipation of heat generated during an operation the control unit must not be covered with cloth.

NOTE!

The user-manual have to be kept at a well-visible place nearby the unit.

NOTE!

Install the device onto a plane surface. It is recommended to secure the device against slipping.

NOTE!

For the correct use of this device it is important that the device adapts to the ambient conditions (room temperature). Please wait about 15 minutes after installation before you begin the application. This applies both to the first use and in the event that the device is transported to another environment.

4.5.1 Switch ON

- Turn on the Flow Therme 7642, by setting the power switch to the "I" position.

The following states of the control elements can be identified:

- the green rocker switch will light,
- the green LED " Control of heating voltage " lights,
- the red LED " Interrupted heat circuit " does not blink.

4.5.2 Switch OFF

• Turn off the flow Therme 7642, by setting the power switch to the "O" position.	The following states of the control elements can be identified: • the green rocker switch will not light, • the green LED " Control of heating voltage "will not light, • the red LED " Interrupted heat circuit " does not blink.
• Disconnect from the mains supply by removing the power cord to unplug the power cord from the wall outlet. Note that the appliance is only completely disconnected from the power supply when the power cord is unplugged.	
• Disconnect the power cord from the power cord socket of the control unit Flow Therme 7642 and keep it close to the unit.	

4.6 FUNCTIONAL TEST

The execution of the functional test is dictated by the standards of IEC 60601-1. It has to be performed prior to each operative intervention. Functional test serves for inspection of the device in conjunction with its accessories (Heating Tube).

Description of Functional Control

1. Join Flow-Therme 7642 with central potential equalization via grounding cable.	-
2. Attach mains cable to Flow-Therme and connect to power supply network.	-
3. Activate mains switch **1**.	⇒ Rocker switch lights up green ⇒ Red LED flashes ⇒ Green LED lights up
4. Attach heating tube cable **5a** to connection socket **2**.	⇒ Green LED lights up ⇒ Red LED does not flash ⇒ The heating tube reaches its operating temperature after about 15 minutes.
5. After completion of the functional control, set mains switch **I** to „**O**“.	-

5 OPERATION

DANGER!

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

DANGER!

Only use sterilized accessories and heating tubes for each patient. Risk of infection!

DANGER!

Accessories that are designed for single use are not safe for a second application. The sterile single use parts are not designed for processing!

CAUTION!

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

CAUTION!

Do not kink, squeeze, overstretch or overturn heating tube! Damaged heating tube must be replaced by an intact!

NOTE!

Please consult the pertinent medical literature for techniques, complications and hazards.

5.1 HANDLING OF THE FLOW THERME

Observe the control LEDs of the Flow Therme 7642 to minimize risks of operating errors.

6 HYGIENIC MEASURES

In order to maintain effectiveness of the unit, maintenance and storage have to be thoroughly taken care of. The accessories coming into contact with human tissue need to be sterilized for avoiding infections to the patient.

DANGER!

Accessories that are designed for single use are not safe for a second application. The sterile single use parts are not designed for processing!

WARNING!

The user is fully responsible for observing the applicable cleaning, disinfection and sterilization regulations. Errors caused by non-observance of the above regulations are not at the expense of the manufacturer and exclude any warranty and damage claims.

WARNING!

It is important to ensure that before surgery, cleaning and disinfecting agents are thoroughly removed. The approved residue limits must be observed.

CAUTION!

Opening of the housing (chassis, accessories), any repairs, modi¬fications and calibrations may only be performed by the manufacturer or by personnel explicitly authorized by the manufacturer!

CAUTION!

All processing operations must only be carried out in case of complete separation from the mains supply!

CAUTION!

Separate plugged instruments. Processing of the instruments is performed in this separate state.

CAUTION!

Please make sure that no liquid enters into the unit or that the controller unit does not get in touch with liquids.

CAUTION!

Only ever use a combined cleanser and disinfectant if no visible soiling is present.

