EN

TETRAFLATOR (7085/1800)

CO_2 – Insufflator for Medical Endoscopy

30 liter flow, gas-heating	7085	L30
30 liter flow, gas-heating and smoke-evacuation	7085	L30SE
45 liter flow, gas-heating	7085	L45
45 liter flow, gas-heating and smoke-evacuation	7085	L45SE

User Manual

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DE

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EN

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.

I

WISAP ringrazia per ogni comunicazione di eventuali errori o mancanze di chiarezza contenuti in questo manuale. Ci riserviamo il diritto di effettuare senza alcun annuncio delle modifiche tecniche in seguito alla continua evoluzione dei nostri prodotti.

CE marking according to Directive 93/42/EEC

Ihr Fachhändler / Your dealer / Su distribuidor / Il vostro concessionario /	Hersteller / Manufacturer / Fabricante / Costruttore /
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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:

30 liter flow, gas-heating	**7085**	**L30**
30 liter flow, gas-heating and smoke-evacuation	**7085**	**L30SE**
45 liter flow, gas-heating	**7085**	**L45**
45 liter flow, gas-heating and smoke-evacuation	**7085**	**L45SE**

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 backside of the device for example.

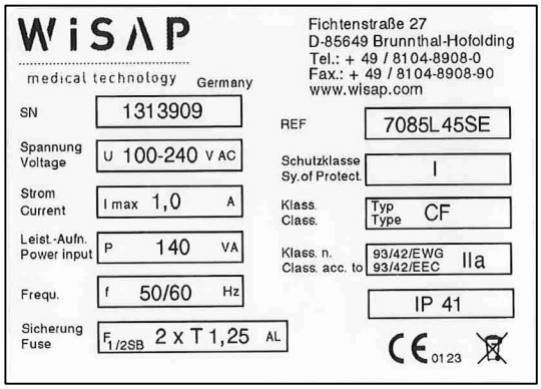


Figure 1: Type Label

Icon, Symbol	Description
ON	Switch „ON“ position
OFF	Switch „OFF“ position
	Connection to the potential equalization
Q	Symbol for gas flow – unit: *L / min*
V	Symbol für Gasverbrauch - Einheit: *Liter*
P	Symbol for pressure – unit: *mmHg*
SN	Serial Number of the Device
REF	Reference Number
	Manufacturing Data
	Manufacturer
	Applied part of type CF
I	Protection class 1
	Fine-wire fuse

Icon, Symbol	Description
	Caution
	Consult instruction for use
	Refer to the Manual!
IP41	Mechanical protection (protection against granular particles larger than 1 mm in diameter and dripping water entering vertically)
	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 mark with identification number of the notified body. The product complies with the Essential Requirements of Council Directive 93/42/EEC concerning medical devices.

2.2 ICONS AND SYMBOLS ON THE PACKAGING

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

2.3 DANGER

DANGER!

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

DANGER!

This unit may only be operated by properly qualified persons who have been trained in its use. Endoscopic instruments and equipment may only be used by physicians who have completed appropriate training.

DANGER!

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

DANGER!

Only use sterilized accessories for each 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!

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 use of endoscopic devices and instruments is restricted to authorized personnel / physicians only.

DANGER!

The WISAP Tetraflator 7085 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 Insufflator 7085.

DANGER!

The Tetraflator 7085 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 Tetraflator 7085 should be observed to verify their intended operation in this used arrangement.

2.4 WARNINGS

WARNING!

Please read these instructions carefully before you put your new unit into operation for the first time.

WARNING!

The use of this device is contraindicated whenever laparoscopy is contraindicated.

WARNING!

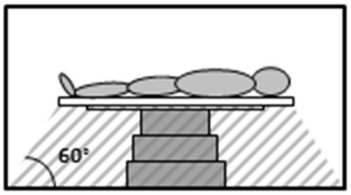
This device must not be used for intrauterine distension (cavum uteri)! Potential danger of embolism.

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 of 60 degrees.



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.

WARNING!

In case of unfavorable 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, since the insufflation draws heat from the body. The body temperature must be monitored during the entire insufflation. The risk for hypothermia can be significantly reduced with the use of gas pre-warmed to body temperature.

WARNING!

If for no apparent reason there is a high gas flow during the operation, immediately check the system for leakage.

WARNING!

Leackages in the insufflation line (e.g. open tube connection) may result in a risk for the patient!

WARNING!

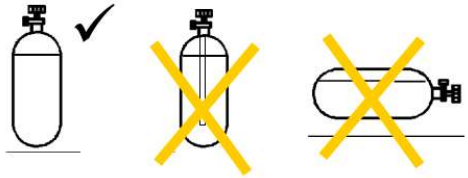
Position the patient nozzle of the insufflator and as much of the associated tubing as is practical above the insufflation site, so that any patient fluids (e.g. rinsing solutions) inadvertently entering the tubing do not drain back into the insufflator under gravity.

WARNING!

Please make sure that no liquid gas enters into the unit! This may results to glaciation and therefore an obvious reduction of the gas flow.

WARNING!

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



WARNING!

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

WARNING!

The Stand-By key does not disconnect the device from the power supply. To disconnect the device pull the power plug in rear of device.

WARNING!

The use of hydrophobic filter is strongly recommended to prevent patient cross-contamination! Reduced flow capacity should be considered when using a hydrophobic filter. Exchange a contaminated filter immediately to ensure unhindered gas flow. Use for each patient a new/sterile filter.

WARNING!

The Tetraflator 7085 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).

WARNING!

A reduction of the pressure pre-setting at a level below the actual body's cavity pressure will not result immediately in a release of gas from the body‘s cavity! A release of gas by the insufflator will only become initiated when the cavity pressure exceeds the pressure pre-set by more than 5 mmHg.
For quick release of pressure, allow gas to escape from any opening in the body cavity (e.g. open a stopcock).

WARNING!

Do not use the unit if possible contamination is suspected, faults or malfunctions are present or suspected, or the unit is obviously damaged.

WARNING!

Have the unit repaired by authorized service personnel.

WARNING!

BEFORE beginning operation for the first time, check whether the site voltage matches the voltage range specified on the nameplate. Incorrect voltage can cause errors and malfunction and destroy the equipment. A connection to the power supply must be performed with complians.

WARNING!

Position the patient nozzle of the insufflator and as much of the associated tubing as is practical above the insufflation site, so that any patient fluids (e.g. rinsing solutions) inadvertently entering the tubing do not drain back into the insufflator under gravity.

WARNING!

To prevent electrical shock, do not open this device. Refer servicing and calibration to qualified service personnel.

WARNING!

Operative procedures should only be performed with insufflators capable of flow rates of at least 4 – 10 L/min. Insufflators with lower flow rates should only be used for diagnostic procedures.

WARNING!

Always work exclusively with sterile substances, sterile fluids, and sterile accessories.

WARNING!

Note the user manual of the appropriate device or system.

WARNING!

PRIOR to starting the insufflation it is obligate to ensure the correct placement of the Primary Insufflation/Veress needle according to given procedures by literature.

WARNING!

The use of a sterile hydrophobic insufflation filter is obligate in order to meet the requirements of safety protection class CF!

WARNING!

If the unit is equipped with a CO_2 heating option it is obligate to use one of the hydrophobic insufflation filters listed in order to maintain safety protection class CF!

WARNING!

The MAX Mode operation is disabled in the NEONATAL Mode!
Always strictly monitor current cavity pressure and ensure that the leakage is not higher than 0.2L/min when performing laparoscopic procedures on children younger than 12 years of age.

WARNING!

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

2.5 CAUTIONS

CAUTION!

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician or other licensed practitioner.

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).

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!

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!

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

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!

Replace the fuse only with a fuse of the same type and rating!

CAUTION!

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

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 prevent symptoms of fatigue, make sure to supply the operating area with enough fresh air, since an increasing CO2 level of the air can result in symptoms of fatigue in the medical personnel.

CAUTION!

Always have a filled CO_2 bottle ready for replacement. This will prevent an interruption of the operation due to insufficient gas for the insufflation.

CAUTION!

It is prohibited to use the smoke evacuation for the suction of liquids!

CAUTION!

The suction tube has to be inserted first before switching on the device.

CAUTION!

The monitoring of the CO2 tank must not be switched “OFF“ when the clinical gas supply system isn’t itself monitored.

CAUTION!

Unplug the unit before cleaning.

CAUTION!

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

CAUTION!

Make sure that no cleaning agents ever get inside the unit.

2.6 NOTES

NOTE!

Report any serious incidents that have occurred in connection with the medical device to the manufacturer and the competent authority at their location.

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 Tetraflator.

NOTE!

Install the device onto a plane surface.

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.

NOTE!

The unit is tested and met the requirements of DIN EN 60601-1-2 (IEC 60601-1-2, EMC). Nethertheless we recommend to switch off and disconnect from power supply unused devices in the near surrounding.

NOTE!

The NEONATAL Indicator illuminates LIGHT BLUE only if NEONATAL Mode is activated and valid.

NOTE!

Please note that when using this equipment from multiple users to change the default setting can lead to misunderstandings.

3 PRODUCT DESCRIPTION

3.1 INTENDED USE / PURPOSE

Endoscopic diagnostic and therapeutic procedures usually place far less of a burden on the patient than traditional procedures.

The WISAP Tetraflator 7085 is used for establishing and maintaining a pneumoperitoneum for endoscopic procedures (diagnostic or operative laparoscopy). The Ultra Low Insufflation Mode of the device enables the indication for pediatric use.
In order to obtain reasonable viewing conditions and sufficient space for endoscopic procedures, the body cavity is to be dilated with CO_2.

