

**THERME-PNEU-COMPUTER  
7070C, 7070CF,  
7070CM, 7070CMF**

**User Manual**

**Dear Customer,**

Thank you for your confidence in WISAP Gesellschaft für wissenschaftlichen Apparatebau mbH. This product combines our longstanding experience and thorough workmanship. You have decided for a modern, high-quality WISAP device.

Please study these instructions prior to putting your new device into operation. Thereby you may prevent damage to you and your patient resulting from wrongful connection or improper handling.

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**CAUTION:** This device is restricted to use by or on the order of authorized expert personnel / physician.

### 1. Intended Use

The WISAP THERME-PNEU Computer 7070C/7070CF/7070CM/7070CMF may only be used for building up a pneumoperitoneum for diagnostic or operative Pelviscopy/Laparoscopy. The unit may be operated with CO<sub>2</sub> gas only. The Flow-Therme incorporated in the unit preheats the insufflation gas to body temperature.

### 2. Contraindications

- Use of this device is contraindicated, whenever Pelviscopy/Laparoscopy is contraindicated.
- Use of this device is restricted to building up a pneumoperitoneum during diagnostic or operative Pelviscopy Laparoscopy.
- Please also observe the operator manual of your endoscope regarding contraindications during Pelviscopy/Laparoscopy.
- The device must not be used for Hysteroscopy or Pertubation.
- Do not use prolonged HI-FLO insufflation. The effects on the patient are unknown.

### 3. Warnings

- Only use medical grade CO<sub>2</sub>.
- Proper device function is only guaranteed, if the pointer of the CO<sub>2</sub>-reserve manometer is in the green range. Have filled replacement gas cylinders available to prevent interruptions during a procedure owing to lack of CO<sub>2</sub> gas.
- CO<sub>2</sub>-cylinders may never be completely emptied and should only be stored with closed cylinder valve! Thus contamination of cylinders until the next filling and proper function of your device are guaranteed.
- Absorption of CO<sub>2</sub> during insufflation may result in hypercarbia or gas embolism. Pneumoperitoneum pressure may create blockage of the vena cava and pulmonary circulation. Use the lowest insufflation pressure possible during the procedure to minimize the risks.
- Be aware of metabolic acidosis and resultant cardiac irregularity. Prolonged intraabdominal pressures greater than 20 mmHg should be avoided. Intraabdominal pressures greater than 20 mmHg can cause any of the following:
  - \* Decreased respiration with compromised diaphragmatic excursion
  - \* Decreased venous return
  - \* Decreased cardiac output
- Adequate respiration helps avoid problems related to CO<sub>2</sub> insufflation.
- Idiosyncratic reactions: patients with sickle cell disease or pulmonary insufficiency may pose increased risks of metabolic imbalance related to excessive CO<sub>2</sub> absorption.
- Beware of carbonic acid irritation of the diaphragm.
- Carefully monitor the patient's intraabdominal pressure when other potential sources of gas are in use. Potential sources of gas are:
  - \* Laser
  - \* Gas-driven irrigation systems

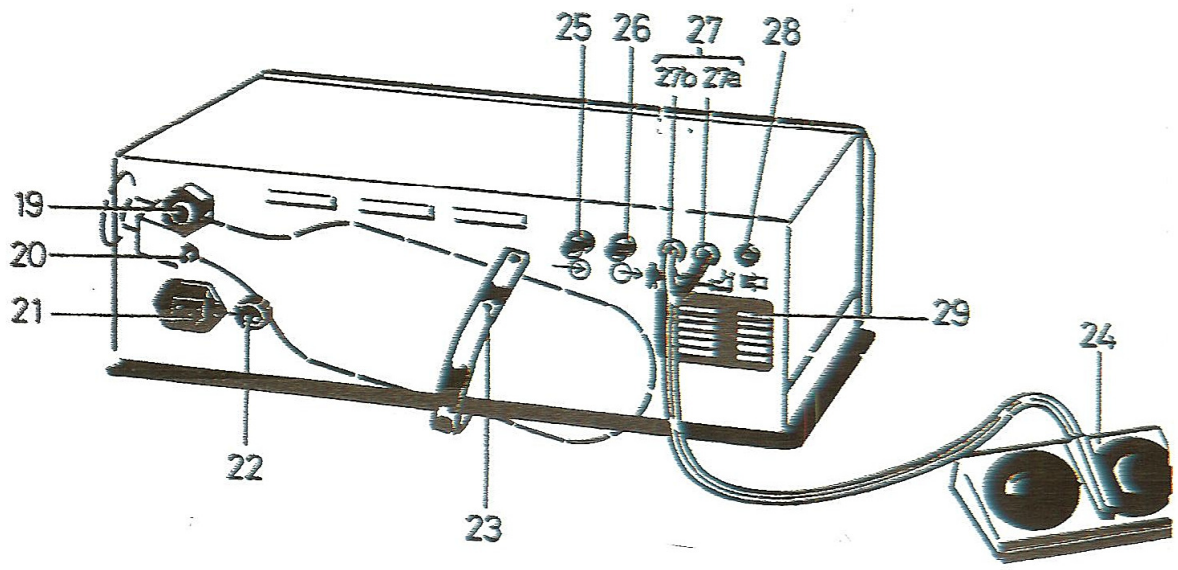
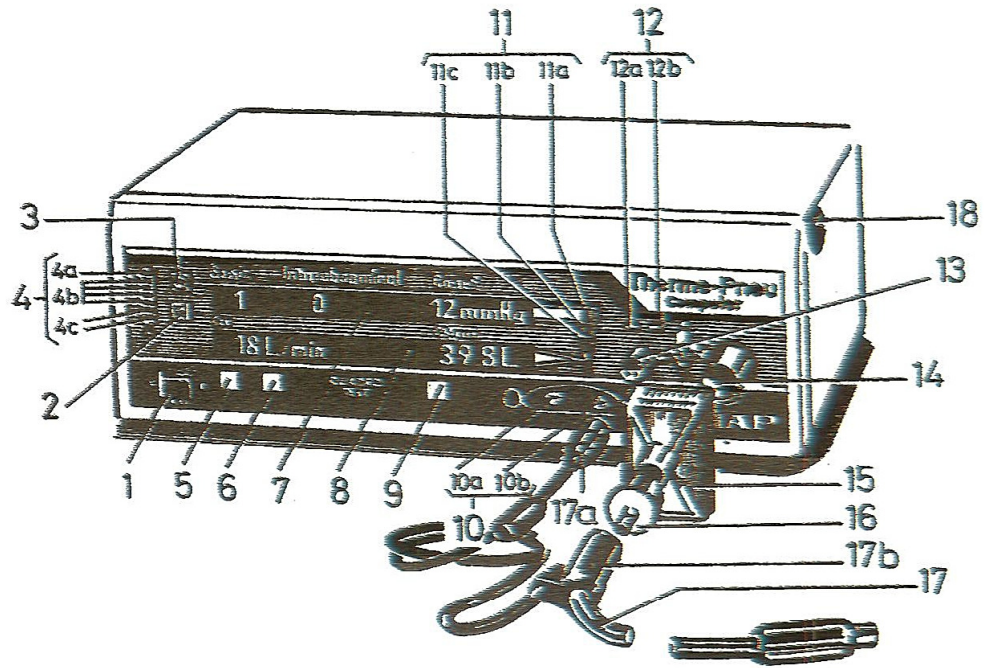


#### 4. Important Hints

- Please study this manual and accompanying labelings prior to putting the unit and its accessories into operation for the first time!
- The WISAP THERME-PNEU-Computer 7070C/7070CF/7070CM/7070CMF is a high-precision device, which is solely to be operated with original WISAP accessories!
- Check device and accessories as to their proper function prior to each intervention (chapter 11 „Functional Control“). If any faults are assumed or found, application of this unit is strictly prohibited!
- For each operative intervention, replacement accessories (filter, filter adaptor, heating tube and Veress needle), as well as replacement gas cylinders have to be kept available.
- Interventions requiring the use of appliances, instruments and accessories described in this manual may only be performed by personnel with adequate training and experience!
- Prior to each intervention, please consult the pertinent medical literature for techniques, complications and hazards!
- Independent from the general recommendations in this manual, the selection of equipment required for the intervention and the determination of the static intraabdominal pressure, as well as selection of the flow rate (gas flow) are within the sole responsibility of the operating surgeon.
- The user is fully responsible for observing the cleaning, disinfection or sterilisation instructions. The manufacturer cannot be held liable for faults resulting from non-compliance with the above-mentioned regulations. Any warranty claims would be declared null and void in such case.
- For avoiding cross-contamination, backflow and contamination, the original WISAP gas filter needs to be used. Gas filter, heating tube and all accessories additionally used have to be changed before treatment of another patient. The gas filter is disposable and thus not re-sterilisable! Heating tube and all further accessories need to be sterilised after each operative intervention (see „Cleaning, Disinfection and Sterilisation“).
- Prior to each operative intervention, please make sure that residues of detergents and disinfectants are carefully removed and that the heating tube is sterilised.
- Have a replacement insufflator or an Abdominal Cavity Expander (REF 7686 or 7686-1) available in the OR to be used in case of failure.
- Flush the system with insufflation gas before each procedure, and replace the unit or accessories by clean or sterilised devices, if any evidence of liquid contamination is found.
- Position the patient port of the insufflator and the heating tube above the insufflation site, so that any patient fluids inadvertently entering the tubing do not drain back into the insufflator under gravity.
- Manual reduction of the intraabdominal pressure must not take place by separation of the heating tube from the unit or by deaeration through the appliance, but only by deaeration through the insufflation instruments or by detachment of the heating tube from the insufflation instrument!
- The device is not destined for operation in explosive-endangered areas!
- Install unit out of patient's reach!
- Please make sure that no fluid enters into the unit or that the device comes into contact with any liquids.
- In order to ensure good dissipation of heat generated during operation of the unit, covering with cloths has to be avoided.
- Opening of the chassis, repairs, modifications and calibrations may only be performed by the manufacturer or by explicitly authorized personnel!