6.1 PREPARATION

Prepare each health measure by following these steps:
- Turn off the Flow Therme 7642 by switching the rocker in the position "**O**".
- Disconnect the power cord from the mains supply by removing the plug from the power cord from the wall outlet.
- Unplug the power cord from the control unit Flow Therme 7642 and keep it close to the machine.
- Remove the connection cap from insufflation device.
- Remove the heating tube from the socket of the Flow Therme 7642.

Follow the instructions of the following chapters, only then can a proper processing can be ensured. A tabular summary is available in chapter 0.

Name of the cleaning solutions is to be understood as an example, the use of equivalent products from other manufacturers is also possible.

6.2 IMPORTANT NOTES

6.2.1 Processing of the Control unit 7642

In case of gross contamination of equipment surfaces, manual cleaning should be done prior to disinfection.

CAUTION!

The controlling unit must not be sterilized!

6.2.2 Processing of the Heating Tube 7642 HS

In the interest of safety for patients, users and third parties, the preparation of the heating tube 7642 HS should consist of the following steps:
- Manual pre-cleaning: Where the reusable heating tube is very heavily soiled, manual pre-cleaning with a disinfectant can take place. However, this should only be to ensure safety of personnel, since pre-disinfection can influence the subsequent cleaning process.
- Processing im WD (Cleaning and Disinfection mashine)
- Sterilization

- The reusable heating tube 7642 HS is delivered in a non-sterile condition and must be processed before usage.
- The reusable heating tube 7642 HS should be processed immediately after each use, as dried residues are difficult to remove and thus the effectiveness of a

subsequent disinfection or sterilization may be compromised. Furthermore, the function of the instrument can be functionally affected.
- Considering all given specifications (see also IFU of the reusable heating tube 7642 HS) a product lifetime at a max of 200 processing cycles is expected.
- Do not kink the heating tube. Ensure a roll up diameter > 20 cm.
- The reusable heating tube can be processed in a medical washing-machine.
- Do not clean heating tube (7642HS) in an ultrasonic bath!

6.2.3 Processing of the Heating Tube 7642 HSE

- The disposable heating tube, REF. 7642HSE is delivered in a sterile condition.
- Pay attention to the expiration date! If the expiration date expires, the disposable heating tube must not be used!
- Pay attention to the integrity of the packaging! If the packaging is damaged, a sterile condition cannot longer be guaranteed and the disposable heating tube 7642HSE must not be used!
- The disposable heating tube is to use only once per patient.
- The disposable heating tube cannot be processed.

6.3 CLEANING

6.3.1 Manual Cleaning Control unit Flow Therme 7642

Conduct the Cleaning as followed:
- The Cleaning of the unit can be carried out at the site of use.
- Wipe with a damp cloth the surface of the device in case of gross contamination.
- The unit must be processed manually.

Preparation for Cleaning:
- mild, biodegradable cleaning agents
- adequate, in clinical practice used for medical devices, cleaning agents

Cleaning Cycle:
- after each application

6.3.2 Manual precleaning of Heating tube 7642HS

See chapter 6.4.2.

6.4 DESINFECTION

6.4.1 Manual Disinfection Control Unit Flow Therme 7642

Conduct the Disinfection as followed:
- The disinfection of the unit can be carried out at the site of use.
- Wipe with a damp cloth with disinfectant the surface of the device. Note the manufacturer's instructions when using the disinfectant!

Preparation for Disinfection:
- Aqueous disinfecting solution concentration according disinfectant manufacturers,
- Disinfectants must be suitable for metal and painted plastic surfaces.

Disinfection cycle: Disinfection after each use.

6.4.2 Manual Disinfection of Heating tube 7642 HS

CAUTION!

The heating tube should not be cleaned in disinfectant for more than 30 minutes. Silicone absorbs different disinfectants and would be damaged during subsequent steam sterilisation!