In addition due to the use of energy processes (like electrosurgery) fumes are formed which could contaminate the surgeon or the surgical staff.
It is now demonstrated by numerous international studies and publications the harmful effects on the human body.
The smoke evacuation of WISAP Tetraflator can act against these harmful fumes.

CAUTION!

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician or other licensed practitioner.

3.2 INDICATION/CONTRAINDICATION

The Use of the device is indicated whenever laparoscopic medical use is indicated. For example, but not exclusively, the following applications may be an indication:

- Diagnostic laparoscopy (e.g., pelvic pain, pelvic masses, acute PID)
- Laparoscopic Evaluation (e.g., amenorrhoe, Ectopic pregnancy, Infertility)
- Surgical laparoscopy (e.g., biopsie, Fibroid removal, sterilization)

The use of this device is contraindicated whenever insufflation or smoke evacuation is contraindicated while diagnostic or therapeutic endoscopic (laparoscopic) interventions.

See the operator's manual of your laparoscope for absolute and relative contraindications.

The use is contraindicated for:

WARNING!

The use of this device is contraindicated whenever laparoscopy is contraindicated.

WARNING!

This device must not be used for intrauterine distension (cavum uteri)!
Potential danger of embolism.

Do not exceed a gas flow of 14 l/min when performing laparoscopy on infants or patients weighing less than 25 kilos (approx. 55 US pounds).

3.3 USER GROUP

The WISAP Tetraflator 7085 may only be operated by surgeons with experience in endoscopic procedures during minimal invasive surgery and gynecology.

DANGER!

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

DANGER!

The use of endoscopic devices and instruments is restricted to authorized personnel / physicians only.

WARNING!

Please read these instructions carefully before you put your new unit into operation for the first time.

3.4 OPERATING PRINCIPLE

The insufflator described in this user manual incorporates the latest technological safety standards and offers the user different types of insufflation mode:

- **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 of pressure limitation, a sudden interruption of a current gas flow may result in pressure peaks that exceed the pressure pre-setting.

- **I2S [Intelligent Insufflation System]**

  Advantages: The system automatically selects the optimal insufflation pressure according to the actual situs of the abdomen. The Insufflator recognizes the actual conditions during the operation (e.g. an exchange of instruments) and is thus able to select the most suitable insufflation mode.

WARNING!

In case of unfavorable 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, since the insufflation draws heat from the body. The body temperature must be monitored during the entire insufflation. The risk for hypothermia can be significantly reduced with the use of gas pre-warmed to body temperature.

WARNING!

If for no apparent reason there is a high gas flow during the operation, immediately check the system for leakage.

WARNING!

Leakages in the insufflation line (e.g. open tube connection) may result in a risk for the patient!

WARNING!

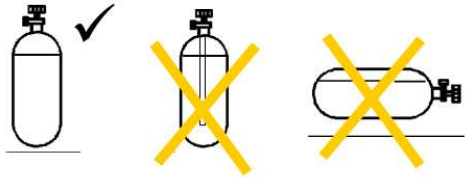
Position the patient nozzle of the insufflator and as much of the associated tubing as is practical above the insufflation site, so that any patient fluids (e.g. rinsing solutions) inadvertently entering the tubing do not drain back into the insufflator under gravity.

WARNING!

Please make sure that no liquid gas enters into the unit! This may results to glaciation and therefore an obvious reduction of the gas flow.

WARNING!

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



NOTE!

The unit is tested and met the requirements of DIN EN 60601-1-2 (IEC 60601-1-2, EMC). Nevertheless, we recommend to switch off and disconnect from power supply unused devices in the near surrounding.

3.5 VARIANTS OF THE MEDICAL PRODUCT

The WISAP Tetraflator 7085 is offered in different variants:

Type REF	*Volume*	*Integr. Gas heating*	*integr. Smoke evacuation*
7085L30	30 Litre	X	
7085L30SE	30 Litre	X	X
7085L45	45 Litre	X	
7085L45SE	45 Litre	X	X

3.6 COMPONENTS OF THE MEDICAL PRODUCT

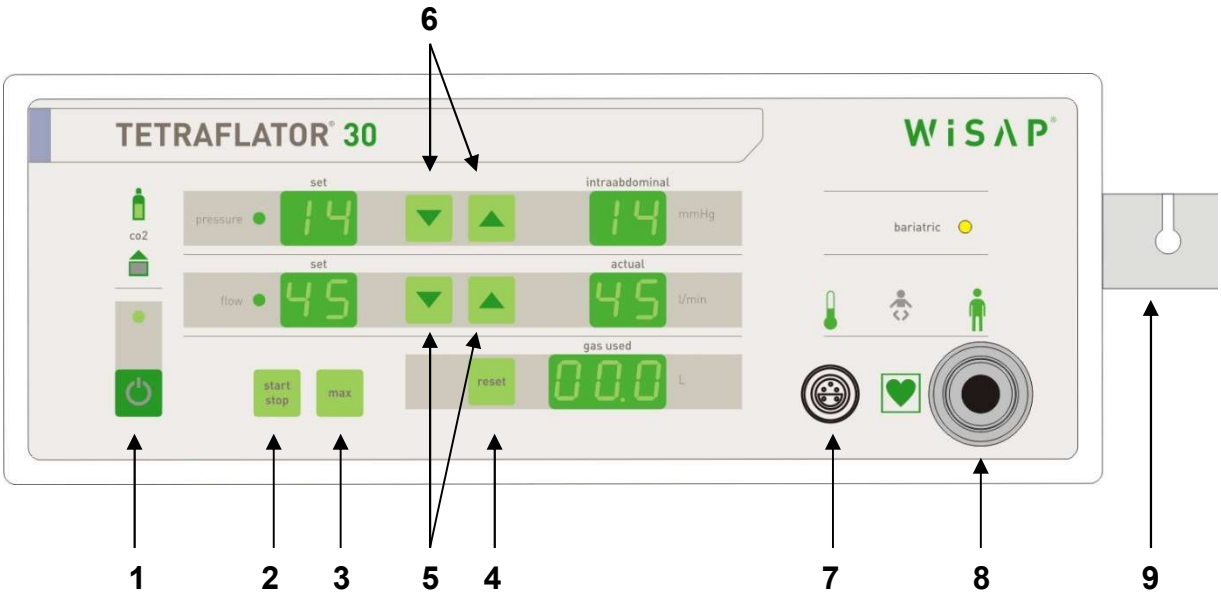


Figure 2: Operating elements on the frontside

No.	Component / Element / Function
1	Pushbutton for STAND-BY
2	Pushbutton to “START / STOP“ insufflation. (Insufflation mode “**LPS**“)
3	Pushbutton for the selection of “I2S“ insufflation mode
4	Pushbutton RESET for resetting the gas consumption display
5	Gas flow rate preselection pushbuttons
6	Pressure preselection pushbuttons
7	Connector for heating hose (only if unit is equipped with a CO2 heater, not available in U.S.A)
8	Patient nozzle (acc. to ISO 5356-1:1987)
9	Hose clamp valve (only for appliances equipped with fume extraction)

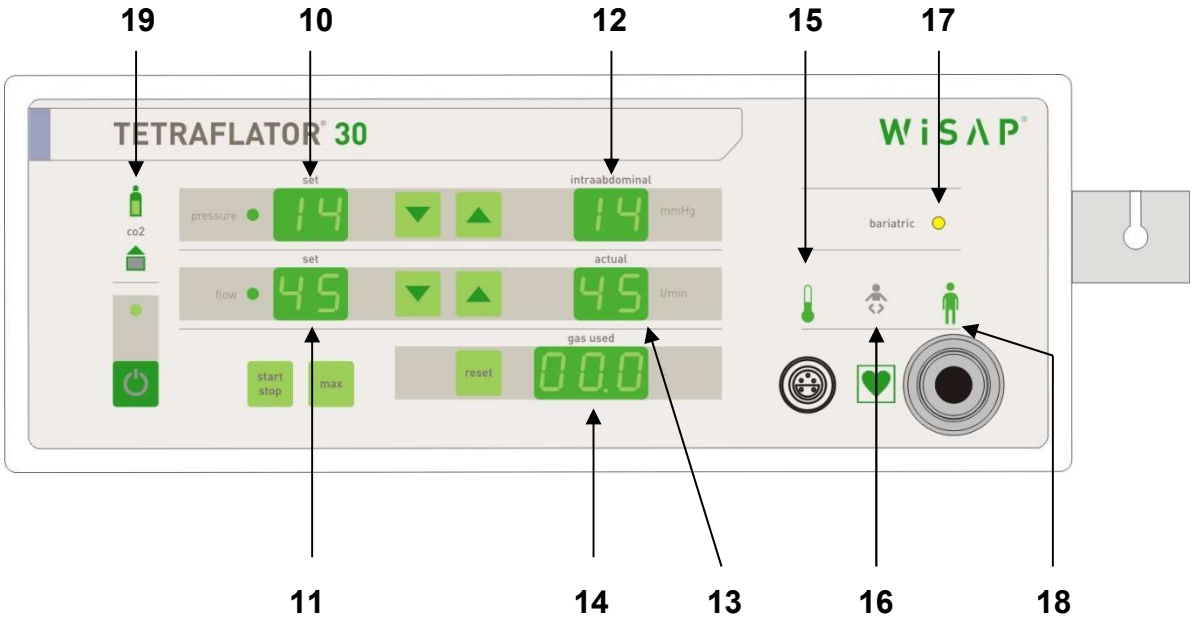


Figure 3: Indicator elements on the frontside

No.	Component / Element / Function
10	Display for indication of pre-set pressure
11	Display for indication of pre-set gas flow rate
12	Display for indication of current cavity pressure (unit*: mmHg*)
13	Display for indication of current gas flow rate (unit*: Liter / Minute*)
14	Gas consumption indicator (unit*: Liter*)
15	Symbol / indicator for heating status (only if unit is equipped with a CO2 heater, not available in U.S.A)
16	Symbol / indicator for Neonatal mode
17	Indicator for Bariatric mode
18	Warning light / Patient symbol
19	CO_2 pressure supply indicator - of high pressure CO2 tank - of clinical wall outlet supply

