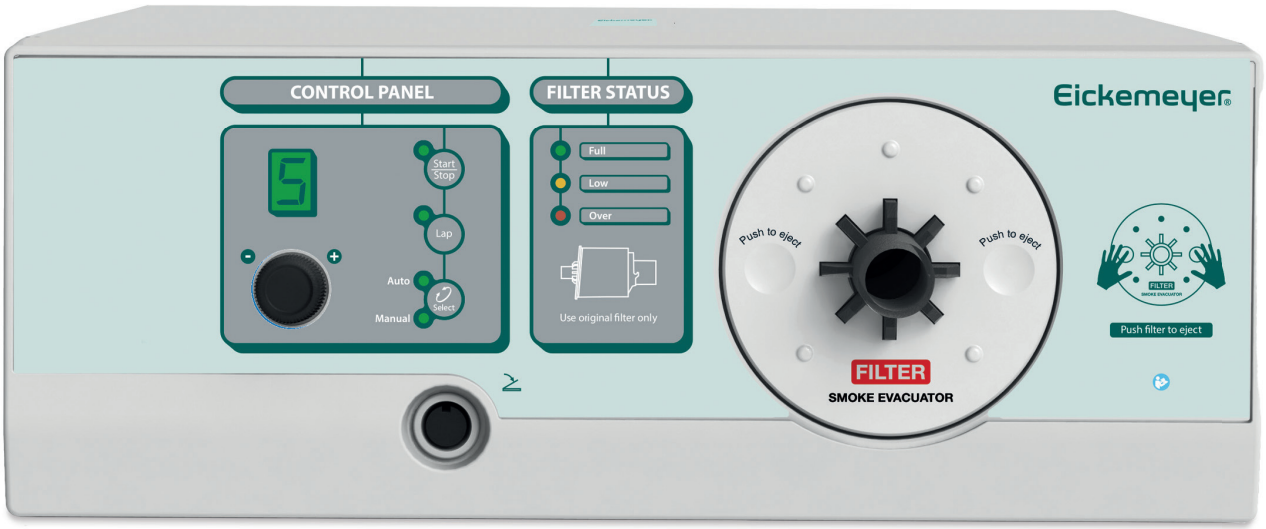
EICKTRON EVAC
SMOKE EVACUATION SYSTEM

USER MANUAL



Item no. 323160

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SUMMARY

IMPORTANT

These instructions are an important part of the device, as they describe its operation and use. They must therefore be read carefully before starting to install and use the device.

All safety instructions and warnings must be observed. Please ensure that these operating instructions are supplied with the device when it is passed on to other operating personnel.

If you require technical assistance, please contact EICKEMEYER®.

Manufacturer

Eickemeyer – Medizintechnik für Tierärzte KG

Eltastraße 8

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INTRODUCTION

GENERAL DESCRIPTION

EickTron EVAC is an advanced system for extracting and filtering surgical smoke (plume) produced during electrosurgical procedures.
The vapours produced during these procedures have a strong, persistent odour and contain water vapour, organic gases, visible and invisible solid particles, and potential viral pathogens. Effective extraction and adequate filtration help to eliminate unpleasant odours, reduce the risk of bacteriological and viral contamination, and improve visibility of the surgical area, which is a particularly critical aspect of laparoscopic procedures.

The suction in the EickTron EVAC can be activated in three ways:

- Automatically: through an electronic remote system that detects the activation of a high-frequency electrosurgical device (only available for compatible generators).
- Manually: by directly controlling the device.
- Via foot switch (optional), for easier handling.

The suction flow is adjustable to meet different operating requirements. In addition, there is a special function for laparoscopic procedures that can be easily activated.

EickTron EVAC is equipped with advanced electronic controls that monitor the wear status of the filters, ensuring optimal operation at all times.

Two types of filters are available, which are easily replaceable and feature ULPA filter technology with an activated carbon stage to neutralise unpleasant odours. Both filters are compatible with a 7/8" (22 mm) connection:

- BLUE filter: included in delivery, ideal for standard use for up to 5 hours.
- RED filter: optionally available, designed for longer use of up to 20 hours.

