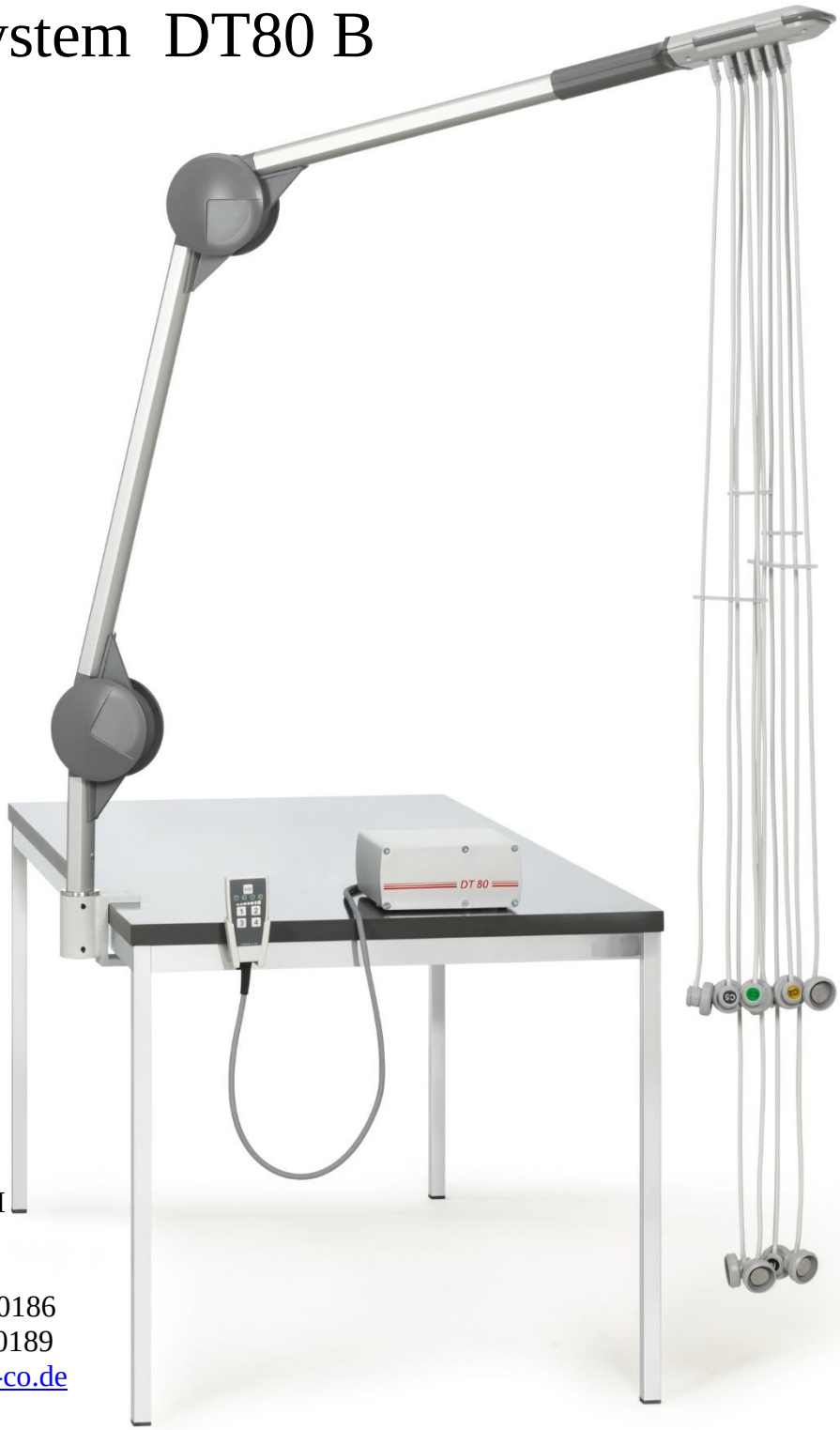
Operating and safety instructions

vacuum system DT80 B



Strässle & Co.
Medizintechnik GmbH
Primelweg 5
D-72461 Albstadt
Tel.: +49 (0)7432 - 220186
Fax: +49 (0)7432 - 220189
Email: info@straessle-co.de
www.straessle-co.de