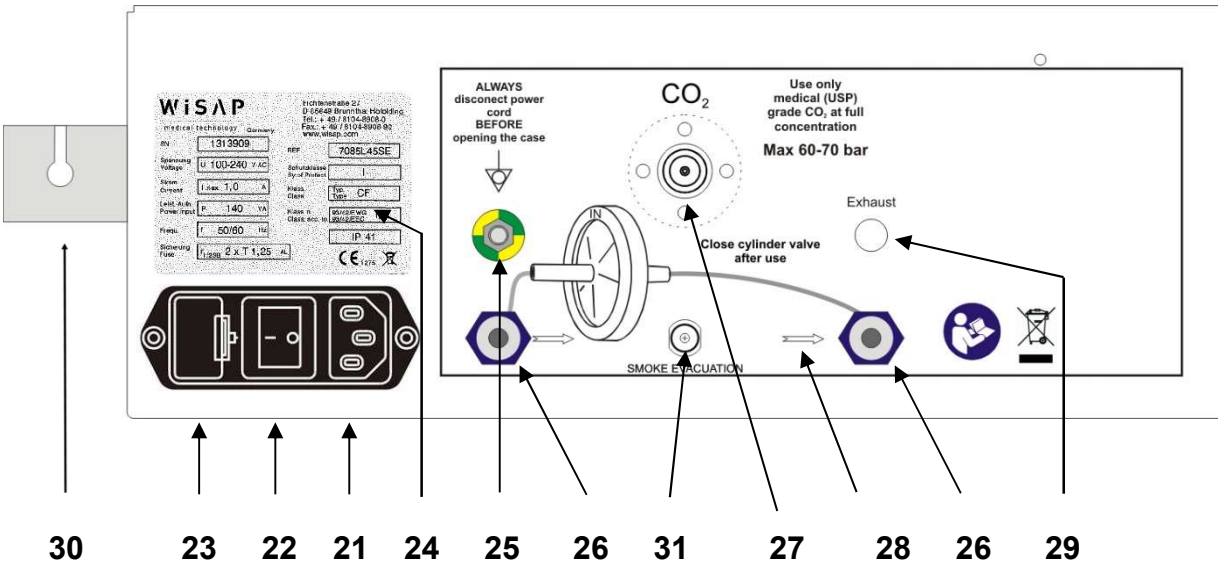


Figure 4: Backside

No.	Component / Element / Function
21	Connection to power supply
22	MAINS switch
23	Fuses (2 x fine-wire fuse as per IEC 127)
24	Nameplate
25	DIN 42801 socket for equipotential bonding conductor
26	Studs for the connection of external gas filter hoses
27	High pressure connection stud according to US-Standard (UNF 7/16“ 20G).
28	Exhaust pipe for exsufflation
29	Blowout opening for exsufflation
30	Back: Pinch Valves for smoke evacuation (only for devices with smoke evacuation)
31	Connection of foot switch for the activation of the smoke evacuation (only for devices with smoke evacuation)

WARNING!

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

WARNING!

The use of hydrophobic filter is strongly recommended to prevent patient cross-contamination! Reduced flow capacity should be considered when using a hydrophobic filter. Exchange a contaminated filter immediately to ensure unhindered gas flow. Use for each patient a new/sterile filter.

CAUTION!

Replace the fuse only with a fuse of the same type and rating!

Push-button for Stand-By

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

The unit performs a self-test when switched on (recognized by all Displays on).

The working parameters stored most recently are used as default settings.

WARNING!

The Stand-By key does not disconnect the device from the power supply. To disconnect the device pull the power plug in rear of device.

Display power supply

Illuminated in GREEN at accurate power supply

Illuminated in RED at inaccurate power supply

CO_2 – tank pressure indicator.

- Pressure level above 18000 mmHg (25 bars) is indicated in GREEN.
- Pressure level below 18000 mmHg (25 bars) is indicated in RED

Change the gas bottle when amount of gas remaining in the tank (see equation) is less than the volume of gas that is estimated for the completion of the operation:

Equation: Contents of CO_2 bottle (kg) x 20 Liters.

Clinical CO_2 – pressure supply indicator

Pressure supply monitoring is disabled!

(Gets illuminated, when a clinical supply has become selected. Alerting happens if gas supply completely absences.)

Pushbutton to START / STOP insufflation

Select insufflation mode LPS.

Gets illuminated brighter if activated.

	**Pushbutton to select I2S mode** Can be activated only if Insufflation is active. Gets illuminated brighter if activated. Store the default settings.
	**Pushbutton to Reset the gas consumption display**
	**Display to indicate the pressure pre-setting** Pre-settable pressure range from 3 – 30 mmHg increased in 1 increments. (SET flashes GREEN if pre-setting cavity pressure) The Display for the pre-setting pressure switches between preselected pressure and “H” if pressure preset ≥ 18mmHg.
	**Pushbuttons for the pre-setting of cavity pressure** Arrow down reduces pressure pre-setting. Arrow up increases pressure pre-setting.
	**Display to indicate the current cavity pressure (green)**

WARNING!

A reduction of the pressure pre-setting at a level below the actual body’s cavity pressure will not result immediately in a release of gas from the body‘s cavity! A release of gas by the insufflator will only become initiated when the cavity pressure exceeds the pressure pre-set by more than 5 mmHg.
For quick release of pressure, allow gas to escape from any opening in the body cavity (e.g. open a stopcock).

	**Display to indicate the gas flow rate pre-setting** (SET flashes GREEN if pre-setting gas flow rate) Pre-settable gas flow range from 0,1 – 2 L/min increased in 0.1 increments greater than 2L/min increased in 1 increments.
	**Pushbuttons for the pre-setting of gas flow rate** Arrow down: Reduce pre-setting of gas flow rate. Arrow up: Increase pre-setting of gas flow rate.

Display of the actual gas flow rate

The current gas flow depends on which insufflation mode is selected and is automatically pre-set by the insufflator according to need.

In LPS mode, the resulting gas flow rate directly depends on the lumen of the connected instrument. In this mode, the gas flow rate is normally less than in the I^2S-mode.

Display of gas used since last RESET.

Display to indicate the status of the CO_2-heater (not available in U.S.A)

The symbol is not illuminated (preheater is not activated) if no heating hose is connected to the insufflator.

When a heating hose is connected to the insufflator, the heater becomes automatically activated and the symbol is illuminated in GREEN.

When the symbol is illuminated in RED, a failure was detected and the electronic fuse was activated (e.g. due to a short circuit somewhere along the connected heating hose). This doesn't affect the insufflation procedure!

- the surgical intervention (operation) may then be finished without preheated gas.
- To reactivate the heater (to reset the electronic fuse) the insufflator is to be switched off for at least 5 sec.!

Patient Symbol and Warning Light

Illuminated in RED when the unit's safety system has detected a malfunction that may be harmful to the patient or personnel.

Neonatal Symbol

Illuminated in LIGHT BLUE if Neonatal mode is activated

bariatric		**Bariatric Indicator** Illuminated in YELLOW if preselect pressure is ≥ 18mmHg

WARNING!

Do not use the unit if possible contamination is suspected, faults or malfunctions are present or suspected or the unit is obviously damaged.

WARNING!

Have the unit repaired by authorized service personnel.

4 PUTTING INTO OPERATION

4.1 KIND OF DELIVERY

4.1.1 Packaging

The device and its accessories are carefully packed with different protecting materials. Remove the Tetraflator 7085 and all its accessories from the packaging.

4.1.2 Receiving Inspection

Inspect the unit and accessories included for obvious damage or missing parts immediately after receiving them.
Damage claims can only be acknowledged if the supplier is notified immediately (within 24 hours).

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

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

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.

4.2 SCOPE OF DELIVERY

The standard delivery of the WISAP Tetraflator 7085 includes:

Image	Definition	Article Number
	Controller-unit	
	Power-Cord	
	Hydrophobic Gas Filter for Heating tube (frontside, 1 piece)	7070TFW
	External Gas Filter for Gas Supply (backside, 1 piece)	7085FE
	Heating tube single use (1 piece)	7642HSE
	Filter adaptor for reusable tube (1 piece)	7070TA
	User Manual	

4.3 CONDITIONS FOR OPERATION

10° to 40°C	Ambient Temperature Operation
30% to 70%	Rel. Humidity
70 to 106 kPa	Air pressure

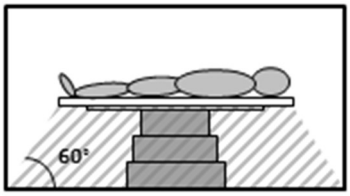
Further detailed operating conditions are listed in chapter 10.

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 of 60 degrees.



4.4 ASSEMBLING / FIRST PUTTING INTO OPERATION

4.4.1 Connection to Power Supply

Place the unit on a clean and level surface. Ambient temperature and humidity should be within the span indicated in the technical data sheet (see chapter 10).

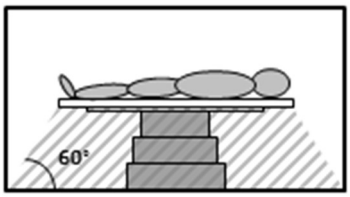
Prior to being put into operation, the unit must have been connected to an equipotential grounding by an appropriate equipotential bonding cable. The Connector for Equipotential Bonding (acc. to IEC 417-5021) is placed on the rear panel of the unit.