5. Device Description



- 1 Mains switch
- 2 Button for volume regulation, green; fading-in of measuring data ON/OFF (with key button 3)
- 3 Button for display of CO<sub>2</sub>-bottle pressure; Reset button for CO<sub>2</sub>-bottle pressure alarm; fading-in of measuring data ON/OFF (with key button 2)
- 4 Display for CO<sub>2</sub>-bottle reserve (LED bars)
- 4a Red flashing LED: danger, bottle excessively filled
- 4b Green LED's: Sufficient gas reserve
- 4c Yellow LED's: Caution, insufficient gas reserve; observe display; yellow flashing LED: Caution, exchange CO<sub>2</sub> bottle
- 5 Orange Flow-ON/OFF button:
  - Gas insufflation 1 l/min „ON“
  - Gas insufflation 1 l/min and HI-FLO „OFF“
- 6 Yellow HI-FLO button:
  - Gas insufflation 31 l/min „ON“
- 7 Upper LED-dot matrix display for indication of:
  - Insufflation pressure "Gas in" in mmHg
  - Static "Intraabdominal" pressure in mmHg
  - Preselected intraabdominal pressure "Preset" in mmHg
  - „Turn on“ messages
  - CO<sub>2</sub> bottle pressure in bar
- 8 Lower LED-dot matrix display for indication of:
  - Gas flow "Flow" in l/min
  - Oscillating arrows as flow indicator
  - Gas consumption "CO<sub>2</sub> used" in Liter
  - „Turn on“ messages
  - Warnings and error messages
- 9 Green RESET button for displayed gas consumption; RESET for time display of measuring data fade-in
- 10 Preset buttons for intraabdominal pressure
  - 10a - demagnification
  - 10b - magnification
- 11 LED-indicator for static intraabdominal pressure
- 11a Red flashing LED, double function:
  - danger, excessive pressure, pressure by at least 7 mmHg greater than preselected pressure
  - display of diminished pressure
- 11b Green LED, preselected pressure is reached
- 11c Yellow LED, preselected pressure is not reached
- 12 LED-indicator for preheating of insufflation gas
- 12a Green LED, display of operating mode
- 12b Red flashing LED, display of faults
- 13 Connecting socket for heating tube cable
- 14 Connection „to patient“
- 15 Filter (for single use)
- 16 Filter adaptor (for repeated use)
- 17 Heating tube (for repeated use)
- 17a Heating tube cable with plug
- 17b Connection cap for insufflation unit
- 18 Maintenance label
- 19 CO<sub>2</sub>-gas connection
- 20 Grounding connection
- 21 Mains connection with fuse drawer
- 22 Spare fuses
- 23 Bottle support
- 24 Double foot pedal, optional
- 25 Socket VIDEO IN; optional
- 26 Socket VIDEO OUT; optional
- 27 Connection for foot pedal
- 27a Connecting pin (right) for green tubing end
- 27b Connecting pin (left) for transparent tubing end
- 28 Circuit breaker
- 29 Type plate



- 1 Mains switch for turning on the appliance, ON = 1, OFF = 0. Green rocker switch is illuminated, when appliance is ON. After activation, an automatic system check is initiated.
- 2 By activation of the green button for volume regulation, the volume of warning and alarm sounds can be adjusted between a minimum and a maximum value. The current volume after release of the button is saved. For safety reasons, the sound cannot be deactivated completely. If no reason is given for release of a warning or alarm sound, an automatic sound is generated upon depressing the button. Short depressing leads to gradual volume change, prolonged depressing causes periodic volume change. In case of optionally available fade-in of measuring data, fading-in of insufflation data on the video image can be activated or deactivated by simultaneously depressing the button for volume regulation and button 3 for CO<sub>2</sub> bottle pressure display.
- 3 Activation of the green button for CO<sub>2</sub>-bottle pressure leads to indication of CO<sub>2</sub>-bottle pressure on the upper LED dot matrix display 7. If bottle pressure drops to under 15 bar and 10 bar, an alarm sound (approx. 8 s) and a correspondent message on the lower LED dot matrix display 8 are activated. The alarm can be deactivated earlier by depressing the button for at least 3 seconds. If the alarm was terminated earlier by depressing the button for instance at 15 bar, no additional alarm is released upon further emptying of bottle under the lower limit value. Only a correspondent warning message on the lower LED dot matrix display 8 is indicated. Reactivation of the alarm sound is only possible after exchange of the gas cylinder for a bottle with a minimum pressure of 10 bar. As excessive pressure (> 80 bar) in the CO<sub>2</sub> cylinder constitutes a serious danger, an alarm released by such condition cannot be turned off. In devices having been modified for connection to a central CO<sub>2</sub> gas supply, the alarm sound is released at pressure values > 10 bar, < 2 bar and 0 bar. Whereas the warning sound for pressures < 2 bar and 0 bar can be terminated earlier by button press, the alarm at a pressure > 10 bar cannot be reset.  
In case of an optionally available fade-in of measuring data, fading-in of the insufflation data on the video image can be activated or deactivated by simultaneously depressing button 2 for volume regulation and the button for display of CO<sub>2</sub>-bottle pressure.
- 4 Depending on the filling condition of the CO<sub>2</sub>-bottle or the gas pressure of a central CO<sub>2</sub>-gas supply, the individual LED bars of the gas reserve display are activated .
  - 4a The red flashing LED signalises danger caused by excessively filled CO<sub>2</sub>-bottle; bottle pressure > 80 bar. The CO<sub>2</sub>-bottle must immediately be removed from the device! Simultaneously with activation of the red blinking LED, an alarm sound and a message alternating to the normal display is indicated on the lower LED dot matrix display 8. This alarm sound can be turned off by activation of the green button for CO<sub>2</sub> bottle pressure. In devices having been modified for connection to a central CO<sub>2</sub>-gas supply, the red flashing LED signalises a CO<sub>2</sub>-pressure > 10 bar.
  - 4b The green LED's driven as luminous row indicate a correctly filled CO<sub>2</sub>-bottle (bottle pressure 30 ... 80 bar) with sufficient gas reserve. The bottle pressure in a filled cylinder is about 59 bar and rises with increasing temperature. In devices having been modified for connection to a central CO<sub>2</sub>-gas supply, the green LED's signalise a CO<sub>2</sub>-pressure of 3,5 ... 10 bar.
  - 4c The yellow LED's driven as luminous row refer to insufficient gas reserve (< 30 bar). When the yellow LED on the top goes out, the bottle pressure has dropped to a value under 15 bar. An alarm sound (8 s) is released accompanied by a message on the lower LED dot matrix display 8 alternating to the normal display. The alarm sound is repeated until complete emptying of the gas bottle, if pressure value is under 10 bar, and the message on the LED dot matrix display 8 is up-dated according to the current bottle pressure.  
If the lower yellow LED starts to blink, the bottle pressure has fallen under a value of 10 bar. In order to ensure proper device function, the bottle has to be exchanged immediately. Insufflation is automatically continued after attachment of a new CO<sub>2</sub> bottle with a pressure > 10 bar. Otherwise, insufflation is blocked for safety reasons. In devices having been modified for connection to a central CO<sub>2</sub> gas supply the yellow LED's refer to a CO<sub>2</sub>-pressure being too low (< 3,5 bar). At pressure values < 2 bar and 0 bar, an alarm sound and a message on the lower LED dot matrix display 8 alternately to the normal display are released. Additionally, the yellow LED at the bottom starts to flash at a pressure of 0 bar; insufflation is stopped and automatically continued at a pressure of >0 bar only.
- 5 With the orange FLOW ON/OFF button (increased light intensity when activated), insufflation is started with a gas flow (flow) of approx. 1 l/min. Depressing the button during insufflation terminates the gas flow, independent from the „HI-FLO“ function additionally selected or not.
- 6 By depressing the yellow HI-FLO button (increased light intensity when turned on), the flow is increased to approx. 31 l/min. (measured at free flow, otherwise dependent on the flow resistance at heating tube/Veress needle or trocar). For safety reasons, the operating mode "HI-FLO" can only be activated after previous start of insufflation by button Flow ON/OFF 5. "HI-FLO" can only be terminated by general stop of insufflation by repeated activation of button Flow-ON/OFF.