Item # 1000.665

CH REP SMQS by Arnold Bott AG Industriestrasse 59 CH-8152 - Glattbrugg

CE

Device symbols

	Follow instructions for use
	This part falls under classification BF
	This part falls under classification CF with defibrillation protection
	This part falls under classification BF with defibrillation protection
I	**ON** Power switch: Power on Remote control: Switch vacuum system to stand-by mode and release vacuum
O	**OFF** Power switch: Power off Remote control: Switch off vacuum system
1 **2** **3** **4**	Vacuum levels

TABLE OF CONTENTS

1. DT80 vacuum system

The DT80 vacuum system is a medical product according to Regulation 2017/745. It is designed for operation with common ECG devices and offers improved safe ECG diagnostics combined with increased economical efficiency.

The DT80 vacuum system suits for ECGs in rest as well as under physical exercise. Owing to the secure fixing of the electrodes it is especially advantageous in ergometry.

The DT80 vacuum system is well suited for the practicing physician for “regular” use in maximal 5 Exercise ECG or 20 Resting ECG per day. The system is not designed for high-use ECG practice and continuous operation.

The vacuum electrodes are to be used according to standard measurement procedures. They are fixed to the patient's body by means of a defined vacuum.

The DT80 vacuum system is qualified for ECG diagnostics of adults, teenagers and children from the age of about 7 years (depending on body size).

Note

The DT80 vacuum system is dedicated only for using in hospital and in medical practice.

The DT80 vacuum system is not designed for continuous cardiac and circulatory monitoring and emergency medicine.

The DT80 vacuum system is designed for temporary applications.

These operating instructions are considered to be a constituent of the device and are to be kept therewith.

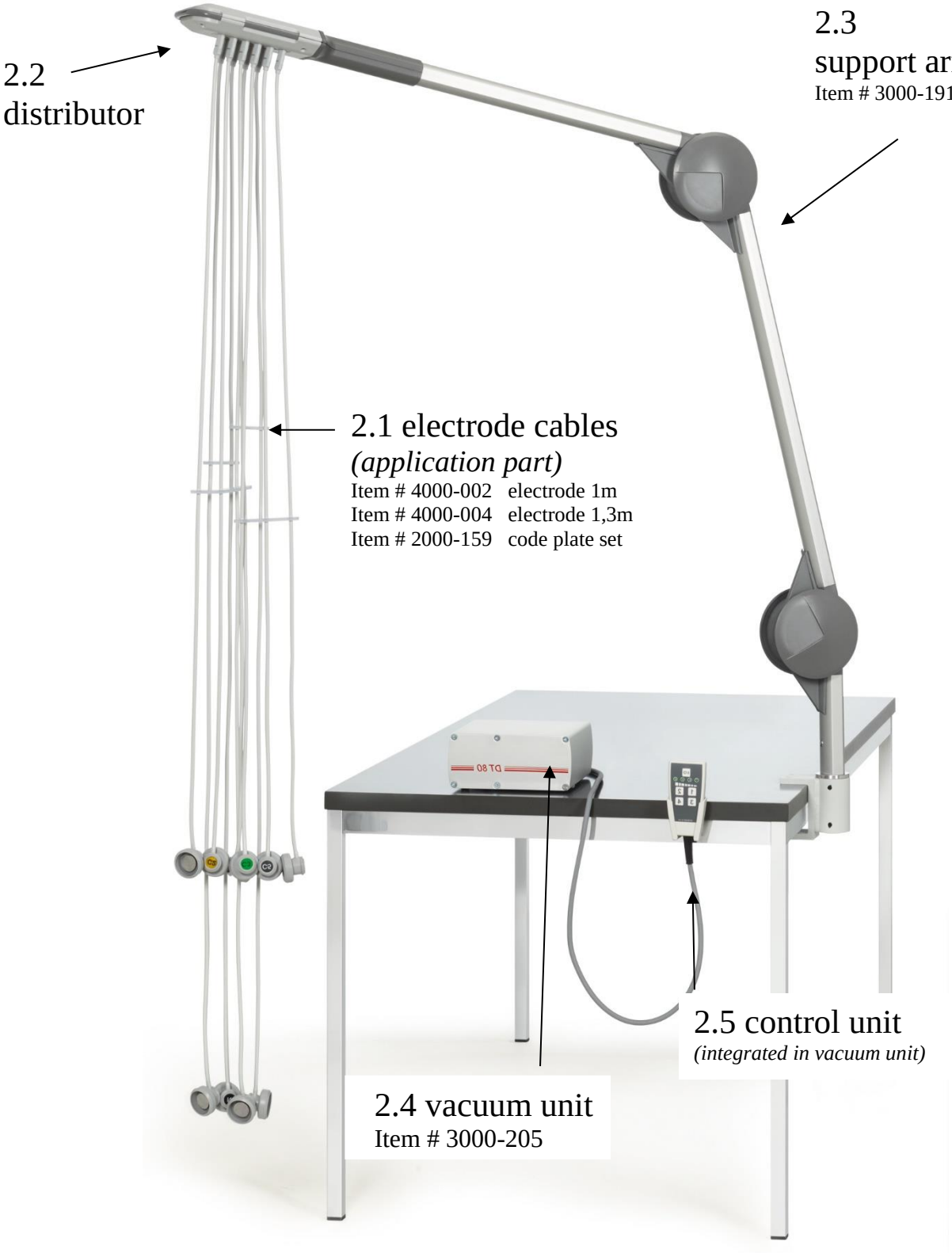
Exact observance of the operating instructions is a prerequisite for the proper operation of the device and thus for the operator's safety.