The device and connected thereto components must be connected to the equipotential bonding of the treatment room before contact with the patient via a proper grounding line. The insufflator is equipped with a rear panel socket that complies with DIN 42801. Use this socket to ground the unit according to local safety regulations.

The power connection must have a grounding contact. Please use the power cord supplied with the unit or an equivalent cord.

WARNING!

If explosive ANESTHETICS are in use, device and accessories must not be operated in the highlighted zone of 60 degrees.



WARNING!

BEFORE beginning operation for the first time, check whether the site voltage matches the voltage range specified on the nameplate. Incorrect voltage can cause errors and malfunction and destroy the equipment. A connection to the power supply must be performed with compliance.

WARNING!

Position the patient nozzle of the insufflator and as much of the associated tubing as is practical above the insufflation site, so that any patient fluids (e.g. rinsing solutions) inadvertently entering the tubing do not drain back into the insufflator under gravity.

WARNING!

To prevent electrical shock, do not open this device. Refer servicing and calibration to qualified service personnel.

CAUTION!

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

CAUTION!

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

CAUTION!

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

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!

Install the device onto a plane surface.

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 will help to remove any condensed water from the electronic circuitries.

This applies both to the first use and in the event that the device is transported to another environment.

4.4.2 Gas supply

The rear panel of the unit is equipped with a US- standard stud (UNF 7/16“ 20G) to allow the connection of a suitable high pressure hose (original equipment) to a CO_2 gas supply (Max. input pressure 16 MPa).

Different high-pressure hoses are available. Check with your local dealer which system is needed to connect the unit to your country`s standard gas supply.

WARNING!

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

WARNING!

The connection of the high-pressure tube to the device must be tightened to avoid injuries.

4.4.3 Gas filtering

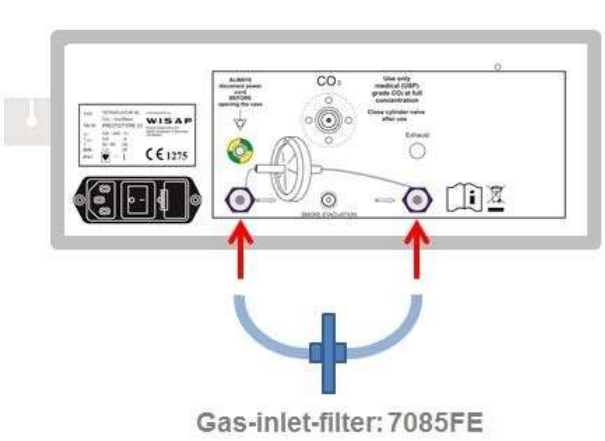
It is strongly recommended to use only medical (USP) grade CO_2 at full concentration.

To ensure purity of the insufflation gas, a gas filter (article No. 7085FE) must be implemented into the gas supply path.
Since this filter element with time due to pollution is increasingly less consistent, it must preserve the maximum Flowrate be regularly replaced.

WISAP recommends:

- Connected to gas bottles: with each bottle exchange
- Connected to house connection: after 10 OP’s (approx. 3000 litre)

For this the unit is equipped with a plug connection on the rear panel for smooth 6x4 polyurethane tubes. These are used to connect the CO_2 filter at the backside of the unit.



Connecting the Plastic Hose

Cut off the plastic tube straight.
Insert it into the threaded connection as far as it will go. The tube and threaded connection are now tight, 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.

4.5 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 and helps to ensure that the unit is ready for use.

This should be done prior to any clinical application:

- Connect unit to power supply and switch on power switch (situated at the rear panel).
    - The STAND-BY pushbutton is illuminated
    - All displays are disabled
- Switch ON unit by striking the STAND-BY pushbutton once
    - Display shows the default pressure presetting.
    - Display shows the default gas flow rate presetting.
    - Display shows the current cavity pressure ("0 mmHg" if patient stud is unconnected)
    - Display shows a flow rate of “0.0“
    - The indicator is lit up in green (patient symbol)
    - Display does not indicate an error message "E – X X"
- Start the insufflation in LPS mode (bottle valve closed)
    - Display has to indicate a flow of “0.0“ l/min
    - An audible and visual alarm is activated by the bottle monitoring system

- After the bottle valve has been opened, the pressure indicator should light up in GREEN (only when the tank is full!).

- Check the connected high-pressure hose to ensure it is secure and 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 deliver a rapidly increasing gas flow.
    - The increasing gas consumption is indicated.

- Slowly close the unit's gas outlet with your thumb until the gas flow stops.

    - The reading should return to "0.0".
    - The indicated pressure has to correspond to the pre-setting (±3 mmHg)

- Select insufflation mode I2S

    - The corresponding pushbutton (MAX) should light up

- Start the insufflation by striking the Start/Stop button

    - When the unit's outlet is open, the indicated gas flow must reach the value that is given in the manual. (± 1 l/min)

- By striking the pushbutton (Start/Stop) once more, insufflation is stopped (toggle mode)

Needle acc. to Veress

- Connect the insufflation needle to the insufflator using an insufflation hose and start insufflation in LPS mode.

    - An undamaged needle should allow a gas flow of at least 1.5 l/min to run at a pre-set pressure of 14 mmHg.
    - If mechanical disruption or blockage should occur (e.g. due to sterile deposits / sediments) the resulting flow rate will not reach its expected value.

WARNING!

Do not use the unit if possible contamination is suspected, faults or malfunctions are present or suspected, or the unit is obviously damaged.

WARNING!

Have the unit repaired by authorized service personnel.

5 OPERATION

WARNING!

Operative procedures should only be performed with insufflators capable of flow rates of at least 4 – 10 L/min. Insufflators with lower flow rates should only be used for diagnostic procedures.

WARNING!

Always work exclusively with sterile substances, sterile fluids, and sterile accessories.

CAUTION!

In order to prevent symptoms of fatigue, make sure to supply the operating area with enough fresh air, since an increasing CO2 level of the air can result in symptoms of fatigue in the medical personnel.

CAUTION!

Always have a filled CO_2 bottle ready for replacement. This will prevent an interruption of the operation due to insufficient gas for the insufflation.

CAUTION!

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

NOTE!

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

NOTE!

The unit is tested and met the requirements of DIN EN 60601-1-2 (IEC 60601-1-2, EMC). Nevertheless, we recommend to switch off and disconnect from power supply unused devices in the near surrounding.

NOTE!

in case the device has a malfunction during the operation, it is recommended to have a spare device at hand.

5.1 NEONATAL MODE

The use of this mode is suggested for dilating very small and pressure sensitive human cavities.

The following insufflation rates should be used:

<1 year: 0,3l/min
>1 year: 0.5l/min
>5 years: 1l/min
>10 years: 2l/min

The flow values listed above for laparoscopic procedures performed on newborns, infants, and children are only suggested values. However, adhering to the values listed above ensures an optimal performance of the Pediatric mode of the WISAP Tetraflator 7085.

Do not exceed a gas flow of 14 l/min when performing laparoscopy on infants or patients weighing less than 25 kilos (approx. 55 US pounds).

The selection of the suitable flow and pressure values is solely the responsibility of the attending physician.

The NEONATALMODE can be entered by pressing (approx. 5 seconds) both pressure select buttons simultaneously for several seconds!

Features:

- modified LPS – mode
- I^2S mode (MAX) is disabled for safety purposes
- Limitation of pre-settable pressure range from 3 to 14 mmHg
- Limitation of pre-settable gas flow range from 0,1 – 2 L/min
- Indicator NEONATALMODE shines light blue.

NOTE!

The NEONATAL Indicator illuminates LIGHT BLUE only if NEONATAL Mode is activated and valid.

In order to return to the standard mode, the unit should be switched OFF for at least 5 seconds.

Hypercapnia
Because pediatric patients are particularly susceptible to hypercapnia, continuous end tidal $C0_2$ monitoring is recommended.

Pneumolabium / pneumoscrotum
Children are at risk of a pneumolabium or pneumoscrotum.

Increased airway pressure
When laparoscopic procedures are performed on children, the increased intra-abdominal pressure also increases the risk for higher airway pressures. Always strictly monitor respiration and airway function when performing laparoscopic procedures on children younger than 12 years of age.

Compression of the vena cava
When insufflating the abdomen of a child with medical CO_2, an increased risk of compressing the vena cava exists. This risk can be reduced by monitoring the systolic and diastolic blood pressure during the entire surgery.

Hemodynamic stability
Laparoscopy performed on children younger than 12 years of age can result in increased CO_2 content in the blood and associated problems of the hemodynamic system. It is recommended to ensure good ventilation at all times and to work with low flow values and pressure values not exceeding 12 mmHg. The patient' circulatory system should be monitored at all times.

Hypothermia
The insufflation gas flow usually drops significantly after the target pressure has been reached and it is then only required to maintain the abdominal pressure. However, leaks within the abdomen or the instrument can lead to a constant gas flow of above 1 l/min. When operating on children younger than 12, a gas flow of more than 1 l/min poses an increased risk of hypothermia for the patient. Corresponding measures to prevent hypothermia include the use of blankets or prewarmed gas. The patient’s body temperature has to be monitored at all times during surgery.

5.2 BARIATRIC INDICATOR

The indicator (17) is illuminated in YELLOW if pressure preset ≥ 18mmHg.

The display for the pre-setting pressure switches continuously between pre-selected body cavity pressure and “H”, if the body cavity pressure preset ≥ 18mmHg.