Conduct the Cleaning/Disinfection as followed:
- The manual processing can be carried out at the place of the use.
- Never use aggressive solutions, such as chlorinated disinfectants, for example.
- Only ever use disinfectants whose bactericidal, viricidal and fungicidal efficacy has been proven.
- Cleaning and disinfectant solution must be compatible. Follow the recommendations of the cleanser and disinfectant manufacturer.
- Carry out the manual precleaning (manual cleaning and disinfection) in accordance to the manufacturer specifications. Consult manufacturers specifications for concentration, contact time and temperature, adjusting these to suit the processing activity in question.
- Rinse thoroughly the lumen with a water pressure gun to remove any residual dirt and soften them.
- The subsequent mechanical treatment should not be delayed more than 6 hours to prevent possible adhesion of organic material residues.
- Check all components after preparation on surface damage!

Preparation for Cleaning/Disinfection:
- Non-protein-fixing cleanser (e.g. gigazyme® from Schülke & Mayr)
- Non-protein-fixing combined cleaning and disinfection solution (gigasept® instru AF from Schülke & Mayr).

Cleaning/Disinfection Cycle:
- Should be processed as soon as possible following each operation and prior to the processing in the WD.
- Visible soiling must be removed immediately following use (within 2 hours). Dried-on residues are difficult to remove, present problems for subsequent disinfection or sterilization, and can also influence the proper function of the instrumentation.

6.4.3 Processing of Heating tube 7642 HS in Cleaning an Disinfection machine with a Vario-TD-program (WD)

Conduct the Disinfection as followed:
- The WD must be validated to EN ISO 15883.
- Note the recommendations and instructions of the WD manufacturer.
- Bring the heating tube (7642HS) into the WD and connect it to the rinsing port.
- Carry out the cleaning, the rinsing and the neutralization in the WD.

  Consult manufacturer specifications for concentration, contact time and temperature, adjusting these to suit the processing case in question.

- Carry out the thermic disinfection in the WD.

  Modify the Temperature and the holding time according to the required A0 value.

- Carry out the final rinsing with deionized water.

  DI water = de-ionized water = de-mineralized water.
  Water that is almost completely "free" of dissolved mineral salts. Not to be confused with "soft" water: with soft(ened) water, only the hardness-forming calcium and magnesium salts have been replaced by sodium ion exchange.
  For reasons of process optimization and validation capability, we recommend using only DI water from the prerinsing stage onwards.

- The level of organic and inorganic residues must not exceed the prescribed threshold values.
- Dry manually using a compressed air gun as required. Always use filtered air. Prior to sterilization the heating tube must be complete dry (at the outside and inside).

Preparation for Cleaning:
- Neutral or alkaline cleanser with a pH value of up to 11 (e.g. thermosept® alka clean forte from Schülke & Mayr GmbH, neodisher MediClean forte from Dr. Weigert).
- The cleaning solution must be suitable for silicone-rubber!

Preparation for Rinsing:
- e.g. thermosept® NKZ from Schülke & Mayr GmbH.
- The Flushing solution must be suitable for silicone-rubber!

Cleaning and Disinfection Cycle:
- Immediately after use (within 2 hours) and prior to the processing in the WD.

We recommend the following schedule:

Nr.	Step	Water	Time [min]	Temp [C°]	Product	Dosage
1	Pre-clean	VE	2	20		
2	Clean	VE	10	55	neodisher MediClean forte thermosept® NKZ from Schülke & Mayr GmbH	10 ml/l
3	Rinse	VE	1	20	thermosept® NKZ from Schülke & Mayr GmbH	
4	Final rinse and thermal disinfection	VE	5	93		
5	Dry		15	70		

6.5 STERILIZATION

6.5.1 Steam sterilization of Heating Tube 7642 HS in steam sterilizer

Conduct the Sterilization as followed:

- The steam sterilizer must be validated. It is important to note that these recommended sterilisation parameter are only valid, if the sterilising equipment has properly been maintained and calibrated.
- Follow the recommendations and instructions given by the steam steriliser manufacturer.
- Pack the heating tube in steam-permeable sterilization material. Double-layer steam-permeable sterilization packaging is permissible.
- Set the following parameters:
  - Conduct steam sterilization with triple fractioned prevacuum
  - Temperature: +134 °C
  - Holding time: 5 minutes.
  - Drying time: 20 minutes at +120 °C.
- Place the sterilized goods in a protective container and store at the prescribed location.