- 7 The upper LED dot matrix display indicates, depending on the operating mode of the device, different messages, measuring and adjusting values. Immediately after activation of the device and during the subsequent system check; „turn on“ messages are displayed followed by indication of insufflation pressure "Gas in" in mmHg, static intraabdominal pressure "Intraabdominal" in mmHg and preselected intraabdominal pressure "Preset" in mmHg. By activation of green button 3 for display of CO<sub>2</sub>-bottle pressure, the CO<sub>2</sub>-bottle pressure (in bar) can be read off.
- 8 The lower LED dot matrix display indicates, depending on the operating mode of the device, different messages, measuring values and values of the flow indicator. Immediately after activation of the appliance and during the subsequent system check, „turn on“ messages are displayed. During insufflation, the "Flow" rate in l/min, the gas consumption "CO<sub>2</sub> used" in liter, as well as the flow indicator in the form of oscillating arrows can be read off (Flow 1 l/min > > > ; HI-FLO > > > ).  
Faults arising during the system check and warnings during normal operation are also shown on the lower matrix display.
- 9 By depressing the green RESET button, the gas consumption indicated under "CO<sub>2</sub> used" 8 can be reset to 0,0 l. In case of an optionally available fade-in of measuring data, depressing of the RESET button simultaneously causes reset of the timer display faded-in on the video image.
- 10 With the yellow preselection button, the intraabdominal pressure value can be adjusted up to 24 mmHg. **After each activation of the appliance, a value of 12 mmHg is automatically preset**, which can be changed by depressing the two buttons 10a and 10b: recommendation 12 – 14 mmHg. The preselected intraabdominal pressure is indicated under "Preset" on the upper LED-dot matrix display 7.
- 10a With the yellow minus button, the preselected intraabdominal pressure can gradually be decreased to 0 mmHg.
- 10b With the yellow plus button, the preselected intraabdominal pressure can gradually be increased up to a value of 24 mmHg.
- 11 The LED indicator for static intraabdominal pressure shows to what extent the preselected pressure matches the actual pressure in the abdomen.
- 11a The red flashing LED has a double function. On the one hand, it signals danger in case of excessive pressure (pressure by at least 7 mmHg higher than the preselected value), on the other hand it is activated in case of diminished pressure (see diminished pressure test). Warning at excessive pressure is combined with an alarm sound.
- 11b The green LED lights up, when the preselected pressure has been reached and is not exceeded by more than 6 mmHg.
- 11c The yellow LED lights up, when the preselected pressure has not been reached.
- 12 LED indicator for preheating of insufflation gas
- 12a Illumination of the green LED shows that the supply voltage for the heating tube is available inside the unit.
- 12b The flashing red LED and the simultaneous illumination of the green LED reveal internal or external interruption of the heating circuit. Possible causes are:
- Heating tube is not connected
  - Heating tube is defective
  - Circuit breaker at the rear of the unit has released.
- 13 To this socket, the connection cable of the heating tube is attached.
- 14 To this pin, the gas filter is attached.
- 15 Gas filter – only use original filter taken out of undamaged packing (WISAP-Art.- No. 7070TF). **Filter is disposable, not re-sterilisable!** For avoiding cross-contamination, it is absolutely necessary to exchange the gas filter after each patient!

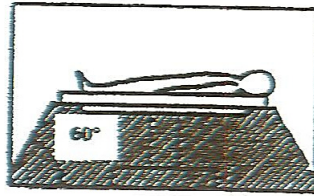
- 16 Adaptor (WISAP-Art.- No. 7070TA) for joining heating tube with filter.
- 17 The heating tube consists of a silicone insufflation tube sheathed by a heating conductor and jacketed by an additional silicone tubing. For avoiding cross-contamination, it is absolutely necessary to replace the heating tube after each patient!
- 17a The heating tube cable is attached to the respective socket **13** of the device.  
**For detachment of the plug, do not grasp the cable! Risk of damage!**
- 17b With the connection cap, the heating tube is attached to connection **14** through adaptor **16** and Filter **15**.
- 18 Maintenance label shows the due date for next maintenance.
- 19 Connection for CO<sub>2</sub>-cylinder (see Technical Description)
- 20 Grounding connection (see Technical Description).
- 21 Mains connection with fuse drawer; only operate device with voltage and fuses indicated on the **type plate** (see Technical Description).
- 22 Spare fuses; turn cap by rotation to the left.
- 23 The bottle support serves for receipt and fixation of the CO<sub>2</sub>-cylinder.
- 24 Double foot pedal for remote control of key button functions "FLOW-ON/OFF" and "HI-FLO". If connected to the correct side, the left pedal actuates FLOW-ON/OFF button **5**, the right one HI-FLO button **6**.
- 25 Video signal input (optional) for camera signal.
- 26 Video signal output (optional) for connection of monitor; signal contains the insufflation data for fading-in on monitor image.
- 27 Pin for connection of double foot pedal.
- 27a Outer, right connection pin for attachment of green tubing end of double foot pedal
- 27b Inner, left connection pin for attachment of transparent tubing end of double foot pedal
- 28 Circuit breaker releases upon excessive strain on heating tube or heating tube cable by for instance squeezing, bending or overstretching. Released fuse can be reset by depressing the black knob.
- 29 On the **type plate**, technical data, as well as type and serial number of the device can be found, which have to be indicated when ordering spare parts or in case of other technical questions.

## 6. Technical Description

These instructions have to be kept at a well-visible place nearby the unit.

Unpack device and accessories followed by removing all packaging parts. Install unit onto a plane surface. The device may only be operated in medically utilized rooms, if those have been installed acc. to the guidelines of VDE 0107.

The device is not destined for operation in explosive-endangered areas. If explosive anaesthetics are used, device and accessories must not be operated in the marked zone.



### 6.1 Connection to the Gas Supply

CO<sub>2</sub>-bottle connection acc. to DIN 477. Attach CO<sub>2</sub>-bottle to gas connection 19. Optional attachment to central gas supply through special connection tubing (device modification by manufacturer is required; indicate type of gas supply and requested tubing length).

### 6.2 Connection to the Mains

Prior to first operation, please check, whether the local mains voltage is in conformity with the voltage indicated on type plate 29. Only then the unit may be connected to the mains. Attach mains cable to receptacle 21 at the rear of the unit.

**Caution:** Do not turn the device on immediately – please wait until the temperature of the CO<sub>2</sub>-Therme-Pneu-Computer is almost equivalent to the ambient temperature (approx. 15 minutes after installation).

### 6.3 Grounding

The device is equipped with pin 20 acc. to DIN 42801 for connection of the grounding conductor through which the device has to be earthed ("guidelines for avoiding danger of ignition due to electrostatic discharge").

**Caution:** Before opening the chassis, exchanging fuse(s) or cleaning, please disconnect mains plug.

### 6.4 Technical Data

Classification acc. to:

- 93/42/EWG:

- Type of protection against electric shock:

- Degree of protection against electric shock:

- Degree of protection against entering of water:

**Operating mode:**

**Mains connection:**

**Fuses:**

**Power input:**

**Gas connection:**

- Minimum bottle pressure:

- Pressure range for connection to central gas supply:

**Insufflation pressure:**

**Static intraabdominal pressure:**

- Preselection range:

- Automatic pre-adjustment:

**Gas flow:**

- LOW-FLOW:

- HI-FLO:

**Dimensions (w x h x d):**

**Chassis:**

**Weight:**

IIa

Protection class I

Device type B

IPX1

Continuous operation

Available for alternating voltage 100 V, 110 V, 115 V, 127 V, 220 V, 230 V, 240 V / 50/60 Hz

2 x 1,25 AT for 100 ... 115 V / 2 x 1,0 AT für 127 V /

2 x 0,63 AT for 220 ... 240 V

100 VA

for CO<sub>2</sub>-gas acc. to DIN 477

10 bar

4 ... 8 bar (optional; modification by manufacturer is required)

0 ... 50 mmHg

0 ... 24 mmHg

2 ... 24 mmHg

12 mmHg

1 l/min ± 10 %

31 l/min ± 10%

450 x 160 x max. 430 mm

Metal plastic-coated /plastic

11,8 kg



**Ambient temperature:**

- Operation: + 10 °C to + 35 °C
- Storage and transport: - 10 °C to + 60 °C

**Air humidity:**

max. 85%

**Air pressure:**

- Operation: 700 - 1060 hPa
- Storage and transport: 700 - 1060 hPa

CE-labeling is performed following the EC-guidelines 93/42/EWG Annex II.