In according to WHO (World Health Organization) the classification of overweight and obesity in adults, according to BMI, is shown in the table below:

Classification	**BMI (kg/m^2)**	**Risk of comorbidities**
Underweight	<18.5	Low (but risk of other clinical problems increased)
Normal range	18.5 - 24.9	Average
Overweight	≥25.0	
Pre-obese	25.0 - 29.9	Increased
Obese class I	30.0 - 34.9	Moderate
Obese class II	35.0 - 39.9	Severe
Obese class III	≥40.0	Very severe

The BMI is defined as the weight in kilograms divided by the square of the height in meters (kg/m^2)

$$BMI\left[\frac{kg}{m^2}\right] = \frac{Weight[kg]}{Height^2[m^2]}$$

Altered Respiratory Physiology
Always monitor the patient's respiratory functions during the entire surgery. The larger body mass supported by the thoracic cage and the larger amount of fat in the abdominal cavity may reduce the elasticity of the thoracic wall. In addition, the increased intra-abdominal pressure secondary to insufflation may alter the normal physiological lung parameters thus resulting in a reduction of the functional lung volume. Shallow, rapid breathing is symptomatic of this condition. Even modest physical stress causes a tremendous increased demand for oxygen, which stands in contrast to the ineffective respiratory musculature that requires more oxygen because it must overcome the reduced elasticity of the thoracic cage. The functional capacity of the lungs is small and even moderate stress can lead to respiratory failure.

Subcutaneous Emphysema
When puncturing the thicker abdominal wall of morbidly obese patients with the Veress cannula or the trocar, carefully monitor the correct position of the instrument in the abdomen.

5.3 SMOKE EVACUATION

5.3.1 General

The smoke evacuation is only available for the models 7085L30SE and 7085L45SE. In order to work, the OP room has to have a separate vacuum source with separator.

The connected smoke evacuation is for the purpose of maintaining good visibility in the abdominal cavity during coagulation. For this purpose, the insufflation as well as the suction of the smoke-filled volume is controlled by the insufflator. The system controls the exchange of gas in the abdomen while guaranteeing that the intra-abdominal pressure does not drop critically. Thus, the operation can be continued without interruption while maintaining good visibility.

Since the tubing has built a particulate filter, the harmful particles are concentrated collected and not flow freely into the operating room.

The tubing for the smoke evacuation system is intended for connection to the clinic's own vacuum supply, the insufflator does not serve as a source of suction.

WARNING!

Note the user manual of the appropriate device or system.

CAUTION!

It is prohibited to use the smoke evacuation for the suction of liquids!

CAUTION!

The suction tube has to be inserted first before switching on the device.

5.3.2 Connecting the foot switch

The footswitch is connected with its luer lock on the rear panel at position **31**. Make sure that the hose is free and not kinked or blocked. The activation of the smoke evacuation is done by pneumatic actuation, thus a blockage of the tube is leading to failure of the foot switch.

5.3.3 Inserting the tubing set

The patient end of the tubing set (Luer-Lock) is best connected to the trocar through which the optical system is introduced into the abdomen.

The other end must be connected to the separate vacuum-source. It should have a liquid separator to prevent the suction-source to be contaminated.

The middle piece silicone tube is inserted into the pinch valve on the right side of the insufflator. To do this, press the push-button on the pinch valve and then insert the silicone piece in the pinch valve. Upon release of the push-button the silicone tube is in position and functionally connected to the device.

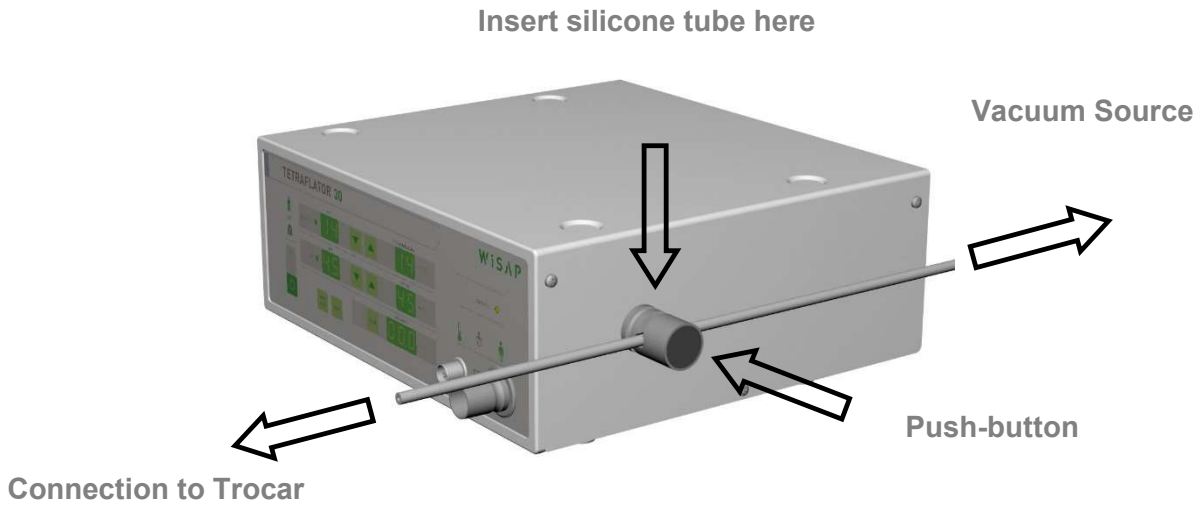


Figure 5: Application of Tubing set into Pinch Valve

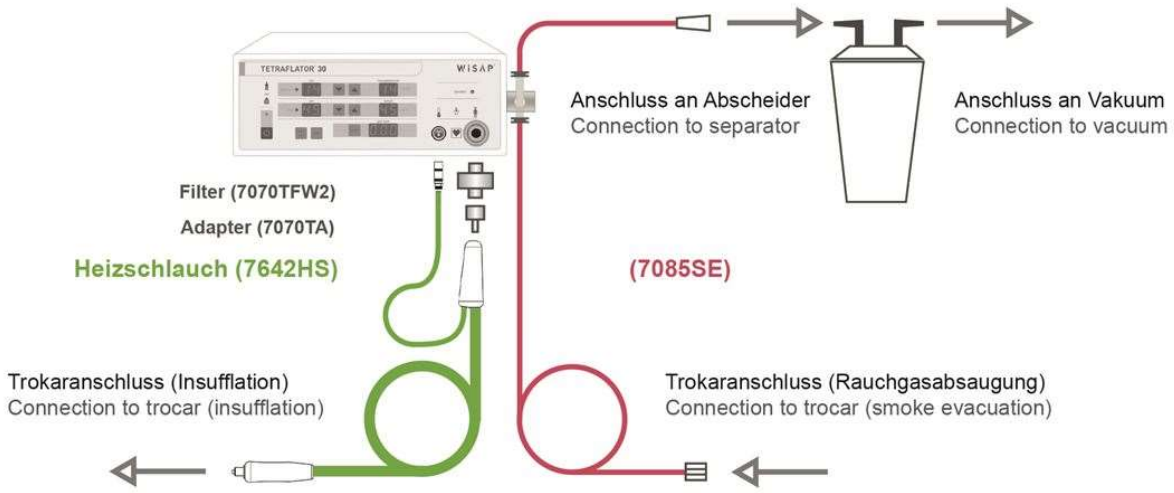


Figure 6: Tubing Connections

5.3.4 Activating the smoke evacuation

It is recommended that the smoke evacuation only is only activated in the MAX mode in order to compensate optimally for the pressure drop in the abdomen.

Pressing the footswitch will activate the smoke evacuation. This does not affect the insufflation procedure.

When smoke evacuation is activated the display changes as follows:

The suction is active for the duration of actuation of the foot switch, but not longer than for a maximum duration of 2.5 seconds.

After this maximum duration the pinch valve closes automatically and hence deactivates by the suction. This prevents the abdominal pressure to drop too drastic.

By releasing the foot switch the suction is turned off and the pressure and flow indicators show again the current pressure and flow values. The pressure regulation of the insufflator compensates for the leakage through customized pressure and flow control.

However, the foot switch is pressed for more than 2.5 sec., the display will not be back again, after the footswitch is released and the insufflation starts optionally independently until reaching the preselected body cavity pressure.

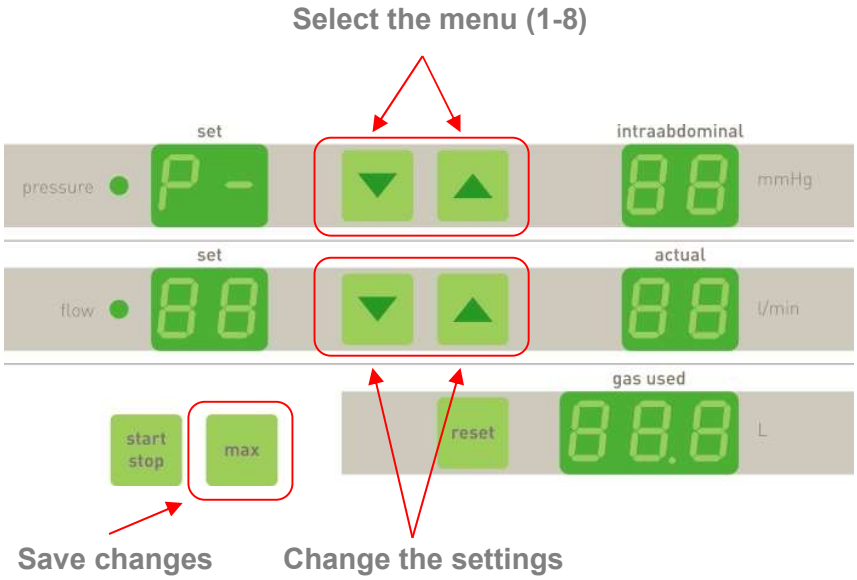
5.4 SYSTEM CONFIGURATION

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

reset

To enter the configurations menu, the RESET button should be pressed at the same time the unit is switched on.