Compliance with the safety instructions provides protection against injury and prevents undue operation of the device.

Each user of this device or each person concerned with installation, maintenance, testing or repair of the device should have completely read and understood these operating instructions before they start working.

Appropriate juridical regulations of the MPG and the MPBetreibV are to be kept.

2. Components



2.1 Electrode cables *(application part)*

Ten electrode cables, that are R, L, N, F and C1 to C6, constitute the adaptation unit. A specially designed combined electrode head, self-locking and equipped with a silver/silver-chloride electrode opens and adheres to the patient's body on slight finger pressure.

2.2 Distributor

The so-called distributor, the topmost part of the support arm, holds the electrodes in such a way that they cannot be connected improperly. Labels show the assignment of plugs and sockets.

2.3 Support arm

The support arm, a swivelling, fold-out positioning device, provides a high degree of comfort. Equipped with two swivel joints, the support arm can easily and quickly be fixed in any position required.

2.4 Vacuum unit

The vacuum unit of the DT80 controls the required vacuum level. A robust vacuum pump including an adapted pressure vessel provides the selected pressure level. A special microprocessor control unit provides for coordinated control of the overall function. Power socket, on/off switch, vacuum connector and the socket for the control unit are located at the rear of the vacuum unit.

2.5 Control unit

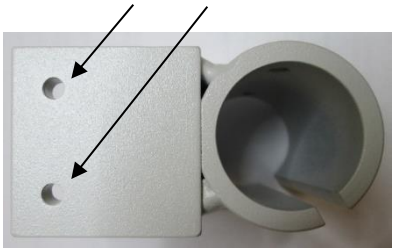
The DT80 comprises a control unit which is connected directly to the vacuum unit. Equipped with an ON/OFF button and four buttons for pressure levels as well as four light emitting diodes, the control unit enables functional, informative and easy handling of the device.

3. Installation

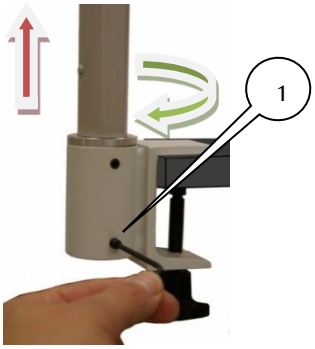
3.1 Installation of the support arm clamping device

Note: Proceed similarly with other clamping devices.
Safety information:
Ensure there is a secure connection when mounting the clamping device for the support arm so that the connection will not come loose! Collisions with other devices are to be excluded.

- Fix the clamping element at the desired position.
- Push the cable and vacuum hose through the cutout of the clamping element and insert the support arm into the clamping element.
- As additional safety, through the two holes at the top the bracket must be screwed with suitable screws at the plate of the table.