Production and testing in compliance with the standards of IEC 601-1, IEC 601-1-2 und IEC 601-1-4.

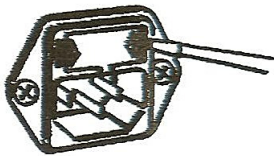
Upon request, circuit diagrams, spare part lists, descriptions, adjusting instructions and other documentation are available to qualified technical personnel of the user for repairing of unit parts, if the manufacturer considers them to be repairable by written confirmation.

## 7. Exchange of Fuse(s)

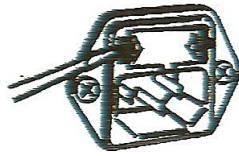
**Caution: Disconnect mains plug prior to exchange of fuse(s)!**

### Exchange of fuse – bipolar

Disconnect mains plug

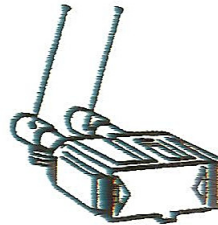


First, press right latch



Press left latch

Exchange fuse



Pull out insert

Have insert audibly locked in place on both sides

## 8. Symbols



Display of CO<sub>2</sub>-bottle pressure



Volume regulation of warning and alarm sound



Switch position "OFF"



Switch position "ON"



Flow indicator LOW-FLOW (1 l/min)



Flow indicator HI-FLO



Caution: Observe accompanying labelings!



Device classification B



Circuit breaker



VIDEO IN



VIDEO OUT

**Gas in**


Display of insufflation pressure



Connection of foot pedal

**Intraabdominal**

Display of static intraabdominal pressure

<b>Preset</b>	Display of preselected intraabdominal pressure
<b>Flow</b>	Display of gas flow
<b>CO<sub>2</sub> used</b>	Display of total gas consumption
<b>CO<sub>2</sub></b>	Identification of CO <sub>2</sub> -gas to be used
<b>SN</b>	Serial number
<b>REF</b>	Type identification
<b>IPX1</b>	Drip-proof
<b>CE 1275</b>	CE-labeling and identification number of the Notified Body. The product is in compliance with the Basic Requirements of the guidelines for medical products 93/42/EWG.
	Display of CO <sub>2</sub> -bottle reserve



## 9. Operating Instructions

### 9.1 Introduction

Thanks to the rapid development of electronics and sensorics, electronically controlled gas insufflators belong to the state-of-the-art technology.

Like no other procedure, the monofil-bivalent system according to Semm<sup>®</sup> allows the monitoring of pressure values being relevant for the patient's safety. By using one single opening for gas insufflation and measuring of static intraabdominal pressure, maximum safety is guaranteed.

Additionally, the Quadro-Test, ensuring permanent display of the measuring data insufflation pressure, static intraabdominal pressure, gas flow and total gas consumption, guarantees optimum safety from the beginning. The operating surgeon is already efficiently supported by the Quadro-Test when positioning and inserting the Veress needle for the first time.

These features are combined in the WISAP<sup>®</sup> THERME-PNEU Computer with innovative, sophisticated microcontroller technology. High-Tech behind an easy-to-clean soft-touch panel, programmed with the longstanding experience gained in insufflator construction and combined with pneumatic safety components proven worth-while, ensure efficient gas insufflation of more than 3 l/min. with maximum safety.

Communication with the user and control of the filling procedure are assigned to separate parts of the multiprocessor system. A controller only destined for activation of displays and key buttons removes the load from the main controller. This allows the recording of many measuring values in each second and thus the dynamic control of the insufflation procedure with optimum, physiologically acceptable speed by sliding adaptation of the filling cycles.

The exact monitoring and display of the CO<sub>2</sub>-bottle pressure allow optimum, economic use of the bottle contents. Necessary exchange is signalled by alarm sound and warning message.

The intentionally simple operation of the device is usually restricted to 2 operating elements, when device is ON, or to 2 foot pedals, if foot pedal is connected (option: 7070CF and 7070CMF). This type of remote control enables the operating surgeon to remain sterile while using the device.

Even under unfavourable light conditions, large-area, brightly illuminating LED dot matrix displays allow clearly visible read off of Quadro-Test measuring values and of certain warning or error messages, also from a long distance, combined with an acoustic alarm. Furthermore, illuminated soft-touch buttons facilitate optimum access and high user safety by acoustic „button click“.

The insufflation procedure and the approach of intraabdominal pressure to the preselected value can also acoustically be assessed by the changing „cycle rhythm“ of the appliance. In danger situations, an alarm sound is generated and the reason is shown on the dot matrix displays or the LED indicator for static intraabdominal pressure. The operating surgeon can thus focus all of this attention on the endoscopy.

The Flow-Therme incorporated in the unit allows connection of a heating tube for preheating of insufflation gas. The gas heated to body temperature prevents hypothermia of the abdominal cavity and thus peritoneal catarrh. The postoperative use of analgesics is significantly reduced.

The option „fade-in on monitor“ (7050CM and 7050CMF) allows fading-in of Quadro-Test measuring values and of additional data on the video image of a connected monitor.

### 9.2. Putting the Unit into Operation

The device is ready for operation when performing the steps outlined below. The order described has to be followed.

**! For ensuring adequate safety, device and accessories must not be used, if faults are found or assumed. In such case, the equipment has to be repaired by the manufacturer or by persons explicitly authorized by him. !**

#### 9.2.1. Electrical Connection

##### • Grounding Connection (see Technical Description)

Grounding pin 20 of the device is to be joined with the central potential equalization of the OR by means of a grounding cable or with the grounding connection at an equipment trolley upon installment of the device.

##### • Mains Connection (see Technical Description)

Prior to connection of the device to the power supply, set mains switch 1 to position "0" = OFF (rocker switch to the left). Attach mains cable to the unit and then to the mains.

**! The device must not be operated with defective mains cable. !**



### 9.2.2. Connection to CO<sub>2</sub>-Gas Supply

The appliance is destined for support of CO<sub>2</sub>-cylinders with a nominal pressure of approx. 60 bar and a net weight of 750 g. In order to ensure that sufficient gas reserve is available for the operative intervention, only sufficiently filled gas cylinders should be used! The electronic measuring of the CO<sub>2</sub> bottle pressure guarantees optimum use of the bottle contents. At bottle pressure values below 15 bar and 10 bar, a correspondent warning message on the lower LED dot matrix display **8** appears alternating to the display of flow values.

**! Proper device function is only guaranteed at bottle pressure greater than 10 bar. In order to avoid interruption of the operation owing to the lack of CO<sub>2</sub>-insufflation gas, filled replacement cylinders have to be available anytime. !**

If the bottle pressure falls below 10 bar (yellow LED at the bottom for display of CO<sub>2</sub>-cylinder reserve **4c** starts to flash, indication of "pCO<sub>2</sub> < 10 bar" on the lower LED dot matrix display **8**), the cylinder should immediately be replaced! Insufflation is stopped upon exchange of the bottle and is automatically continued after connection of a new CO<sub>2</sub>-cylinder with a pressure > 10 bar. Otherwise, insufflation is blocked for safety reasons.

The accurate bottle pressure can be detected anytime by depressing green button **3** for pressure display when device is ON. If bottle pressure is below 15 and 10 bar, a signal is activated for approx. 8 seconds and falling of pressure under the limit value is shown on the lower LED dot matrix display **8** alternating to the normal display. **The signal can earlier be terminated by depressing button 3 for pressure display for at least 3 seconds. However, the signal can then no longer be activated, if pressure falls under lower limit values!** Only connection of a gas cylinder with a pressure of at least 10 bar re-activates this acoustic signal function.

**Caution: CO<sub>2</sub>-cylinder should never be emptied under a pressure of 10 bar and should only be stored with closed bottle valve! Thus you prevent contamination of bottles until the next filling, and proper function of your appliance is thus ensured!**

Gas cylinders with a pressure greater than 80 bar are excessively filled and constitute a safety risk. At such pressure values, an acoustic signal is released and a warning message appears on the lower LED dot matrix display **8** alternating to the normal display. **As immediate exchange of bottles with pressure values higher than 80 bar is absolutely necessary, the signal is not limited in time.** Termination of the acoustic signal by activating the button for pressure display is impossible.

- Attachment of CO<sub>2</sub>-cylinders with German, Italian or Swiss connection

Pull out rod of bottle support **24**, place CO<sub>2</sub>-cylinder onto rod and apply onto gas connection **23**, whereby correct seat of the sealing has to be ensured. Tighten coupling nut with wrench (device accessory).