6.6 TABULAR OVERVIEW: CLEANING, DESINFECTION AND STERILIZATION

Correct method:

x = yes, - = no

	Cleaning				Disinfection			Drying	Sterilization			
	Mechanically	Chemi-cally	Ultra-sound	Washing machine	WD	Spraying	In solution	Hot air up to 120°C	Ethylene oxide	Steam		Hot air 180°C
										121°C/ 2,1bar (20 min)	134°C/ 3,0bar (5 min)	
Control unit, REF. 7642 Flow Therme	x	-	-	-	x	-	-	-	-	-	-	-
Heating tube, REF. 7642HS	x	x	-	x	x	x	x	x	x	x	x	-

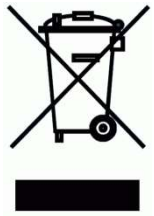
WD = Washer-Disinfector

7 TROUBLE SHOOTING

Fault Description	Possible Causes	Remedy
• No device function • No display is activated • Mains switch 1 does not light up	• Breakdown of mains supply • Mains fuses are defective • Voltage on type plate does not match with mains supply	• Have supply network checked • Exchange fuses: observe type of fuse • Have device serviced by manufactorer or authorized dealer
• Heating tube 5 does not warm up • Red LED 4 flashes; Green LED 3 lights up	• Heating tube is not connected • Heating tube or connection cable to heating tube is defective • Circuit breaker at the rear of the unit has released • Interruption or short-circuit at heating tube	• Check heating tube cable as to correct connection to the unit • If the fault can clearly be simulated by moving the heating tube cable, the heating tube is defective – exchange heating tube • Depress circuit breaker. If circuit breaker releases again, use other heating tube or have device and heating tube serviced by manufacturer or authorized dealer.
• Green LED 3 does not light up	• Device failure	• Fault can only be removed by opening the unit (manufacturer or authorized dealer).

8 DISPOSE

At the end of product life, the components of this device should be disposed of properly. Pay attention to a careful separation of materials. The materials used do not contain dangerous goods. The housing material is recyclable. The electronics boards should be disposed through an appropriate recycling process.



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

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

9 LIST OF ACCESSORIES

The following parts, for use of the Flow-Therme 7642, can be ordered at WISAP Customer Service:

Components

REF.-Nr.	Article	Note
190-0001	Mains cable	

Accessories

REF.-Nr.	Article	Note
7642HS	Heating tube	For the insufflation of heated gas, capable of sterilization, 2,75m
7642HSE1	Heating tube	Disposable, sterile, Silicone connection tube with LL-connection, L=2,8m, 10 piece/pac.
7160W	Veres Needle	L=100mm
7160W1	Veres Needle	L=120mm
7160W2	Veres Needle	L=70mm
7160W3	Veres Needle	L=150mm
7070TFW2	Filter	Sterile, piece/pac.
7070TA	Filter adaptor	

Spare parts

REF.-Nr.	Article	Note
500-0009	Housing L-angle	
590-0031	Housing socket	
416-0006	Fuse	0,315 A
464-0002	Fans	
449-0007	Transformer	
437-0044	Heating control board	
506-0010	Front frame	
560-0012	Front panel foil	

411-0003	Build-in rocker switch	Illuminated, 250V
501-0010	Lid	

10 TECHNICAL DATA

Control unit 7642 Flow-Therme

Classification acc. to:	
- 93/42/EWG:	IIa
- Type of protection against electric shock:	Protection class I
- Degree of protection against electric shock:	Device type B (heating tube is the application part)
- Degree of protection against entering of water:	IPX1
Operating mode:	Continuous operation
Mains connection:	Available for alternating voltage 100 V, 110 V, 115 V, 127 V, 220 V, 230 V, 240 V / 50/60 Hz
Fuses:	2 x 0,63 AT for 100 ... 127 V 2 x 0,315 AT for 220 ... 240 V
Power input:	60 VA
Dimensions (w x d x h):	150 x 180 x 80 mm
Heating voltage:	20 VDC ± 10 %
Heating current:	1 A ± 10 %
Chassis:	Metal, plastic-coated/plastics
Weight:	2211 g
Ambient temperature:	
- Operation:	+ 10 °C to + 35 °C
- Storage and transport:	- 10 °C to + 60 °C
Air humidity:	
- Operation:	max. 85% (not condensing)
- Storage and transport:	max. 85% (not condensing)
Air pressure:	
- Operation:	700 - 1060 hPa
- Storage and transport:	700 - 1060 hPa