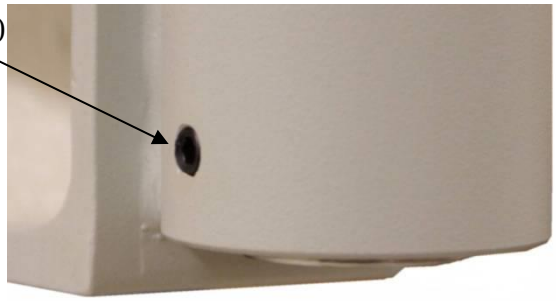


Please note!
Bores must match!

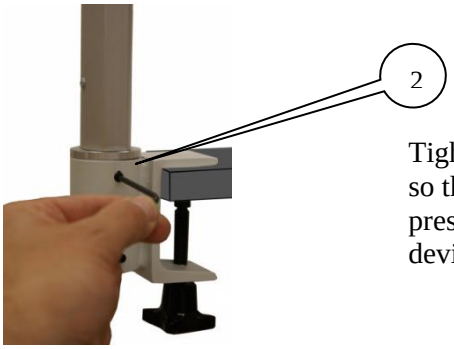


The threaded hole at the foot of the support arm must match the lower threaded hole of the clamping device.

Turn in the grub screw (M6x10) flush with the exterior of the clamping device.
Do not tighten the screw!



When correctly assembled, the support arm can be rotated easily but cannot be pulled out.

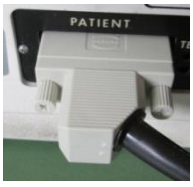


Tighten the upper grub screw (M6x6) so that the foot of the support arm presses firmly against the clamping device.

Note: The arm should be moveable without blockade by **pin 1**.
Together with the pressed foot of the arm by **pin 2** results a swiveling unit with excerpt protection.

3.1.1 Connecting the patient cables to the ECG device

Only CE marked devices may be connected
(see also operating instructions ECG)

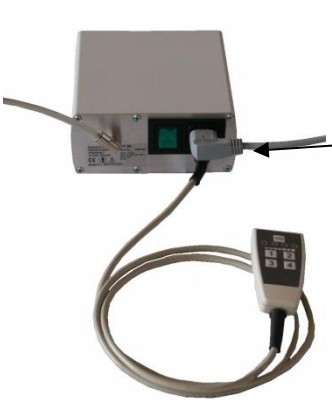


[example]

3.2 Connect the vacuum unit

plug in
vacuum hose

(If you want to remove the vacuum hose, push back the ring of the vacuum hose elbow connector, in order to pull off the hose.)



plug in
power cable

bottom of the device

For a secure fixing in mobile operation we recommend replacing the stands with a Velcro tape fixation. Stands and Velcro tape are adhesive und thus easily replaceable without tools.

bottom of the device

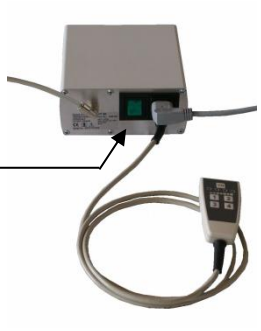
3.3 Connecting the vacuum lines on the distributor

Plug in the vacuum lines into the delta distributor sockets as indicated by the codes.

Note: To disassemble the system, the instructions of chapter 3.3 to 3.1 have to be executed in reversed order!

3.4 Operation

Press power switch to switch
on the vacuum unit
(green light will turn on)

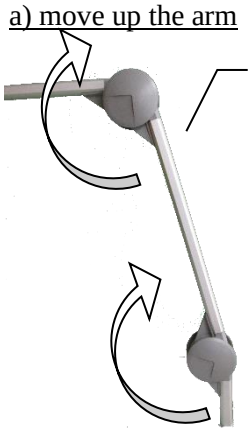


3.4.1 Operation - Starting

Push the ON/OFF button at the control unit to start operation.
All LEDs of the control unit will be lit. Simultaneously, the blow-out mode will be triggered for approximately 5 seconds.
Air will be blown through the electrodes with increased power in order to remove any residual moisture.
Starting at the highest pressure level, the LEDs will turn off subsequently, until all but the one for the lowest pressure level are off. Alternating flashing of the LED associated with the selected pressure level and simultaneous flashing of the remaining LEDs will signal general readiness of the device.