- Attachment of CO<sub>2</sub>-cylinders with Pin-Index connection

Unscrew handwheel of gas connection **23** almost completely. Pull out rod of bottle support **24**, place CO<sub>2</sub>-cylinder onto rod and have it locked in place on the arresting bolts of the gas connection, whereby correct seat of the sealing has to be ensured. Tighten handwheel of connection.

- Attachment of CO<sub>2</sub>-cylinders through high-pressure connection tubing

By connecting the CO<sub>2</sub>-cylinder through a high-pressure tubing, the device can be operated separately from the cylinder. Furthermore, the use of bottles with higher net weight/volume is thus possible. When joining a high-pressure tubing with CO<sub>2</sub>-gas connection **19**, correct seat of the sealing and tight screwing are to be ensured. Connect CO<sub>2</sub>-cylinder to the other end of the high-pressure tubing, whereby correct seat of the sealing and tight screwing are also required.

**Caution: The CO<sub>2</sub>-cylinder must not be operated in horizontal position. It needs to be ensured that the bottle valve is located higher than the bottom. A minimum inclination angle of 20° is to be observed. If these instructions are not followed, serious malfunctions at the unit may occur!**

The CO<sub>2</sub>-cylinder has to be adequately positioned and to be fixed with appropriate means (bottle support, strap)!

- Connection to the central gas supply

The standard version of the unit is not destined for connection to a central gas supply! Upon request, the device can be modified in the manufacturer's facility for connection to a CO<sub>2</sub>-gas supply with a pressure of 4 ... 8 bar. When ordering the special connection tubing, please indicate the type of gas supply and the requested tubing length.

### 9.2.3. Connection of Heating Tube

Attach plug **17a** of heating tube cable to the respective socket **13**, whereby red markings on plug and socket have to be observed. Connecting cap **17b** of heating tube **17** has to be joined with connection „to patient“ **14** through adaptor **16** and filter **15**.

**Caution: Do not bend, squeeze, overstrain or overturn heating tube. Hold heating tube tightly while attaching Veress needle or trocar followed by turning the instruments onto the tube coupling. Do not perform this step in reversed order.**

Gas filter 15, WISAP-Art.- No. 7070TF (only use original filter taken out of undamaged packing) is disposable and not re-sterilisable. For avoiding cross-contamination, it is necessary to exchange the gas filter after each patient!

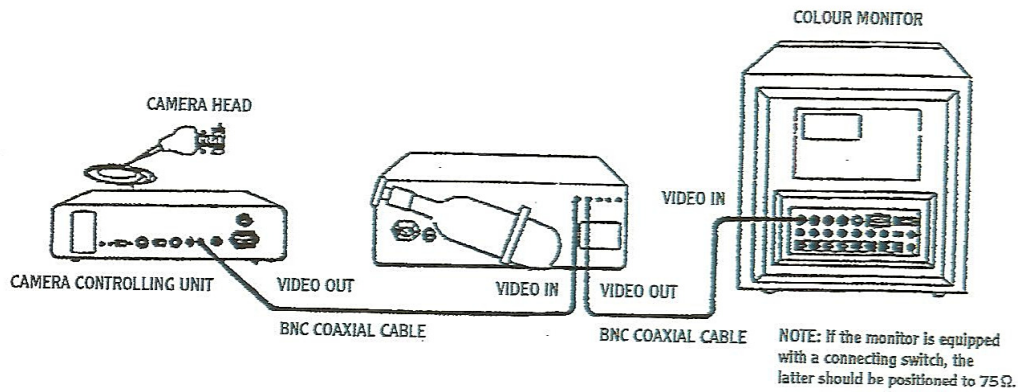
#### 9.2.4. Connection of Double Foot Pedal (optional)

Remote control of flow functions "FLOW ON/OFF" and "HI-FLO" is possible through a double foot pedal. The green tube end of double foot pedal 24 is to be joined with the right connection pin 27a, the transparent tube end with the left connection pin 27b. In this configuration, the left pedal serves for actuation of button 5 FLOW-ON/OFF, the right pedal for actuation of button 6 HI-FLO. Parallel to the remote control, operation of these two buttons on the soft-touch panel is still possible.

#### 9.2.5. CAMERA AND MONITOR CONNECTIONS (optional)

It is possible to have all data measured by the THERME-PNEU COMPUTER faded-in on the video image of a connected monitor. For such purpose, it is necessary to connect camera and monitor to the THERME-PNEU COMPUTER, as described below:

1. Connect „VIDEO OUT“ outlet of camera with inlet „VIDEO-IN“ of the THERME-PNEU COMPUTER through a BNC coaxial cable.
2. Connect „VIDEO OUT“ outlet of the THERME-PNEU COMPUTER with the „VIDEO-IN“ inlet of the monitor through an additional BNC coaxial cable.
3. Check switch at the rear of the monitor to ensure that switch is positioned to „terminal resistance“ or 75 Ohm. For connection in series with more than one monitor, the last monitor in the chain must be applied with a terminal resistance.
4. Only monitor/camera equipment being in compliance with IEC 601-1 may be used.





## 9.3. Activation of the Unit

### 9.3.1. Turning on of mains switch

Set mains switch to "I" = ON

- Rocker switch illuminates green
- Activation of device is signalled by short acoustic "beep"
- 

### 9.3.2. „Turn on“ messages / System check

See point 4 of „Functional Control“.

### 9.3.3. Normal display

See point 5 of „Functional Control“.

### 9.3.4. Opening of cylinder valve

See point 6 of „Functional Control“.

### 9.3.5. Display of accurate CO<sub>2</sub>-bottle pressure

The exact bottle pressure can be read off anytime on the upper LED dot matrix display 7 by activating button 3 for pressure display.

pCO<sub>2</sub> = 59 bar

In case of full and correctly filled gas cylinder and normal room temperature, the pressure is about 59 bar. Lower temperatures lead to reduced bottle pressure and vice versa.

Depending on the type of operative intervention, use of gas cylinders with a pressure below 30 bar is not recommendable due to the low gas quantity being available.

Devices having been modified for connection to a central CO<sub>2</sub>-gas supply should be operated with a pressure of 4 ... 8 bar.

## 9.4. Building up of Pneumoperitoneum

### 9.4.1. Needle test

Prior to insertion of the Veress needle into the abdomen, the flow resistance at a flow (gas flow) of 1 l/min and at a preselected intra-abdominal pressure "Preset" (displayed under 7) of 12 mmHg. For such purpose, the orange FLOW ON/OFF button 5 is to be actuated after connection of the Veress needle to heating tube 17, whereby gas insufflation is started. During gas insufflation, the actual insufflation phases are periodically interrupted by measuring cycles detecting the intraabdominal pressure. The permanent change between these two phases is, among other things, detectable by the click sound of the valves. If Veress Needle is completely open, the following indications should appear on the two LED dot matrix displays 7 and 8:

- Insufflation pressure "Gas in" not higher than 3 ... 8 mmHg
- "Intraabdominal" pressure 0 mmHg
- "Flow" display shows 0,9 ... 1,1 l/min during the insufflation phases and 0,0 l/min during the measuring cycles
- Display of flow indicator > > > during the insufflation phase
- On the display "CO<sub>2</sub> used", the gas volume used since start of the insufflation procedure is indicated
- Only the lower yellow LED 11c of the LED intraabdominal pressure indicator 11 illuminates

If Veress needle is partly closed, the insufflation pressure is higher than 3 ... 8 mmHg. If Veress needle is completely closed during a measuring phase, („Flow" display 0,0 l/min, no flow indicator), an insufflation pressure even higher than before is generated in the following insufflation phase (50 mmHg at the maximum). In the subsequent measuring phase, the same measuring value appears on the „Intraabdominal" display. As the intraabdominal pressure is thus by more than 7 mmHg greater than the „Preset" pressure of 12 mmHg, an alarm sound is released and the upper red flashing LED 11a of intraabdominal pressure indicator 11 is activated (lower yellow LED 11c - off). Insufflation is immediately stopped and automatically continued, as soon as the "Intraabdominal" pressure is below the "Preset" pressure (Veress needle is to be opened).



If proper function of the Veress needle including its snap mechanism (snap test) has been detected, gas insufflation is terminated by depressing the orange FLOW ON/OFF button **5** followed by repeated control of the static intraabdominal pressure ("Preset"), which can be corrected by activation of preselection button **10**, if necessary. The value for gas consumption displayed under "CO<sub>2</sub> used" can be reset to 0,0 l by shortly depressing green RESET button **9**.

#### 9.4.2. Insertion of Veress needle and aspiration test

After detachment of the successfully tested Veress needle from heating tube **17**, the needle is commonly, for instance, intraumbilically, inserted into the abdominal cavity followed by instillation of approx. 5 ml saline solution with attempted reaspiration. If the aspiration test turns out negatively, the Veress needle is re-attached to heating tube **17**.