You will find the following display:



The device is now in the configuration menu.

By using the “increase pressure” button or “decrease pressure” button you can select the different menu steps.

By using the “increase gas flow” button or “decrease gas flow” button you can change the settings in the menu steps.

See the following table:

Menu Step 1 Selection of Gas Supply		
Indicator Pressure Step 1 Indicator Gas Flow Setting 0		**High pressure CO_2 tank is selected** Graphic of CO_2- tank is illuminated *(Factory setting)*  co2 - Pressure level above 25 bars is indicated in GREEN - Pressure level below 25 bars is indicated in RED

Indicator Pressure Step 1 Indicator Gas Flow Setting 1		**Clinical gas supply is selected** Graphic of house is illuminated  This might be required when the unit is connected to a clinical gas supply system in order to **disable the pressure monitoring** of the CO_2 tank. Otherwise, there will be a permanent (false) pressure supply alarm.

CAUTION!

The monitoring of the CO2 tank must not be switched “OFF“ when the clinical gas supply system isn’t itself monitored.

NOTE!

Please note that when using this equipment from multiple users to change the default setting can lead to misunderstandings.

Menu Step 2 Configure display Gas Consumption		
Indicator Pressure Step 2 Indicator Gas Flow Setting 0		**Adding Consumption** When the insufflator is switched ON, the gas consumption display shows the last gas consumption and adds the new consumption. Display can be set to “0” by pressing the RESET button *(Factory setting)*
Indicator Pressure Step 2 Indicator Gas Flow Setting 1		**Automatic Reset** When the insufflator is switched ON, the units gas consumption display gets an automatic reset. No memorizing of previously used amount of gas.

Menu Step 3 Acoustic Signal “on / off” when Insufflation is started		
Indicator Pressure Step 3 Indicator Gas Flow Setting 0		**Acoustic signal OFF** No acoustic Signal when start Insufflation gets activated.
Indicator Pressure Step 3 Indicator Gas Flow Setting 1		**Acoustic signal ON** Acoustic Signal (several beeps) when start Insufflation gets activated. *(Factory setting)*

Menu Step 4 NEONATAL MODE activating permanent		
Indicator Pressure Step 4 Indicator Gas Flow Setting 0		**Neonatal Mode OFF** When switched OFF (“0.0”) the unit starts in LPS mode *(Factory setting)*
Indicator Pressure Step 4 Indicator Gas Flow Setting 1		**Neonatal Mode ON** When switch ON (“1.0”) the unit, starts *always* in Neonatal mode. Symbol lights blue: 

Menu Step 5 Predefine Pressure Value		
Indicator Pressure Step 5 Indicator Gas Flow Setting 0		**Memory of last used Pressure setting** The unit always starts with last preselected pressure value when not exceeding 14 mmHg. In case of a pressure > 14 mmHg the value is limited on 14 mmHg. This value could increase if needed. *(Factory setting)*
Indicator Pressure Step 5 Indicator Gas Flow Setting 1		**Predefined pressure setting** The pressure preset value can be set that will be displayed when the device switched on. The values are adjustable from 10 - 14 mmHg. The set value can be changed any time during the operation of the keypad.

Menu Step 6 Predefined mass flow		
Indicator Pressure Step 6 Indicator Gas Flow Setting 0		**Memory of last used Flow setting** The unit always starts with last preselected mass flow value. *(Factory setting)*
Indicator Pressure Step 6 Indicator Gas Flow Setting 1		**Predefined flow setting** In Step 6, the mass flow preset value can be set that will be displayed when the unit is in LPS mode. The values are adjustable from 1 - 10 mmHg. The set value can be changed any time during the operation of the keypad.

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

Menu Step 8 Restore Factory Settings		
Indicator Pressure Step 8 Indicator Gas Flow Setting 0		Enter Step 8 und switch to Setting 1 in order to reset the system to factory settings
Indicator Pressure Step 8 Indicator Gas Flow Setting 1		After pressing the max button, the factory settings are restored. The display returns to the menu Step 1.

Menu Step 9 Not in use		
		***Only for Service***

Menu Step 10 Not in use		
		***Only for Service***

Store the selected configuration:

Every “STEP“ is to be stored separately by pressing the MAX Pushbutton.

When the corresponding menu is left without the MAX –pushbutton being pressed, then all alterations to the menu will be lost.

In order to return to the **standard mode**, press the ON/OFF Pushbutton.

5.5 APPLICATION / NOTES

5.5.1 How to proceed

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

The following notes should only be taken as a general guide and as a reminder of some of these procedures.

- Before each endoscopic procedure, flush the system with the insufflation gas, in order to remove any air that has penetrated the insufflation system. Replace the unit with a clean one if any evidence of liquid contamination is found.

- Start the operation, if possible, only with a full CO_2 bottle. Always have a filled CO_2 bottle ready for replacement.

- CO_2 condenses at a pressure of 60 bars and at a (room) temperature of approx. 20°C. As long as any condensed CO2 remains in the tank, the pressure does not change. Because of this, the amount of gas in the bottle cannot be determined based only on information concerning the pressure in the tank!

- Always start the primary insufflation in LPS mode.

- Hazardous insufflation, in the event of an incorrect positioning of the Veress needle, can be avoided when the desired pressure inside the body cavity is preset below the venous blood pressure (“ZVD“).

WARNING!

PRIOR to starting the insufflation, it is obligate to ensure the correct placement of the Primary Insufflation/Veress needle according to given procedures by literature.

- The use of a **hydrophobic filter** is strongly recommended to prevent patient cross contamination. Use for each patient a new/sterile filter. Reduced flow capacity should be considered when using a hydrophobic filter.
  Exchange a contaminated filter immediately to ensure unhindered gas flow.

WARNING!

The use of a sterile hydrophobic insufflation filter is obligate in order to meet the requirements of safety protection class CF!

- Always try to determine why there may be a high gas flow during the operation. A leakage somewhere along the insufflation path may impose increased risk to the patient.

WARNING!

Position the patient nozzle of the insufflator and as much of the associated tubing as is practical above the insufflation site, so that any patient fluids inadvertently entering the tubing do not drain back into the insufflator under gravity.

- When the abdomen is filled, a reduction of preselected intra-abdominal pressure will not result in an immediate decrease of the actual abdominal pressure. To reduce the abdominal pressure quickly, first reduce the pressure pre-setting. Then create a great leakage for example by opening the trumpet valve of a trocar.

- Disconnect the patient tubing or occlude it with a stopcock or roller clamp under the following circumstances:
  When the CO_2 cylinder is exhausted, during its replacement and before the power switch or flow selector is turned on.

- Disconnect the patient (at the end of a procedure) 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 the high-pressure hose is removed / disconnected from the insufflator.

- CO_2 evaporates 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.

- In order to achieve maximum performance, we recommend the use of high flow insufflation instruments. Only then laparoscopic insufflation flow rates of CO_2 will range safely from 0 to 20 L/min or even more.

5.5.2 Known possible side effects

- **Idiosyncratic reactions**
  Patients with sickle cell disease or pulmonary insufficiency may pose increased risks of metabolic imbalance related to excessive CO_2 absorption.

- **Dehydration**
  Insufflation can lead to dehydration of the tissue. This can result in organ tissue damage and cardiovascular reactions of the patient. Long surgeries and large leaks increase the risk of dehydration (especially at the insertion points of the trocars or when changing instruments).

- **CO_2 Embolization**
  To reduce risk of embolization always start insufflation at a pressure pre-setting of less than 12 mmHg in LPS mode and ensure that the insufflation instrument is correctly positioned.
  Check the position of the insufflation instrument immediately if the actual pressure rapidly reaches the pre-setting pressure value.

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

- **Blood pressure drop, heart failure, venous thrombosis, pneumothorax, pneumomediastinum**
  Laparoscopic insufflation should be used cautiously in patients with a decreased venous return or increased ventilation pressures. Abdominal decompression may relieve elevated ICP.

- **Hypercapnia**
  The penetration of CO2 into tissue layers may cause emphysema and the development of hypercapnia. This can usually be compensated by increasing the respiratory minute volume.

- **Severe nausea and vomiting**
  Nausea and vomiting may be a consequence of CO2 gas insufflation in individual cases.

- **Increased intercranial pressure**
  Laparoscopic insufflation should be used cautiously in patients with a baseline elevated ICP or head trauma. Abdominal decompression may relieve elevated ICP.

- **Moderate pain in the area of the abdominal wound, discomfort during urination, rib and shoulder pain**
  Moderate pain and discomfort are a usual consequence of laparoscopic insufflation.

- **Wound healing disorders, bleeding or injury to abdominal organs, infections, blood clots (thrombosis)**
  Wound healing disorders, bleeding or injury to abdominal organs, infections, blood clots may be a consequence of laparoscopic insufflation in isolated cases. Be prepared to treat any side effects appropriately.

- **Cardiac output reduction, hypotension, cardiogenic shock**
  This outcome can be mitigated with preoperative intravascular fluid volume status optimization, appropriate heart failure medications, and limiting IAP to <15 mm Hg. Hypertension must be managed perioperatively with vasodilators to optimize left ventricular workload during pneumoperitoneum. Desufflation of the abdomen does not lead to immediate recovery of baseline hemodynamics. Therefore, it is critical to monitor for cardiovascular decompensation in the immediate postoperative period, with close attention to blood pressure, HR, intravascular fluid volume status, and urine output, with early intervention provided when necessary.