INTENDED USE

Medical device for removing and filtering vapours and aerosols from the surgical site generated during electrosurgical and laser procedures.

INTENDED USER

Device for professional use. Operation is reserved for qualified medical personnel, such as physicians and veterinarians, who are specially trained in high-frequency electrosurgery.

STANDARD AND OPTIONAL COMPOSITION

Code	Description	EickTron EVAC
-	Device code	EKM10200.10
00100.03	SIE-IEC power cable (2 m)	■/1
00900.01	Kit with handpiece holder for surgical smoke evacuation (ø22 mm)	■/1
00900.02	Surgical smoke evacuation kit (ø22 mm)	■/1
00900.FST/10	ULPA filter for initial delivery (5 hours) – BLUE	■/
00100.	IT-IEC power cable (2m)	○
00100.01	SIE-IEC power cable (5 m)	○
00100.04	US-IEC power cable (2 m)	○
00100.05	GB-IEC power cable (2 m)	○
00100.07	BR-IEC power cable (2 m)	○
00100.09	AU-IEC power cable (2 m)	○
00100.10	JP-IEC power cable (5 m)	○
00304.00	Waterproof single foot switch	○
00900.01/12	Kit with handpiece holder for surgical smoke evacuation (ø22 mm)	○
00900.02/06	Surgical smoke evacuation kit (ø22 mm)	○
00900.04	Autoclavable evacuation tube (ø22 mm)	○
00900.05	Autoclavable evacuation tube (ø7 mm with adapter ø 7/22)	○
00900.06/06	Hydrophobic filters (ø22 mm)	○
00900.07	Kit with handpiece holder for autoclavable surgical smoke evacuator (ø22 mm)	○
00900.08/12	Evacuation kit for TROCAR Luer Lock (ø22 mm)	○
00900.FU01/10	ULPA filter (20h) - RED	○
TR003	Trolley with 3 shelves	○
TR003W	Trolley with 3 wide shelves	○
TR004	Trolley with 4 shelves	○
TR005	Trolley with 5 shelves	○
TR005W	Trolley with 5 wide shelves	○

■/ Item= STANDARD ○= OPTIONAL

SAFETY

It is recommended that you read all warnings, precautions and operating instructions carefully before using the device. Improper use of the device or its accessories may result in personal injury or property damage.
EICKEMEYER® declines any responsibility for direct or indirect damage, arising from improper use of the device.
The accessories supplied are compatible with the device, but may not be suitable for use with other devices. Any use of accessories and/or components not supplied by EICKEMEYER® is the sole and exclusive responsibility of the end user, who must verify their suitability and compatibility in terms of safety, essential performance and electromagnetic compatibility with the supplied devices. Disposable accessories such as hoses and filters must be disposed of in accordance with the applicable regulations for the disposal of hospital waste.

WARNINGS

- Connection to the mains: Electrical safety is only guaranteed if the device is properly connected to a grounded mains supply that complies with current safety regulations. If you are unsure, consult a qualified technician. Ungrounded use is strictly prohibited.

- Supply voltage: Before connecting the device, check that the voltage indicated on the rear panel corresponds to that of the available main supply.

- Adapters and extension cables: If the available socket is not compatible with the power cord, only use adapters that are certified and comply with safety regulations.

- Weather protection: Do not expose the device to rain, direct sunlight or excessive moisture. Protect it from liquids and do not block the ventilation slots.

- Switching off: The device should be switched off when not in use to avoid unnecessary consumption and wear.

- Hazardous environments: Do not use the device in environments that are potentially explosive or saturated with flammable gases.

- Intended use: The device may only be used for the purpose for which it was designed. Any other use is considered improper and potentially dangerous. EICKEMEYER® is not responsible for damage caused by improper or unauthorised use.

- Unauthorised modifications: It is prohibited to modify or attempt to modify the characteristics of the device, as this may compromise its safety and functionality.

- Liquid extraction: The EickTron EVAC and its filters are not designed for liquid extraction. If there is a risk of accidental vacuuming, a liquid collection system should be installed along the suction circuit. Vacuuming liquids can damage the device and the filters.