#### 9.4.3. Diminished pressure test (manometer test)

When strongly elevating the abdominal wall, diminished pressure is generated in the abdomen. If the Veress needle is correctly positioned in the abdomen, diminished pressure is signalled by a negative sign accompanying the displayed "Intraabdominal" pressure **7** and by simultaneous illumination of the lower yellow LED **11c** and by flashing of the upper red LED **11a** of LED intraabdominal pressure indicator **11**.

**! If a fault is found or assumed when performing the steps described above, building up of the pneumoperitoneum must not be continued! !**

#### 9.4.4. Start of insufflation with CO<sub>2</sub> gas

While re-elevating the abdominal wall, the orange FLOW ON/OFF button **5** is to be depressed. The following values should appear on the LED dot matrix displays **7** and **8**:

- If needle is freely positioned in the abdomen, the insufflation pressure „Gas in“ during the insufflation phase (visible at the flow indicator > > >) must, at first, not exceed the test value detected with absolutely opened Veress needle at a flow of 1 l/min.
- Under "Flow", a value of 0,9 bis 1,1 l/min is displayed during the insufflation phase (during the measuring cycle, a value of 0,0 l/min is shown accompanied by disappearance of the flow indicator lights > > >)
- "CO<sub>2</sub> used" shows the gas quantity used since start of the insufflation and thus the size of the intraabdominal gas bladder.
- The "Intraabdominal" pressure increases during insufflation of the first liter CO<sub>2</sub>-Gas from 0 mmHg to 2 mmHg.
- Despite the intermittent change between insufflation and measuring phase, the insufflation pressure "Gas in" and the "Intraabdominal" pressure are continuously displayed.
- As long as the "Intraabdominal" pressure is lower than the preselected „Preset" value, the lower yellow LED **11c** of the LED intraabdominal pressure indicator **11** illuminates. In case of diminished pressure, the upper red flashing LED **11a** additionally lights up. Up to a filling volume of 1 l, the displayed „gas in" and „intraabdominal" pressure values should not significantly change. If the value of the displayed „Intraabdominal" pressure skips to a value close to the insufflation pressure „gas in", the needle is not freely positioned in the abdominal cavity (volume test). **The insufflation needs to be terminated immediately followed by re-positioning of the Veress needle!**

#### 9.4.5. Continuation and termination of insufflation at "1 l/min" (current flow 0,9 ... 1,1 l/min)

As of approx. 1 l filling volume, the "Intraabdominal" pressure display slowly starts to indicate the increasing pressure from 2, 3 to 5 mmHg. At the same time, the insufflation pressure "Gas in" also rises owing to the addition of intraabdominal and insufflation pressure. With increasing intraabdominal pressure, the electronics gradually reduces the time of insufflation phases until complete stop, as soon as the intraabdominal pressure has reached the preselected "Preset" pressure. With insufflation stop, the LED intraabdominal pressure indicator **11** switches over from the lower yellow LED **11c** to the upper green LED **11b**. At the same time, the characteristic insufflation sounds are terminated. We would urgently recommend to record the gas quantity used until the preselected pneumoperitoneum has been reached, in order to be exactly informed of the intraabdominal gas bladder volume. Gas loss at the instruments leads to additional insufflation phases.

Many operating surgeons already activate the „HI-FLO" function after 1 liter filling volume by depressing the yellow HI-FLO button **6**. During the insufflation phases, a modified flow indicator >>>> is displayed on the lower LED dot matrix display **8**. Depending on the flow resistance of the Veress needle, a gas insufflation of approx. 3 ... 6 l/min is possible. This considerably shortens the insufflation time. However, it is important that the surgeon has the necessary experience for such rapid filling cycle and that he has previously discussed this with the anaesthetist.

Furthermore, the insufflation pressure displayed under "Gas in" increases, depending on the quality of the Veress needle, to 50 mmHg within a very short period of time owing to the transport of a higher gas volume. However, the intraabdominal static pressure must not exceed the value preselected under "Preset". If the "Intraabdominal" pressure also exceeds 15 or even 20 mmHg, the insufflation procedure has to be immediately stopped. The Veress needle is not located in the free abdomen or the patient is insufficiently relaxed. As soon as the intraabdominal pressure is by approx. 7 mmHg greater than the preselected value under „Preset“, the upper red flashing LED 11a of the LED intraabdominal pressure indicator 11 and a simultaneous acoustic warning signal are activated. Especially position HI-FLO causes dynamic reduction of filling cycles, so that the preselected pressure is reached in the fastest, most careful manner.

### 9.5. Insertion of Optics Trocar

After performance of the sounding test as precaution to ensure that the space for placing the trocar is free from adhesions, the Veress needle is removed, the trocar is inserted by Z-puncture and connected with heating tube 17.

Prior to introduction of the endoscope, function HI-FLO is activated by depressing the yellow HI-FLO button 6, so that the electronics is able to compensate the gas loss of the optics trocar. Also in this case, the electronics works with dynamic reduction of filling cycles. In order to minimize the gas loss, we would recommend to interrupt insufflation by depressing the orange FLOW ON/OFF button 5 and to continue insufflation by depressing the same button again with subsequent activation of the HI-FLO function.

### 9.6. Termination of Gas Supply

Upon completion of the endoscopic intervention, the trocar valve is to be closed followed by detaching the heating tube from the trocar and by termination of the preselected insufflation mode (1 l/min. or HI-FLO) by repeated depressing of the orange FLOW ON/OFF button 5. Thus a backflow through gas filter 15 and a vacuum in the measuring system are prevented after termination of the gas supply (uncontrolled vacuum in the measuring system leads to destruction of the pressure measuring system inside the unit). After the total quantity of CO<sub>2</sub> gas has been recorded according to the value shown under "CO<sub>2</sub> used", the display can be reset to 0,0 l by depressing the green RESET button 9.

### 9.7. Operation of Foot Pedal

The optionally available double foot switch 24 allows remote control of the flow functions and thus sterile operation by the operating surgeon. After correct attachment of the foot pedal to the correspondent connection pin (foot pedal connection) 27 at the rear of the unit, the left pedal serves for activation of Flow ON/OFF button 5, the right pedal for activation of HI-FLO button 6. The function of both buttons remain unchanged after connection of the foot pedal.

Appliances not disposing of the necessary foot pedal connection 27 can be modified by the manufacturer.

### 9.8. Fading-In of Measuring Data

This option allows fading-in of insufflation on the video image of connected camera and monitor. Such fading-in can be activated or deactivated by simultaneously depressing button 3 for display of bottle pressure and button 2 for volume regulation. Apart from the Quadro-Test data, the CO<sub>2</sub> bottle pressure and the total insufflation time are displayed. The display for total insufflation time is started or stopped by turning the flow on or off through the FLOW ON/OFF button. The display for total insufflation time can be reset together with the display for gas volume used by activation of RESET button 9.

Gas in=20	Pres=14 Intraabdom.	14mmHg
01:23:54	Flow=12.4l/min	Used=112.3l
WISAP	CO <sub>2</sub> -THERME-PNEU	CO <sub>2</sub> =42bar

#### Explanation of Monitor Displays:

<b>Gas In=</b>	Insufflation pressure in mmHg
<b>Pres=</b>	Preset (preselected intraabdominal pressure) in mmHg
<b>Intraabdom.</b>	Static intraabdominal pressure in mmHg
<b>HH:MM:SS</b>	Total insufflation time in hours:minutes:seconds
<b>Flow=</b>	Flow rate in liter/min
<b>Used=</b>	Gas consumption in liter
<b>CO<sub>2</sub>=</b>	CO <sub>2</sub> -bottle pressure in bar

Alternatively, the display line at the bottom may also indicate warning or error messages.



## 10. Alarm Signals, Warning and Error Messages, Malfunctions

The electronics integrated in the device allows unrestricted surveillance of measuring values and device functions. If limit values are exceeded or not reached, the messages below are indicated on the respective displays and alarm sounds are activated.

The text passages marked with "\*" are valid for appliances having been modified for connection to a central CO<sub>2</sub>-gas supply.