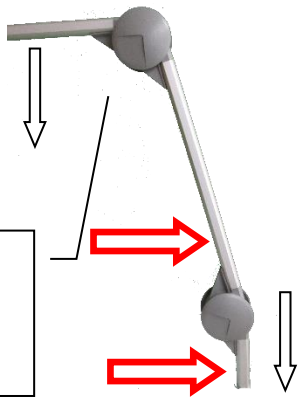
3.4.2 Position the support arm as desired

a) move up the arm



a) Example for a higher arm position:
When moving up the arm, a clicking in regular intervals is heard in the down hinge. These are the rest positions for the vertical adjustment of the arm.

b) move the arm downward



b) Example for a lower arm position:
Simply push down the arm until the desired position is reached.
Attention: When adjusting the arm, grab here.

Note:
The support arm should be adjusted to a position in which

- the patient will not collide with the support arm
- the electrodes can be applied without tension
- the vacuum lines will not be bent

3.4.3 Switch on the vacuum

a) Press the I/O button to release vacuum

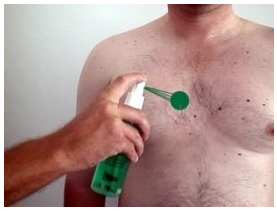
b) Pressure level 1 LED will turn on

Select vacuum level.
Press the appropriate key to select a vacuum level.
The selected vacuum level will be displayed by light emitting diodes.
Pressure allocation (standard programming)

Level 1	for smooth skin
Level 2	for slightly hairy skin
Level 3	for moderately hairy skin
Level 4	for very hairy skin

Note:
The lower the vacuum level selected, the better it will be tolerated by the skin.
(Look at safety instructions)

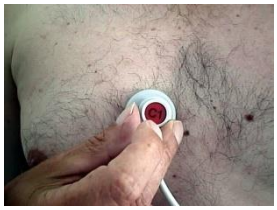
3.4.4 Applying the vacuum electrodes

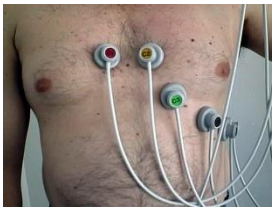


First, spray individual spots with electrode spray on skin.
Note

- Use only Signa Spray®.
- Spray only individual spots, in order to prevent short circuits between electrodes.
- The electrodes may only be applied to unwounded intact skin.
- Conductive parts of the electrode leads and connected plug-in devices of the application parts, including the electrode, must not touch other conductive parts, including earth!

The electrodes are applied by touching the code plates.
This will switch on the vacuum at the electrode.





In order to ensure artefact-free measurement, take care that there is no tension acting on the electrode lines when applying the electrodes.

3.4.5 Switch off the vacuum

To switch off the vacuum press the I/O button.
Subsequently the blow-out feature will be started.

- The electrodes will go off automatically.

3.4.6 Stand-by operation restored (status 3.4.3)
Stand-by operation is maintained for 30 minutes. If the system isn't restarted within this period, the sleep mode will be activated (status 3.4.1.).
After interruption of the supply network, the system also falls into sleep mode.

3.4.7 particularities
The system is very quiet and can easily be "overheard". The DT80 has a run time shutdown to protect its main components, which will operate after 90 minutes of non-operation of the keypad.
Another special feature is the integrated temperature-backup mode. If the device overheats due to excessive use, a temperature sensor will reduce the suction power until the pump has cooled down sufficiently. On the control panel, this status is indicated by flashing the respective set pressure level.

4. Technical appendix

4.1 General information

The device is suitable for continuous operation.
Integrated defibrillation protection protects subsequent devices.
High-frequency fields and emissions may influence the quality of the ECG measurements.
The DT80 ECG vacuum unit is provided with a CE label according to the Regulation given by the European Parliament and of the Council on medical devices 2017/745 and meets the basic requirements of Annex IX of the named Regulation.
The CE label includes only accessories listed in the accessory list.

4.2 Transport and storage

- Ambient temperature range -40 degrees C to +70 degrees C
- Relative humidity range 10% to 80%
- Atmospheric pressure range 500 hPa to 1060 hPa

4.3 Operating conditions

The device is operable in the following ambient conditions:
Ambient temperature between +10 degrees C and +40 degrees C,
relative humidity between 30% and 75%, atmospheric pressure between 700 hPa and 1060 hPa.