- Cleaning and maintenance: Before cleaning or servicing the device, disconnect it from the mains by unplugging the power cord or switching off the main switch.

- Repairs: In the event of a malfunction, switch off the device immediately and contact an authorised service centre. The use of non-original spare parts may compromise the safety and compliance of the device.

- Failure to follow these instructions may compromise the safety of the device and pose a risk to the operator.

- Any serious accident that has occurred in connection with the device must be reported to EICKEMEYER® (Eltastraße 8, 78532 Tuttlingen) and the competent authority: Ministry of Health – Directorate-General for Medical Devices and Pharmaceutical Services Viale Giorgio Ribotta, 5 – Rome
  Email: segr.dgfdm@sanita.it
  Tel.: +39 06 5994 3199 / +39 06 5994 3207

COMMISSIONING

- Check the device for transport damage. Claims for damages will only be accepted if they are reported to the carrier immediately and a report of the damage found is drawn up and submitted to EICKEMEYER® or its seller. If the device is returned to EICKEMEYER® or the seller, it is necessary to use the original packaging of the product or packaging that guarantees equivalent transport safety.

- Remove the device from its packaging and carefully read the documentation and operating instructions supplied. The mains voltage indicated on the type plate must correspond to the local mains voltage (mains frequency: 50-60 Hz). If necessary, replace the fuses with ones that match the rated power specified on the type plate.

- Connect the main cable to a mains socket with a good earth connection.

OPERATING THE DEVICE WITHOUT A GROUND CONNECTION IS PROHIBITED.

- The appliance must be installed on a level surface that is at least the same size as the base of the appliance. There must be at least 25 cm of space around the appliance.

- Connect the power cord to a mains outlet with a proper ground connection.

- Connect the bonding point on the left rear of the device to the bonding socket on the system.
- Connect the foot switch (optional) to the connector on the front of the device.
- Insert a new filter into the device and ensure that it is seated correctly.
- Connect the suction tubing to the filter by following the instructions in the reference illustrations.
- Only use the device in dry environments. If condensation occurs, allow it to evaporate completely before operating the device.
- Avoid extreme environmental conditions that may interfere with the proper operation of the device.
- Environmental conditions:

	OPERATION 10 to	TRANSPORT / STORAGE
Temperature:	40 °C	from -10 to 50 °C
Relative humidity:	from 30 to 75 %	from 10 to 100 %
Air pressure:	from 70 to 106 kPa	from 50 to 106 kPa

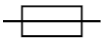
CONNECTORS AND CONTROLS

LABELLING ON THE REAR

Equipment safety requirements stipulate that data and graphic symbols must be printed on the control cabinet or on at least one of the switchboards of the generator set in order to define its characteristics and monitor its operating conditions.

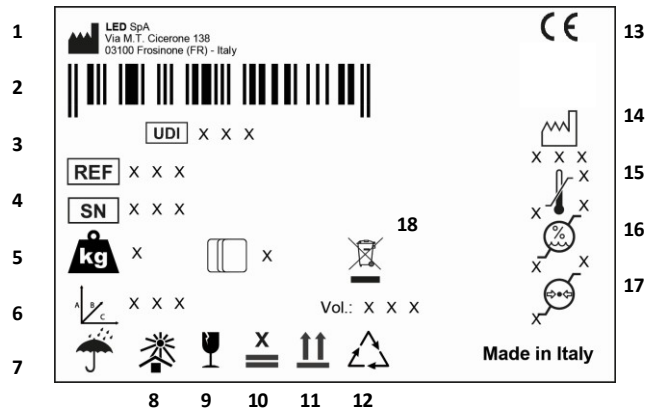
MEANING OF GRAPHICAL SYMBOLS

No.	SYMBOL	DESCRIPTION
1		Type CF Applied Part, protected against the effects of defibrillation
2.		Follow the instructions for use
3.	CE	CE marking (2017/745/EU)
4.		The product should not be disposed of in municipal waste containers, but should be disposed of separately.
5.		Manufacturer
6.	SN	Serial number
7.		Date of manufacture
8.	UDI	Unique device identification
9.		Distributor
10.		No maintenance required by the user
11.	REF	Catalogue number (code)
12.		Temperature limits
13.		Limits for humidity
14.		Limits for atmospheric pressure
15.		High page
16.		FRAGILE – Handle with care
17.		Keep away from sunlight
18.		Protect from moisture
19.		Maximum number of stackable packs
20.	kg	Weight
21.		Dimensions