Display	Alarm Sound	Reason	Note
<p>Lower LED-dot matrix display <b>8</b> shows alternately to normal display:</p> <p><b>pCO<sub>2</sub> &gt; 80 bar.</b> <b>(pCO<sub>2</sub> &gt; 10 bar) *</b></p> <p>Additionally, the red flashing LED <b>4a</b> of the CO<sub>2</sub> reserve display is activated</p>	Not limited in time; cannot be reset by activation of button <b>3</b> for display of bottle pressure	CO <sub>2</sub> -bottle pressure greater than 80 bar (CO <sub>2</sub> -gas pressure of central gas supply is higher than 10 bar) *	Close bottle valve immediately and replace bottle (Adjust gas pressure of central gas supply to 4 ... 8 bar) *
<p>Lower LED dot matrix display <b>8</b> shows alternately to normal display:</p> <p><b>pCO<sub>2</sub> &lt; 15 bar.</b> <b>(pCO<sub>2</sub> &lt; 2 bar) *</b></p> <p>Furthermore, only the yellow LED <b>4c</b> of the CO<sub>2</sub>-bottle reserve display located at the bottom is activated.</p>	Limited to approx. 8 seconds; can be reset by depressing button <b>3</b> for display of bottle pressure for at least 3 seconds	CO <sub>2</sub> -bottle pressure is lower than 15 bar, but at least 10 bar (CO <sub>2</sub> -gas pressure of the central gas supply is lower than 2 bar) *	Refers to limited gas reserve, display for gas reserve has to be further observed, have new gas cylinder available (adjust gas pressure of central gas supply to 4 ... 8 bar) *
<p>Lower LED-dot matrix display <b>8</b> shows alternately to normal display:</p> <p><b>pCO<sub>2</sub> &lt; 10 bar.</b> <b>(pCO<sub>2</sub> = 0 bar) *</b></p> <p>Additionally, only the yellow LED <b>4c</b> of the display for CO<sub>2</sub>-bottle reserve at the bottom still flashes</p>	If previous alarm (15 bar) was not reset, a repeated alarm sound for approx. 8 seconds is activated, which can be reset by depressing button <b>3</b> for display of bottle pressure for at least 3 seconds.	CO <sub>2</sub> -bottle pressure is lower than 10 bar (CO <sub>2</sub> -gas pressure of the central gas supply is 0 bar)	Close cylinder valve and immediately exchange bottle! At a bottle pressure below 10 bar, proper device function cannot be guaranteed! (Adjust gas pressure of central gas supply to 4 ... 8 bar) *
On the LED indicator for intraabdominal pressure <b>11</b> , only the upper red LED <b>11a</b> flashes	Alarm sound can only be reset by decreasing the intraabdominal pressure	Excessive intraabdominal pressure; the pressure measured in the abdomen is by at least 7 mmHg greater than the preselected pressure displayed under „Preset“	Possible causes: Veress needle or trocar not opened, contaminated or wrongfully placed; contaminated or bent heating tube, patient insufficiently relaxed.
On the LED indicator for preheating of insufflation gas <b>12</b> , the green LED illuminates accompanied by flashing of the red LED, heating tube does not warm up.		Cable of heating tube <b>17a</b> is not connected to socket <b>13</b> , circuit breaker <b>28</b> at the rear of the unit has released, interruption or short-circuit inside the heating tube	Check cable of heating tube as to correct connection to the unit, depress black knob of circuit breaker at the rear of the unit. If fault can clearly be simulated by moving the heating tube/cable, the tube is defective.



Display	Alarm Sound	Reason	Note
Under "Intraabdominal", a negative pressure value is indicated on the upper LED dot matrix display 7. At the indicator for intraabdominal pressure 11, the lower yellow LED 11c lights up. Additionally, the upper red LED 11a flashes.	-	Intraabdominal diminished pressure caused by elevation of the abdominal wall. Intraabdominal diminished pressure is caused by heating tube still attached to the device and by the instrument still connected to heating tube 17 with closed valve after termination of insufflation.	The displays described simplify placement of the Veress needle. After termination of gas supply, the instrument is to be detached from the heating tube followed by separation of the heating tube from the appliance! Uncontrolled diminished pressure may lead to breakdown of the measuring electronics.
„Flow“ display 0,0 l/min., no flow indicator, no click sound of solenoid valves despite activated flow function buttons 5, 6.  Flow function buttons are fully illuminated, i. e. button activation is confirmed by the unit.	-	Intraabdominal pressure is equivalent or greater than the preselected value displayed under „Preset“  CO <sub>2</sub> bottle pressure is below 10 bar	Exchange gas cylinder
On the LED indicator for preheating of insufflation gas 12, neither the green nor the red LED are illuminated, heating tube does not warm up, remaining device functions and displays are normal	-	Fault at the unit	Fault can only be removed by opening the device by manufacturer or authorized dealer
Lower LED-dot matrix display 8 shows error message with fault code  <b>! Error ... !</b>  A number is displayed instead of the three points.	-	Fault at the unit	Fault can only be removed by opening the chassis by manufacturer or authorized dealer, indicate exact error code!
No device function, no activated display, mains switch 1 does not illuminate.	-	Device without current	Check mains connection and fuses (see Technical Description). In case of several successive change of fuses, have device checked by manufacturer or authorized dealer)
Measuring data faded-in on the monitor are torn in stripes, eventual monitor display „No Sync“	-	Missing synchronisation	It is not sufficient to connect „VIDEO OUT“ outlet 26 of the device with the monitor. For synchronisation of data fade-ins, connection of „VIDEO OUT“ of camera with „VIDEO IN“ 25 of the appliance is required.

<p>No video image and no measuring data faded-in on the monitor</p>	<p>—</p>	<p>„VIDEO IN“ 25 and „VIDEO OUT“ 26 mixed up at the unit</p> <p>Defective camera, device or connection cable</p>	<p>Correctly connect „VIDEO IN“ 25 and „VIDEO OUT“ 26 of the device with camera and monitor.</p> <p>For testing, connect camera directly to the monitor; perform test with both BNC video cables; if video image is produced on the monitor with both video cables, there is a fault at the insufflator. Have device checked.</p>
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## 11. Functional Control

The functional control is prescribed by the guidelines of IEC 601-1. It has to be performed prior to each operation. The functional control serves for investigation of insufflator, filter, gas filter adaptor, heating tube and Veress needle.

**Hint:** Sterilise re-usable instruments prior to operation in order to avoid infections to the patient.

Description of Functional Control	
1. Join insufflator with central potential equalization through grounding cable. Optionally available fading-in of measuring data: Connection of camera and monitor to the THERME-PNEU Computer (see 9. „operating instructions“).	-
2. Connect mains cable to insufflator and join with power supply network. Optionally available fading-in of measuring data: connect mains cable to camera and monitor and join with power supply network.	-
3. Connect gas cylinder to CO <sub>2</sub> -gas connection 19 at the rear of the unit. Bottle valve remains closed.	-
4. Activation of mains switch 1	<p>⇒ Rocker switch illuminates green</p> <p>⇒ The following key buttons are only slightly illuminated:</p> <ul style="list-style-type: none"> <li>- Green key button for volume regulation 2</li> <li>- Green display of CO<sub>2</sub>-bottle pressure 3</li> <li>- Orange Flow-ON/OFF button 5</li> <li>- Yellow HI-FLO button 6</li> <li>- Green Reset button 9</li> <li>- Yellow preset buttons for intraabdominal pressure 10a and 10b</li> <li>- Red LED 12b flashes</li> </ul> <p>⇒ Short acoustic „beep“</p> <p>⇒ Green LED 12a illuminates</p> <p>⇒ The following values appear on dot matrix displays 7 and 8:</p> <p>a)</p> <div style="border: 1px solid black; padding: 2px; width: fit-content; margin: 2px auto;">CO<sub>2</sub>-THERME-PNEU</div> <div style="border: 1px solid black; padding: 2px; width: fit-content; margin: 2px auto;">WISAP Computer</div> <p>b)</p> <div style="border: 1px solid black; padding: 2px; width: fit-content; margin: 2px auto;">Quadro Test</div> <div style="border: 1px solid black; padding: 2px; width: fit-content; margin: 2px auto;">Semm System</div> <p>c)</p> <div style="border: 1px solid black; padding: 2px; width: fit-content; margin: 2px auto;">_____</div> <div style="border: 1px solid black; padding: 2px; width: fit-content; margin: 2px auto;">System Check</div> <ul style="list-style-type: none"> <li>- Display for CO<sub>2</sub>-bottle reserve 4 completely illuminates</li> <li>- LED-indicator for static intraabdominal pressure 11 completely illuminates</li> </ul> <p>d)</p> <div style="border: 1px solid black; padding: 2px; width: fit-content; margin: 2px auto;">_____</div> <div style="border: 1px solid black; padding: 2px; width: fit-content; margin: 2px auto;">System Check</div>