Application part: Heating tube 7642HS (reusable)

Classification acc. to:	
- 93/42/EWG:	IIa
- Type of protection against electric shock:	Protection class II
- Degree of protection against electric shock:	BF
- Degree of protection against entering of water:	IPX7 (temporary immersion)
Operating mode:	Continuous operation
Input voltage:	ca. 20 Vdc
Input current:	ca. 1 A
Electrical resistance:	ca. 20 Ohm
Surface temperature:	ca. 33 °C (without gas)
Power consumption:	ca. 20 W
Dimensions (lenght x diameter):	ca. 2,75 m x 12 mm
Material:	Silicone-rubber
Weight:	450 g
Ambient temperature:	
- Operation:	+ 10 °C to + 35 °C
- Storage and transport:	- 10 °C to + 60 °C
Air humidity:	max. 85% (not condensing)
Air pressure:	
- Operation:	700 - 1060 hPa
- Storage and transport:	700 - 1060 hPa

Application part: Heating tube 7642HSE (disposable)

Classification acc. to:	
- 93/42/EWG:	IIa
- Type of protection against electric shock:	Protection class II
- Degree of protection against electric shock:	BF
- Degree of protection against entering of water:	IPX1
Operating mode:	Continuous operation
Input voltage:	ca. 20 Vdc
Input current:	ca. 1 A
Electrical resistance:	ca. 20 Ohm
Power consumption:	ca. 20 W
Surface temperature:	ca. 31 °C (without gas)
Dimensions (lenght x diameter):	ca. 2,80m x 14 mm
Material:	PVC (medical grade)
Weight:	350 g
Ambient temperature:	
- Operation:	+ 10 °C bis + 35 °C
- Storage and transport:	- 10 °C bis + 60 °C
Air humidity:	max. 85% (not condensing)
Air pressure:	
- Operation:	700 - 1060 hPa
- Storage and transport:	700 - 1060 hPa

CE mark certifcation is in accordance with EC Directive 93/42/EEC Annex II

The nameplate contains technical data such as the type and serial number of your unit, which must always be specified when ordering replacement parts or requesting other information.

Upon request, circuit diagrams, spare part lists, descriptions, adjusting instructions and other documents will be made available to qualified technicians for repairing of unit parts, if the manufacturer considers them to be repairable.

General warning symbols in the Technical Description (IEC 60601-1-2 Sec. 5.2.2):

a) The use of accessories, transformers and cabling other than those specified - with the exception of transformers and cabling as sold by the manufacturer of the medical electrical product or system as replacement parts for internal components - may lead to an increase in emissions or reduced interference immunity on the part of the medical electrical product or system.
b) Medical electrical devices or systems may not be positioned in the immediate vicinity of one another or stacked with other equipment. However, if an operation requires close proximity to or stacking with other equipment, then the medical electrical device or system must be kept under observation so as to monitor its proper operation in the configuration as used.

11 OVERVIEW TO EMC

Manufacturer's Declaration for Electro-Technical Compatibility
Acc.to IEC 60601-1-2
for the WISAP Insufflation-gas-heating system Flow Therme 7642 incl. Accessories