No.	SYMBOL	DESCRIPTION
22		Number of parts
23		Recycle
24.		Model/trade name
25.		Fuse

BOX LABEL

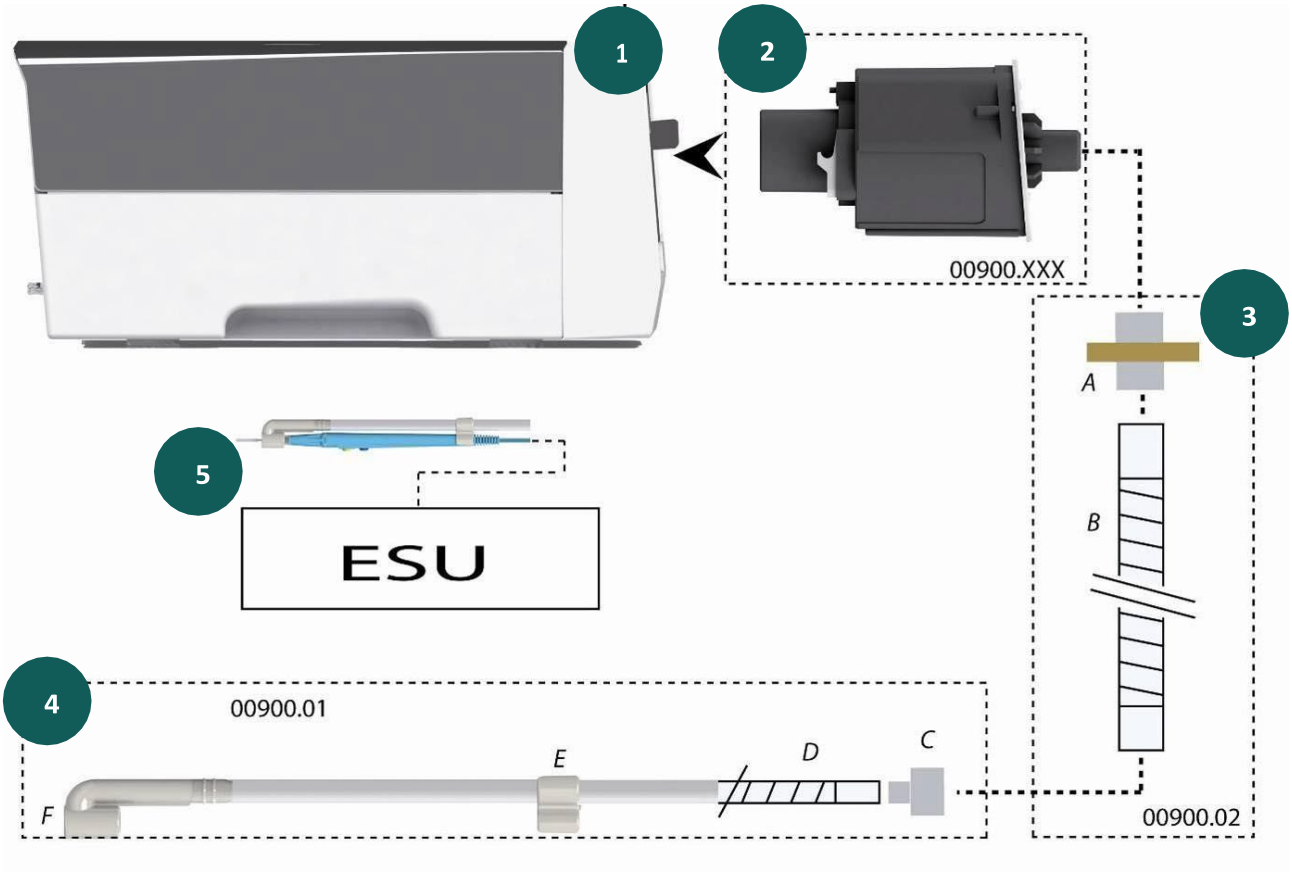
With reference to ISO 15223-1 "Medical devices — Symbols for use with medical devices, labels, marking and information to be supplied" and ISO 780 "Packaging — Packaging for distribution — Graphic symbols for handling and storage", the following information is provided on the packaging label of the unit:



1. ISO15223-1 (5.1.1) MANUFACTURER
2. ISO15223-1 (5.7.10) UDI code = EAN code
3. ISO15223-1 (5.1.6) CATALOGUE NUMBER
4. ISO15223-1 (5.1.7) SERIAL NUMBER
5. WEIGHT OF BOX
6. BOX DIMENSIONS
7. ISO15223-1 (5.3.4) KEEP DRY (The transport packaging must be protected from moisture)
8. ISO15223-1 (5.3.2) PROTECT FROM SUNLIGHT (The transport packaging must not be exposed to sunlight)
9. ISO15223-1 (5.3.1) FRAGILE (The contents of the package are fragile and must be handled with care)
10. STACKING LIMIT BY NUMBER (Indicates the maximum number of identical products that can be safely stacked on the bottom packaging)
11. ISO780 (3) HIGH SIDE (Indicates the correct vertical position of the transport package)
12. ISO 7001:2007 RECYCLE (Indicates the location of a container)
13. CE marking (2017/745/EU)
14. ISO15223-1 (5.1.3) PRODUCTION DATE
15. ISO15223-1 (5.3.7) TEMPERATURE LIMITS (Specifies the temperature limits within which the transport container must be stored and handled)
16. ISO15223-1 (5.3.8) HUMIDITY LIMITS (Specifies the humidity limits within which the transport container must be stored and handled)
17. ISO15223-1 (5.3.9) AIR PRESSURE LIMITS (Specifies the air pressure limits within which the transport container must be stored and handled)
18. WEEE PRODUCT (Directive 2012/19/EU)

CONNECTING ACCESSORIES

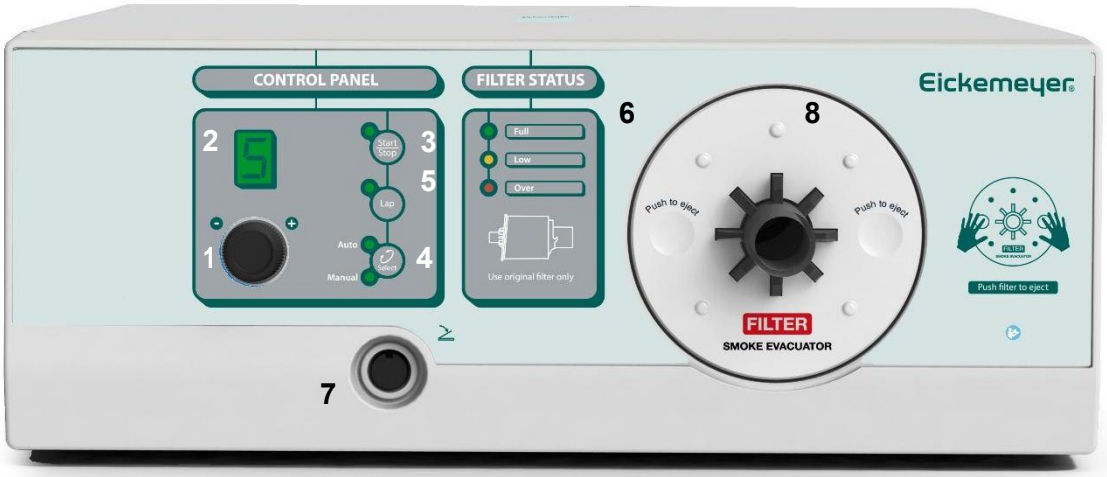
Please refer to the image below for the correct connection of the accessories.