4.4 Cleaning and disinfection of vacuum electrodes

The surface of the vacuum electrodes must not be scratched or damaged. The surface cleaning is done by spraying the alcohol disinfectant after each use (and maybe cleaned with a cleaning cloth)
For safe disinfectant to the manufacturer's instructions, especially the required exposure times, are observed. The number of cleaning cycles under operating conditions has no negative impact on durability. Cleaning increases the life and ensures consistently good signal.

quick disinfection and cleaning cloths (100 pcs.)	Item #	1000-352
250ml quick disinfectant and detergent	Item #	1000-354
5l quick disinfectant and detergent	Item #	1000-351
750ml disinfectant foam	Item #	1000-327

1.

External spraying of the hoses and suction cups

2.

Use of wipes from the dispenser

3.

External cleaning of the hoses and suction cups with wipes

4.

Spray of the inside of the electrode

5.

Clean the sealing lip and the electrode surface with wipes

4.4.1 Chemical-thermal disinfection

In the case of suspected contamination, the used vacuum lines should immediately be submitted to chemical-thermal disinfection. With it, the vacuum lines will be submitted to a validated process of exterior and interior cleaning/disinfection (for informations please ask the manufacturer).

4.5 ECG plug-in cable

The plug-in connector of the ECG plug-in cable at the support arm is connected to the ECG standard connector. Other ECG devices are connected via adapters.

4.6 Maintenance

The devices should be checked (STK) according to the latest instructions given by the manufacturer at intervals of 2 years or after repair (or after intervention in the device). The check should be carried out by persons authorized by Strässle & Co Medizintechnik GmbH. The exchange of fuses on the power supply should be effected only by qualified personnel. Disconnection from the mains is compulsory. **The power cable must be disconnected!** No other fuses than 2 x 0,315AT are allowed.
No service or maintenance should be performed while the unit is being used on a patient.

4.7 Specifications

Medical product class I (Regulation 2017/745)

- Supply voltage 230V~ 50Hz
- Rated consumption 22VA
- Vacuum range 60hPa - 200hPa
- Protection class I
- Protection type IP 40
- Degree of protection BF (supporting arm BF or CF defibrillation protected)
- Dimensions 162x190x75 (w x l x h) vacuum unit only

4.8 Scope of delivery (depending on model version)

- Power cable (1000-099) - *removable part*
- Vacuum unit with control unit (3000-205)
- Holder for control unit (2000-237) - *accessory*
- Support arm (3000-191)
- Electrode set 6x1m / 4xEXT 1,3m (4000-005) - *removable parts*
  (alternatively electrodes 10x1m or 10x1,3m) (4000-001 or 4000-003) - *removable parts*
- Electrode spray (1000-158) - *accessory*
- Velcro fastening strips (2000-463) - *accessories*
- optionally with mounting kit (various mounting kits possible) - *accessories*

4.9 Warranty

Strässle & Co. Medizintechnik GmbH grants warranty according as stated in the terms for sales, delivery, and payment. Wearing parts and disposable material are not included in warranty.

Warranty will lapse in case of

- damage caused by improper operation and undue usage.
- inaccurate assembly, actions taken by unauthorized personnel, or use of accessories, disposable material or replacement parts which are not original parts of Strässle & Co. Medizintechnik GmbH.
- changes, extensions, repairs or actions whatsoever effected by persons not authorised by the manufacturer.
- the electrical installation of the location where the device is connected not complying with the requirements according to VDE 0107.
- using the device disregarding the operating instructions.

Even after warranty has expired, original parts and accessories of the manufacturer should be used. Only thereby safe and proper operation can be ensured, as these products are continually improved and optimized.