- **Myocardial ischemia**
  Optimal β-blockade before surgery and during the perioperative period can prevent myocardial ischemia in patients with ischemic heart disease who are chronically on β-blockers. It may be reasonable to start β-blockers preoperatively in patients with intermediate- to high-risk ischemia on stress test or an Revised Cardiac Risk Index score of >3, but they should not be started the day of surgery because of increased risk of stroke, hypotension, bradycardia, and death. Peri- and postoperative pain predispose patients to myocardial ischemia and should be mitigated with adequate analgesia.

- **Valvular Heart Disease**
  In patients with AS, hypotension and subsequent reduction in coronary perfusion pressure should be avoided. Intraoperative hemodynamic monitoring with arterial line placement and TEE is preferred, but pulmonary artery catheter placement may be considered in selective high-risk patients. Perioperative management of HR with β-blockers is essential to maintain optimal diastolic filling time preventing further elevations in LAP, which in turn can cause pulmonary edema in patients with mitral stenosis. Pre-operative evaluation should identify patients with valvular heart disease and optimize intravascular fluid volume status, HR, and systemic arterial pressure. Perioperative management must avoid hypotension in AS, tachycardia in mitral stenosis, and increased afterload in left-sided regurgitant valve lesions**.**

- **Congenital Heart Disease**
  Minimizing positive end expiratory pressure and administering inhaled nitric oxide to lower pulmonary vascular resistance and RAP reduces the RAP-LAP gradient decreasing right-to-left shunt. CO2 gas embolism can be avoided by careful insertion of the needle into the peritoneum and slower abdominal insufflation. In the period after surgery, unexplained hypoxemia not reversible with 100% oxygen

should trigger an evaluation for atrial septal defect/patent foramen ovale. TEE can be performed intraoperatively to monitor for shunts in patients at risk.

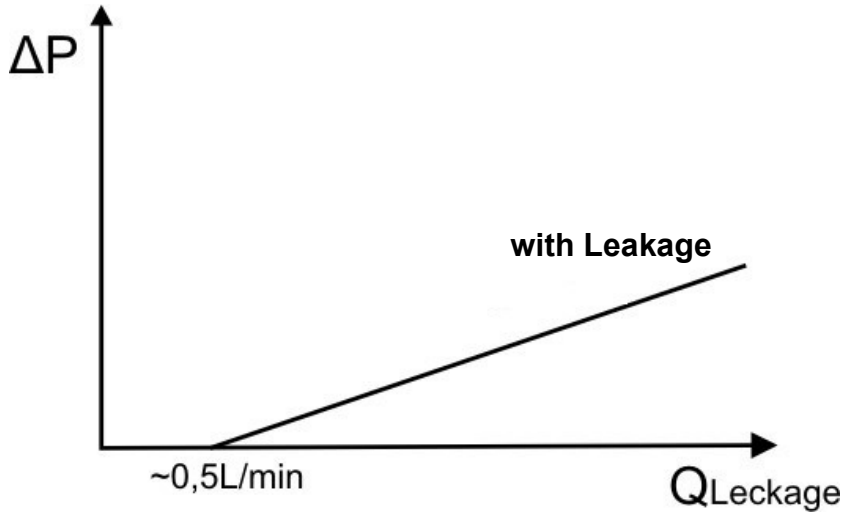
- **Chronic Obstructive Pulmonary Disease and Pulmonary Hypertension**
  Hyperventilation after intubation is required. If acidosis develops and cannot be reversed, then the procedure may need to be converted to open laparotomy. Special care must be given to patients with severe chronic obstructive pulmonary disease because higher airway pressures are required to ventilate patients during laparoscopy, predisposing patients to bullae rupture.

5.5.3 Leakage effects

In case of an insufflation system with a significant leakage flow (starting with 0,5L/min) the device wouldn't reach the desired target pressure because of the physical correlation between in- and outflow of the abdomen.

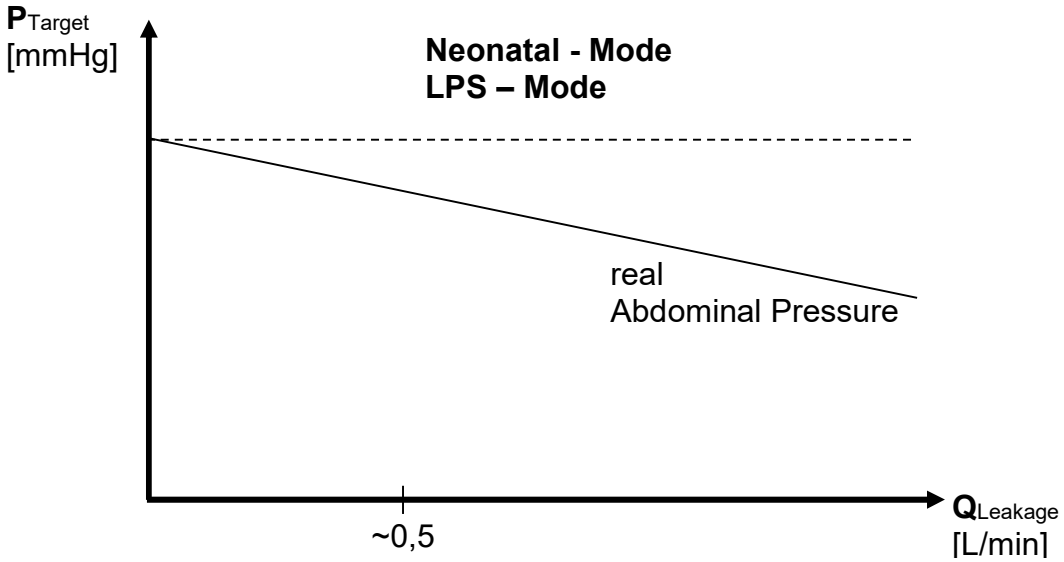
The pressure difference ΔP between preselected pressure and actually pressure depends of the size of leakage volume and of the preselected pressure (see diagram below).

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



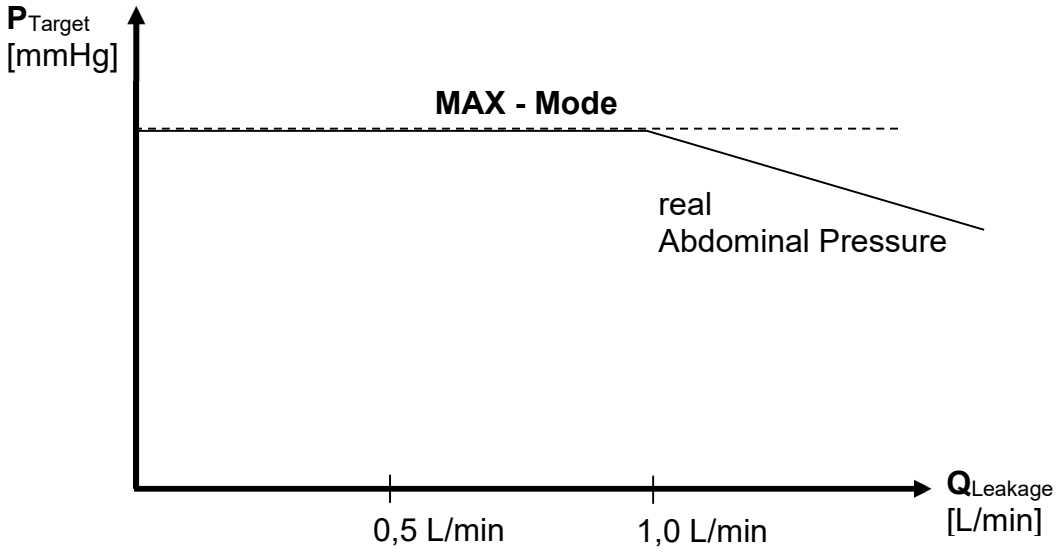
Example: If the target pressure is equal to the impact pressure (e.g.: 14mmHg) and a leakage flow is present (e.g.: 2L/min) the device can't establish the preselected target value.

As described in the example before this is especially the situation when insufflating under *Neonatal* or *LPS* mode conditions. The following diagram shows the typical relation of an increasing leakage flow and the deviation value of the target pressure:



In reference to the previous description where the impact pressure is equal to the target pressure an improved capability supports the MAX – mode operating to adjust the target value. This is caused by a higher impact pressure than the desired target pressure.

See the following diagram for MAX – mode operating:



As pictured in the diagram before, the deviation to the target pressure is constant (zero) up to a leakage flow of about 1L/min.
The subsequent deviation and the threshold value (typically 1L/min) depends on the instruments respectively the veress needle used in the system.

WARNING!

The MAX Mode operation is disabled in the NEONATAL Mode!
Always strictly monitor current cavity pressure and ensure that the leakage is not higher than 0.2L/min when performing laparoscopic procedures on children younger than 12 years of age.

5.5.4 Safety Features

General
The unit is equipped with an acoustic signal device that can emit audible alarms and provide acoustic signals to the user (to acknowledge pressing a key or to display a stored value).
A graphically illustrated warning light (symbol of a person) at the front of the unit illuminates in RED when an optical signal is needed. The corresponding display blinks to inform the user why the alert has occurred.

Pressure Alarm
If the abdominal pressure exceeds the preselected value by more than 5 mmHg, the unit will emit an intermittent warning signal as long as the condition persists. The pressure display will blink simultaneously. The Patient Symbol shines red.

Monitoring of the CO_2 tank
When the filling pressure of the connected CO_2 tank drops under / below a pressure level of 25 bars, an optical and an audible warning is activated with the red light located in the symbol illustrating a CO2 tank on the front panel of the unit.