Guidance and Manufacturer Declaration - Electromagnetic Emissions		
The system 7642 is designed for operation in an environment as stated below. The customer or the operator of the device must ensure that it is operated in an environment of this kind.		
Emitted interference/ emission test	**Compliance**	**Electromagnetic Environment -Guidance**
RF emissions CISPR 11	Group 1	The level of unintentionally generated RF emissions is very low and is unlikely to cause disruption to neighboring electronic equipment. The device is suitable for use in all establishments, including those in residential areas, as well as those connected directly to a public power grid that is also utilized for residential purposes. (1*) The power input 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 Declaration - Electromagnetic Interference Immunity			
The system is designed for operation in an environment as stated below. The customer or the operator of the system must ensure that it is operated in an environment of this kind.			
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 constructed from wood or concrete or be covered with ceramic tiles. If floors are covered with 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.
Surges 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 supply voltage variations in accordance with 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 Flow Therme 7642 requires continued operation even in the event of power supply interruptions, it is recommended to power the Flow Therme 7642 from an uninterruptible power supply or a battery.
Magnetic field at power frequency (50/60) Hz IEC 61000-4-8	**30** A/m	**30** A/m	Magnetic fields at power frequency should cor- respond to the typical value expected to be found a commercial or hospital environment.
U_T = Alternating mains voltage before application of test level			

Guidance and Manufacturer Declaration - Electromagnetic Interference Immunity			
The system is designed for operation in an environment as stated below. The customer or the operator of the system must ensure that it is operated in an environment of this kind.			
Interference immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic Environment - Guidance**
			Portable and mobile radio equipment should not be used in the vicinity of the device system, including its cabling than the recommended protective distance. **Recommended protective distance:**
Conducted RF disturbances IEC 61000-4-6	6 $V_{Effektivwert}$ 150 kHz to 80 MHz	6 $V_{Effektivwert}$	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 RF wireless communications 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 power rating of the transmitter in watts (W) and E is the immunity test level according to the transmitter manufacturer and d is recommended protective distance in meters (m). The field strength of stationary radio transmitters should be lower than the b compliance limit at all frequencies, as a verified by an on-site inspection Disturbances are possible in the vicinity of equipment marked with the following symbol: 
Note 1: At 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 of stationary transmitters, e.g. Base stations of cellular and land mobile radios, amateur radio stations, AM and FM radio and television broadcasters cannot be precisely predetermined. In order to avoid the electromagnetic interference from the stationary transmitter, the device Flow Therme 7642 including the accessories and cables must be kept at least 30cm away from the stationary transmitters.
b: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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

The device is intended for use in the electromagnetic environment in which radiated RF disturbance 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 equipment.

Rated maximum output power of transmitter in Watt	**Separation distance according to frequency of transmitter in meter**		
	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 rated at 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 rating of the transmitter in Watt (W) according to the transmitter manufacturer.

Note 1:
At 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 accessories need to pass a regular function and safety test according to IEC 60601-1. **Annual maintenance is therefore required.**

CAUTION!

Opening of the housing, any repairs, modifications and calibrations may only be performed by the manufacturer or by personnel explicitly authorized by the manufacturer!

CAUTION!

The changes of the mechanical condition or the use of external accessories / components are not permitted because they can change the important EMC properties of the device including the accessories used!

12.2 INSPECTION BEFORE STARTING, AFTER CHANGES AND AFTER REPAIRS

Testing prior to the first intended use, any modification and after maintenance is carried out in accordance with DIN EN 62353 ("Medical electrical equipment – Iteration-test and test after repair of medical electrical equipment").

Following tests must be conducted in a regular interval:

- Change Fuses when appropriate
- Check mechanical condition of the unit including the accessories
- Check the tight fit of all electrical equipment including the protective conductor connection
- Check the readability of all functionally important inscriptions and the nameplate
- Check the availability of all necessary documentation (instructions for use)
- Check the function of all controls, sockets and lights on the device
- Check the protective conductor resistance according to DIN EN 62353:2008-08, Section 5.3.2
- Check the leakage according to DIN EN 62353:2008-08, Section 5.3.3.

If no change in mechanical condition or use of unofficial components is detected during the test, no action for EMC must be taken. 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 test is the responsibility of the operator, but should regularly (12 month interval) be carried out by the manufacturer or a person authorized by him.

The individual test points can be found in chapter 12.2.

12.4 CHANGING THE FUSES

DANGER!

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

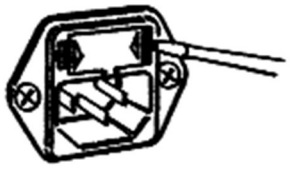
Turn OFF the device by pressing the OFF switch on the front of the device.