<p>8. Start of insufflation by actuating the orange Flow-ON/OFF button 5. Optionally available foot pedal: start of insufflation by activating the left foot pedal</p>	<p>⇒ Key button illuminates with full intensity  ⇒ Device starts to cycle. On the lower LED-dot matrix display, the following values are indicated:</p> <ul style="list-style-type: none"> <li>- Flow: 1l ±0,1</li> <li>- the flow indicator &gt;&gt;&gt; is activated</li> <li>- the quantity of CO<sub>2</sub>-gas used is displayed under „CO<sub>2</sub> used“</li> </ul>
<p>9. Additional activation of yellow HI-FLO button 6. Optionally available foot pedal: start of insufflation by activating the right foot pedal</p>	<p>⇒ Key button illuminates with full intensity  ⇒ On the lower LED-dot matrix display 8, the following values are indicated:</p> <ul style="list-style-type: none"> <li>- Flow: 31l ±0,1</li> <li>- The flow indicator &gt;&gt;&gt;&gt; is activated</li> </ul>
<p>10. Terminate insufflation by depressing Flow-ON/OFF button 5. Optionally available foot pedal: terminate insufflation by actuating the left foot pedal. Optionally available fading-in of measuring data.</p>	<p>⇒ Key button illuminates with full intensity</p> <p>⇒ On the monitor display, the indicated time needs to stop</p>
<p>11. Attach gas filter 15, filter adaptor 16, heating tube 17 and Veress needle to connection „to patient“ 14 and join heating tube cable 17a with correspondent socket 13.</p>	<p>⇒ The red flashing LED 12b is no longer activated.</p>
<p>12. Start of insufflation by actuating Flow-ON/OFF-button 5; valve of Veress needle is opened.</p>	<p>⇒ Key button illuminates with full intensity  ⇒ On the upper LED-dot matrix display 7, the following value is indicated:</p> <ul style="list-style-type: none"> <li>- Gas in: 3 ... 8</li> </ul> <p>⇒ On the lower LED-dot matrix display 8, the following value is indicated:</p> <ul style="list-style-type: none"> <li>- Flow: 1l ±0,1</li> </ul>
<p>13. Increase to highest value by depressing preset button for intraabdominal pressure 10b; additional actuation of HI-FLO button 6. Close Veress needle at the beginning of the filling phase.</p>	<p>⇒ Key button illuminates with full intensity  ⇒ On the upper LED-dot matrix display 7, the following values are indicated:</p> <ul style="list-style-type: none"> <li>- Gas in: 50 ± 2mmHg</li> <li>- Intraabdom.: 48 ± 3mmHg</li> <li>- Preset: 24mmHg</li> </ul> <p>⇒ Red LED 11a flashes and the acoustic alarm is activated</p>
<p>14. Terminate insufflation by depressing Flow-ON/OFF button 5.</p>	<p>⇒ Key button illuminates with normal intensity</p>
<p>15. Open Veress needle and have pressure dropped to 10 - 20mmHg; close Veress needle.</p>	<p>⇒ Yellow LED 11c illuminates  ⇒ Reduce pressure preselection through preset button 10a until change from yellow LED 11c to green LED 11b ; change from green LED 11b to red flashing LED 11c and activation of the acoustic alarm have to take place at a pressure difference of 7 mmHg between preselected and intraabdominal pressure</p>
<p>16. Adjust preselected pressure to 8 mmHg with preset buttons for intraabdominal pressure 10. Start of insufflation by actuating Flow-ON/OFF button 5.</p>	<p>⇒ Increase preselected pressure by preset button 10b; at a preselected value being by 1 mmHg higher than the intraabdominal pressure, insufflation has to start.</p>
<p>17. Terminate insufflation by actuating Flow-ON/OFF button 5.</p>	<p>⇒ Key button illuminates with normal intensity</p>
<p>18. Re-position displayed gas consumption on the lower LED dot matrix display 8 „CO<sub>2</sub> used“ to 0 by depressing the green Reset button 9; open Veress needle.  Optionally available fading-in of measuring data.</p>	<p>⇒ On the lower LED-dot matrix display 8, the following value is indicated:</p> <ul style="list-style-type: none"> <li>- CO<sub>2</sub> used: 0.0l</li> </ul> <p>⇒ The time and CO<sub>2</sub> used value displayed are reset to 0</p>

<p>19. Check heating tube and accessories as to tightness! Set preselected pressure to 12 mmHg by actuating the preset buttons <b>10</b> for intraabdominal pressure. If valve of Veress needle is closed, insufflation has to be turned on by depressing Flow-ON/OFF button <b>5</b>.</p>	<p>⇒ The value for static intraabdominal pressure indicated on LED dot matrix display <b>7</b> must not drop by more than 1 mmHg in 1 s.</p>
<p>20. Check as to tightness of high-pressure connection! Terminate insufflation by actuating Flow-ON/OFF button <b>5</b>, close valve of gas cylinder. Depress key button <b>3</b> for display of CO<sub>2</sub>-bottle pressure</p>	<p>⇒ Pointer of CO<sub>2</sub> reserve manometer <b>8</b> must keep its position for at least 15 minutes. ⇒ The value for static intraabdominal pressure indicated on the upper LED-dot matrix display <b>7</b> must not drop by more than 1 bar.</p>
<p>21. After completion of the functional control, set mains switch <b>1</b> to position „0“.</p>	<p>-</p>



## 12. Cleaning, Disinfection and Sterilisation

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

### Cleaning of the Device

After use, the device has to be turned off followed by disconnection of mains cable, gas bottle and remaining accessories. For cleaning the outer surfaces of the unit, an aqueous disinfectant is suitable. The solution concentration is to be taken from the recommendations given by the disinfectant manufacturer. Wipe the surface of the unit with a cloth dampend with disinfectant. Entering of liquids into the device has to be avoided.

**The device must not be sterilised!**

### Cleaning of Heating Tube, Gas Filter Adaptor and Veress Needle

Rinse heating tube, gas filter adaptor and Veress needle with running cold and warm water. After thorough cleaning with demineralised water, the parts have to be dried with sterile cloths.

### Disinfection of Heating Tube, Gas Filter Adaptor and Veress Needle

Only parts thoroughly cleaned may be disinfected. Soak parts in solution and observe the manufacturer's recommendations regarding solution concentration and soaking time. Prolonged soaking time or wrongful concentration may lead to damage at the parts. Do not pile up parts. Disinfectant residues should be rinsed off with sterile water under sterile conditions. Dry all parts with sterile cloth followed by wrapping them into a sterile cloth. The disinfected parts have to be stored in a closed, sterile container.

**CAUTION:** The heating tube should not be soaked in disinfectants for more than 30 minutes. Silicone absorbs different disinfectants and would be damaged during subsequent steam sterilisation.

### Sterilisation of Heating Tube, Gas Filter Adaptor and Veress Needle

The parts to be sterilised should be cleaned, disinfected and dried. Wrapping in transparent sterile packages, transport after sterilisation and determined deaeration times are described in the operator manual of the sterilising unit.

### WISAP recommends the following sterilisation methods:

1. Steam sterilisation at 134 °C/3,0 bar/5 min.

Please read the tabular overview on **page 28** for additional cleaning, disinfection and sterilisation information.

**CAUTION:** Steam sterilisation is not recommended for the heating tube, as prolonged sterilisation would impair reliability of the tube (warranty is not applicable in such case).

WISAP would recommend that the personnel responsible for sterilisation studies the operator manuals of the different sterilising units. Please read the instructions for metal articles with lumen and porous articles with lumen. It is important to note that these recommended sterilisation parameter are only valid, if the sterilising equipment has properly been maintained and calibrated.



## 14. General Hints

### Protection against Damage

Protection against damage is only guaranteed, if the unit is adequately operated, maintained and installed safely. The unit needs to be protected against humidity, dirt, flammable or explosives. In order to ensure good dissipation of heat generated during operation of the unit, covering with cloths has to be avoided!

### Environment / Waste Disposal

At the end of the product's operating life, the insufflator components and accessories should be adequately disposed of, while also ensuring careful separation of material. The materials used do not contain any hazardous substances. The chassis material can be recycled. The electronic circuit boards should pass an appropriate recycling procedure.

### Packing / Transport

In order to avoid misunderstandings in case of potential transport damages, we would like to stress the importance of adequate packing. If inappropriate packing can be found, repair costs resulting from this incident will be charged.

### Maintenance

In order to prevent accidents due to aging or normal wear-and-tear, the unit including accessories need to pass a regular (annual maintenance) functional and safety test.

### Operating Life

If all maintenance/service requirements are observed and fulfilled, a minimum operating life of 10 years can be expected.

### Service / Repairs / Modifications

In accordance with the international safety regulations valid for medical devices, all activities such as check ups, repair, modifications, calibrations etc. may only be carried by the manufacturer or by explicitly authorized personnel. All services performed must be entered in the table "Technical Service Notes".

### Liability

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

- assembly, re-adjustment, modifications or repair are performed by personnel authorized by us
- the electric installation of the respective room corresponds to the guidelines of VDE 0107
- the instructions in the user manual are strictly observed when operating the unit

### Warranty

According to our warranty conditions (§ 3 of our General Terms and Conditions). 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.

### Accessories

Filter (REF 7070TF), filter adaptor (REF 7070TA), heating tube (REF 7642HS), Veress needle (REF 7160), mains cable

**WE RESERVE THE RIGHT TO CHANGE TECHNICAL FEATURES AND DOCUMENTATION!**



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