Occlusion test
(Monitors the insufflation line) In the event there is no gas flow during a period of 15 seconds, despite insufflation being “ON“, the unit checks whether the insufflation line is occluded (e.g. insufflation hose kinked, stop-cock closed etc.) or the body cavity has just filled up according to the pre-settings.
If an occluded insufflation line is detected, an intermitting audible alarm is activated. The gas flow display blinks simultaneously. The alert condition is maintained until gas flow resumes.

Diagnostic System
The unit 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, discontinue use immediately and contact service personnel. The meanings of appearing error codes can be looked up under 10. System Messages

External Filter
The device is equipped with a removable, external gas filter to protect both the patient and the sensors from gross pollution. This is easily accessible placed on the rear panel and protects it from contamination as well as his fluid (e.g. Oil)
Since this filter element with time due to pollution is increasingly less consistent, it must preserve the maximum Flowrate be regularly replaced.

WISAP recommends:

- Connected to gas bottles: with each bottle exchange
- Connected to house connection: after 10 OP’s (approx. 3000 litre)

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.

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

- Disposable filters, disposable tube sets and/or instruments are designed for one-time use and must be disposed of according to the appropriate regulations.

6.1 CLEANING AND DESINFECTION

6.1.1 Control Unit 7085

CAUTION!

Unplug the unit before cleaning.

The exterior surface may be treated with a cleaning agent or disinfectant that does not damage the paint.

CAUTION!

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

CAUTION!

Make sure that no cleaning agents ever get inside the unit.

6.1.2 Accessories

Luer lock adapters and metal instruments should be cleaned of coarse contaminants and then rinsed in clean water and carefully dried inside and outside. For cleaning and disinfection instructions for your Luer lock adapters and metal instruments see the respective manufacturer's operating instructions for details.

6.2 STERILIZATION

CAUTION!

The controlling unit must not be sterilized!

Luer lock adapters and metal instruments are sterilizable after being cleaned of coarse contaminants and then rinsed in clean water and carefully dried inside and outside. For Sterilization instructions for your Luer lock adapters and metal instruments see the respective manufacturer's operating instructions for details.

Whether your Silicone tubing is sterilizable see the respective manufacturer's operating instructions for details. Silicone tubing’s should only be sterilized as often as labeled on its package. Never exceed the number of uses recommended by the manufacturer.

WISAP recommends the following sterilization method:

In an autoclave (dry air) at 134 °C / **by steam sterilization** at 134 °C

(See the respective manufacturer's operating instructions for details).
Refer to DIN 58946, Part 7 and recommendation of EN 285.

7 TROUBLE SHOOTING

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

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

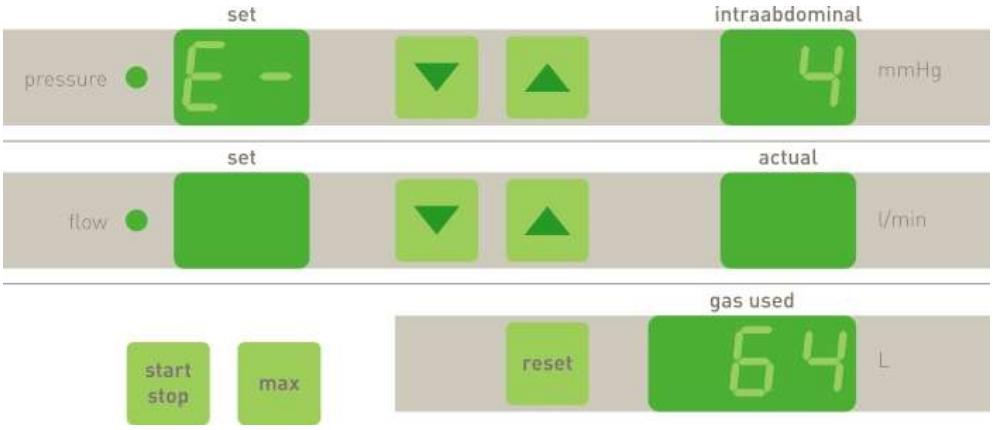


Figure 7: Sample for E - 4 64

Fatal errors which require an immediate abort (e.g.: code check errors):

Error	*Display pressure pre-setting*	*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 which require a user notification in a specified period of time. After finishing the present operation a check by authorized personnel is required:

Error	*Display pressure pre-setting*	*Display current cavity pressure*	*Display gas con-sumption*	*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 initialisation (baud Rate) error
ERROR_CAN_BUS_OVERLOAD	E	4	16	CAN Bus overload executions
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 initialise neonatal mode (Hardware error)
ERROR_READ_DEVICE_CLASS	E	4	512	Can't read device class (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!

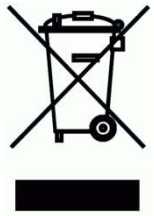
Do not use the unit if possible contamination is suspected, faults or malfunctions are present or suspected, or the unit is obviously damaged.

WARNING!

Have the unit repaired by authorized service personnel.

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 accessories could be purchased about the WISAP customer service:

Item No.	Description
9919	High pressure tubing US (UNF 7/16“ 20G) to PIN INDEX system
9919-1	High pressure tubing US (UNF 7/16“ 20G) to German (DIN 477) system
9919-3	High pressure tubing US (UNF 7/16“ 20G) to Italian (ISO 5145) system
9912-2	Low pressure tubing US to clinical supply D (L=4m)
9912-3	Low pressure tubing US to clinical supply D (L=8m)
7642HS	Heating tube multi use (1 piece)
7642HSE1	Heating tube single use (10 pieces)
7070TFW	Hydrophobic Gas Filter for Heating tube (frontside, 1 piece)
7085FE	External Gas Filter for Gas Supply (backside, 1 piece)
7160W1	HIGH FLOW Nadel acc. to Veress 120 mm
7085SE	Tubing set for smoke evacuation

WARNING!

If the unit is equipped with a CO_2 heating option, it is obligate to use one of the hydrophobic insufflation filters listed in order to maintain safety protection class CF!

WARNING!

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

10 TECHNICAL DATA

- Line voltage:	100 ... 240 Vac	
- Maximum power consumption:	55 VA 100 VA 100 VA	without CO_2 heater unit equipped with CO_2 heater with Smoke Evacuation (SE)
- Mains fuses:	2 x 0,65 AT (SB) 2 x 1,0 AT (SB) 2 x 1,25 AT (SB)	without CO_2 heater unit equipped with CO_2 heater with Smoke Evacuation (SE)
- Frequency:	50 / 60 Hz	
- Protection class:	1	
- Protection symbol:	CF – 	only if specified insufflation filter is used
- Classification as per Annex IX of Directive 93/42/EEC	IIa	
- Weight:	approx. 8.0 kg approx. 8.2 kg	without CO_2 heater unit equipped with CO_2 heater
- 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 ... +70^0C 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 :	**0,1 - 20** l/min **0,1 - 30** l/min **0,1 - 45** l/min	Type: Tetraflator 7085L with 20l Type: Tetraflator 7085L with 30l Type: Tetraflator 7085L with 45l
- Pressure setting range:	3 ... 30 mmHg	
- Tolerances :		
Display for		
- Abdominal pressure:	± 3 mmHg	
- Gas flow:	± 0.5 l/min	
- Consumption:	± 15 %	
- Manufactured and tested according to:	IEC 60601-1:2006 93 / 42 / EWG	

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.

11 OVERVIEW TO EMC

Manufacturer's Declaration for Electro-Technical Compatibility

Acc.to IEC 60601-1-2
For the WISAP Tetraflator 7085 series

Guidance and Manufacturer Declaration - Electromagnetic Emissions		
The Tetraflator 7085 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 Tetraflator 7085 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 Tetraflator 7085 requires continued operation even in the event of power supply interruptions, it is recommended to power the Tetraflator 7085 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 Tetraflator 7085 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 Tetraflator 7085 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 Tetraflator 7085 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.

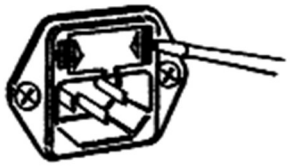
Turn OFF the device by pressing the OFF switch on the front of the device.

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 Tetraflator and keep it close to the device.

The fuses are located above the mains socket.

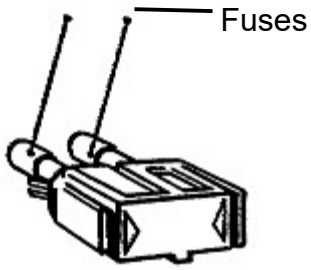
Slide a suitable tool (screwdriver) into the right recess and press the lock to the left, so that the fusebox comes out slightly.



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 10 years can be expected.

12.7 SERVICE TABLE

Date	Description	Signature

12.8 REPAIR AND RETURNS

If a repair should be 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 free. Describe the error or malfunction and call us a competent person for further inquiries.

*) The repair must be shipped devices and accessories must, to protect service personnel and transport security, have been prepared in accordance with the information in this manual.
THE CONTAMINATION OF CERTIFICATE SHOULD CLEARLY THE ACCOMPANYING THIS 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 repair accept contaminated products may refuse the manufacturer.

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 WARRANTY / LIABILITY

The manufacturer guarantees that the unit and accessories have been carefully checked before leaving the factory. He is only responsible for the safety characteristics under the statutory provisions if all work on the product made by factory authorized service personnel and the equipment and accessories are used exclusively for the intended use after. Authorized service personnel may be strictly trained and certified by the manufacturer.

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-month warranty on production- and material faults. Faults or defects caused by mishandling are not covered by warranty.

Consumables, which are subject to the usual attrition are excluded from the warranty. This is especially for re-sterilizable materials, such as the Heating Tube 7642 HS.

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.

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