5. Safety instructions

- The device should be operated only with a functioning mains supply according to VDE 0100-710, or applicable regulations, respectively. The device is assigned to group 1 (medical equipment-ECG) according to VDE 0100-710.
- In order to avoid electrical shock hazard, the device should be connected only to a mains supply with a protective conductor. It should not be used with a mains supply with protective disconnector.
- Installation is to be performed by qualified personnel authorized by the manufacturer.
- When assembling the vacuum system, please ensure that you comply with the relevant provisions set out in the accident prevention regulations and in Paragraph 9 of the EN60601-1 Standard (Protection from mechanical hazards from ME equipment and systems) when mounting the supports. This applies in particular to the mounting of supports that are not original supports produced by Strässle & Co. Medizintechnik GmbH as well as to the combination of Strässle & Co. Medizintechnik GmbH products with those of other manufacturers.
- If problems arise during installation or operation of the device, contact your dealer.
- The main switch serves an all-conductor disconnector.
- The device should be operated only by instructed technical personnel and must be documented.
- The instructed personnel should check the system optical and functional for each using.
- The device must complete undamaged and functional to be operated in only.
- The distributor must be locked in the arm to prevent a self-acting release from the support arm (see 3.3)
- By mounting error, improperly performed repair, improper modification and the use of third party products (screws, plugs, connectors, etc.) it may due to imperfect fit to shear or abrasion, and ultimately solve coming of fortifications, to ensure defibrillation protection.
- Improper repairs, improper modifications or non-use of original spare parts and original accessories will affect the protection of the medical equipment used when unloading a defibrillator.
- In the presence of visible damage, stiffness, etc. the supporting arm must be checked by trained personnel
- Only original accessories and original replacement parts should be used. The device may only be operated with an original mains cable.
- Replacement parts should be disposed in an environmentally beneficial way.
- Modification of this device is not allowed without prior consent by the manufacturer (Strässle & Co. Medizintechnik GmbH).
- Electrodes may not be brought in contact with oxidising acids or Cyanid solutions.
- The specifications of vacuum level under 3.4.3 are to be kept. Too highly selected vacuum levels can lead to blisters on the skin.
- To protect the skin, especially sensitive patients, who are repeat measurements with the same absolute placement of the electrodes are to be avoid, without adequate recovery period 48h or after medical judgment.
- Operation in conjunction with HF surgical devices is only permissible if the connected ECG device is suitable for this (see the operating instructions for the ECG device).
- When used in conjunction with an EEG device, the connected EEG device must be able to withstand 110V input voltage in the event of defibrillation.
- If several devices are connected to each other, the summation of leakage currents can lead to a potential hazard.
- Serious incidents that have occurred must be reported to the manufacturer
- WARNING: Avoid using this unit directly next to other equipment or with other equipment in stacked form, as this could result in incorrect operation. If it is necessary to use this unit in the manner described above, this unit and the other equipment should be observed to ensure that they are working correctly.
- WARNING: The use of ACCESSORIES, converters and cables other than those specified or provided by the manufacturer (Strässle & Co. Medizintechnik GmbH) of this device may result in increased electromagnetic interference emissions or reduced electromagnetic immunity of the device and lead to faulty functionality.

5.1 Installation site

- The device may only be operated in medical rooms.
- The device should not be operated in locations where explosions might occur.
- The device should be installed in conditions where it is not exposed to excessive smoke, dust, shock, humidity, temperature changes or direct solar radiation. An adequate distance should be kept from other devices, such as computers, monitors, etc.
- The device should be installed at a place where it can´t be climbed or sit upon.
- The device should not be stacked with other devices.
- Precautions should be taken if the place of use is near AM, FM or TV transmitting antennas (e.g. at a distance of less than 1.5 km).

5.2 Cleaning

Before cleaning, press the I/O button to switch off the DT80 vacuum system and disconnect the power cable.

The device should be cleaned with a soft cloth which is moistened only slightly with water. Never use scouring agents, benzene, thinner, or similar solvents.

Before starting operation, wait until the cleaned surfaces are perfectly dry.

For cleaning of the vacuum electrodes see chapter 4.4.

5.3 Disposal of discarded DT80 suction devices

Discarded suction devices should be returned to the manufacturer. Strässle & Co. Medizintechnik GmbH disposes of them in a professional way. For the production of DT80 suction devices, Strässle & Co. Medizintechnik GmbH has provided a number of specifications which require the use of non-polluting materials and enable separation by pure materials. This greatly reduces the amount of waste.

5.4 General information

In case the device is not used according to the above directions and such use causes injuries or severe effects or damages, the manufacturer holds no responsibility whatsoever. On demand, further technical documentation is available.

5.5 Lifetime

The service life of the suction unit is fixed for an indefinite period. If used as intended, the suction unit can be operated for many years.