Disconnect the power cord from the power supply by removing the mains plug of the power cord from the power outlet.

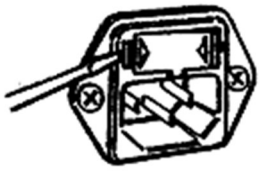
Remove the power cord from the power connector of the power drive and keep it close to the device.

The fuses are located above the mains socket.

Slide a suitable tool (screwdriver) into the right recess and press the lock to the left, so that the fusebox comes out slightly.

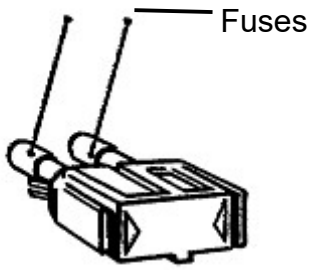


Slide a suitable tool (screwdriver) into the left recess and press the lock to the right, so that the fusebox comes out entirely.



Pull out the fusebox.

Remove the fuse and install the new one(s). Only use fuses with the correct electrical values (specification see chapter 10)



Install the fuse. Correct assembly on both sides is indicated by an audible "click".

12.5 SERVICE / REPAIR / MODIFICATION

All services such as regular maintenance, inspection, repair, modification, calibration, etc., shall be carried out with consideration of the special safety regulations for medical equipment by the manufacturer or by expressly authorized by him shall.

Performed services are filled in the table in chapter 12.7.

12.6 PRODUCT LIFE TIME

In observance and execution of all maintenance / service work a minimum service life of the Flow Therme 7642 of 10 years can be expected.

12.7 SERVICE TABLE

Date	Description	Signature

12.8 REPAIR AND RETURNS

If a repair is required, please advise us or 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 its original packaging and return it to us. Describe the error or malfunction and provide us the contact of a competent person for further inquiries with this repair.

*) Devices and accessories must be shipped in accordance with the information in this manual for the protection of service personnel and transportation safety.

THE CERTIFICATE OF DECONTAMINATION SHOULD CLEARLY ACCOMPANYING THE PACKAGE.
If this is not possible, the contaminated product must be clearly visible in and double-wrapped in a security film with an indication of the contamination.
The manufacturer may refuse contaminated products for repair.

13 INSTRUCTION

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

_____.

Training was conducted by Mr./Ms.: _____

The following person(s) received training:

_____ Function: _____

_____ Function: _____

14 WARRENTY / LIABILITY

This device is made with great care and has been thoroughly checked before delivery.

14.1 LIABILITY

We, as manufacturer of this device consider ourselves only liable for safety, reliability and efficiency of the unit, if:

- maintenance, assembly, extensions, readjustment, modifications or repairs have been performed by our service personnel or by personnel authorized by us.
- the electric installation of the respective room corresponds to the standards of VDE 0107
- the instructions in the operator manual are strictly observed when operating the unit.

14.2 WARRANTY

WISAP - Medical Technology granted a 12-months warranty on production- and material faults. Faults or defects caused by mishandling are not covered by warranty.

In case of unauthorized opening, modifications and/or repairs, we cannot be held liable for proper and safe function of the device. All warranty claims are declared null and void then.

- The unit is handled Improperly,
- Operator-errors cause damage to the unit,
- Failure to observe the instructions for use,
- Implementation of changes to the device (modifications, alterations extensions etc.) without written permission,
- Opening of the housing by unauthorized persons,
- Use of non-original accessories,
- Acts of God (such as lightning),
- Transport damage resulting from improper packaging when returning; in order to avoid transport damages, we advise you to pack the device including all components safe for transport,
- In case of defective packaging Repair costs are invoiced. Even during the warranty period will void any warranty,

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

WISAP Medical Technology GmbH
Fichtenstrasse 27
85649 Brunnthal-Hofolding
Deutschland

Telefon: +49 (0) 8104 89 08 00
Fax: +49 (0) 8104 89 08 90
E-Mail: info@wisap.de
Web: www.wisap.com

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