1. EickTron EVAC – smoke extraction device.
2. FILTER – Filter component for air purification.
3. SUCTION HOSE SET (00900.02)
    - A – Filter
    - B – Ø22 mm tube
4. HANDPIECE SUCTION SET (00900.01)
    - C – 10/22 mm adapter
    - D – Ø10 mm tube
    - E – Fastening clip
    - F – Handpiece adapter
5. Connecting the handpiece to kit 00900.01. The handpiece must be connected to the electrosurgical unit (ESU*).

* The handpiece is not included.

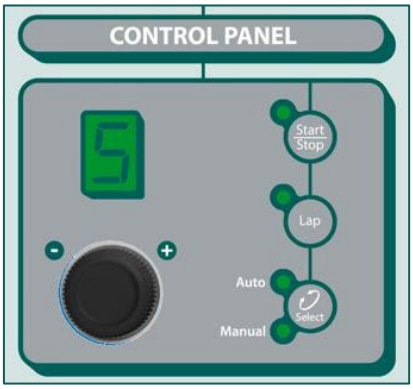
FRONT PLATE



1. Adjustment knob for suction height
2. Display showing suction level
3. START/STOP button for vacuuming in manual mode
4. Mode selection button (AUTO/MANUAL)
5. Special button for laparoscopic procedures (L)
6. Filter status LED
   Green: filter OK
   Yellow: filter running low
   Red: replace filter
7. Connector for foot switch
8. Suction filter

OPERATING MODES

CONTROL PANEL



To adjust the suction level, turn the knob. The set level is shown on the display.
The device generates a high vacuum, so it is important to regulate the suction flow and position the end of the tube correctly to avoid injury to the patient or accidental suction of surgical material or samples.
Before activating the suction, always check that the selected level is safe for the patient and will not lead to accidental aspiration of tissue or samples.

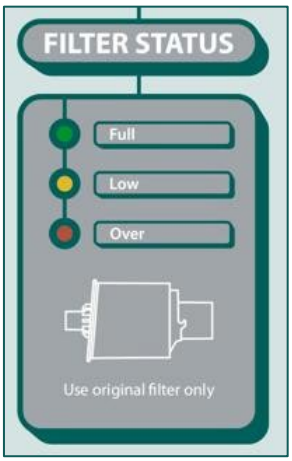
Use the SELECT button to choose between two operating modes:

- **AUTO (automatic activation):** The device starts automatically when it detects activation of the electrosurgical unit and stops after a preset delay when the output is complete.
- **MANUAL (manual activation):** Suction is activated or deactivated manually by pressing the START/STOP button.

Pressing the L button activates the special mode for laparoscopic procedures, with a maximum level that can be set to 3.

FILTER STATUS

The filter status is indicated by indicator lights with the following meanings:



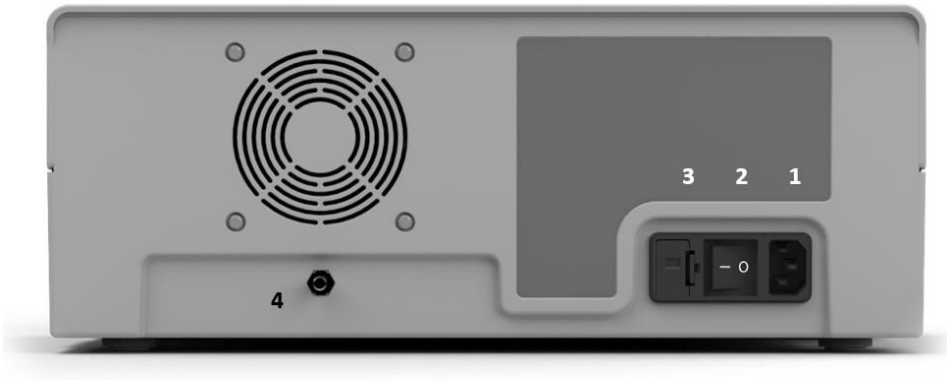
Indicator	Condition	Remaining autonomy
Continuous green	Normal	20 to 5 hours
Continuous yellow	Reserve	5 to 1 hour
Flashing red	Running low	< 1 hour (until the end of the last activation)
Continuous red	Depleted	Replace the filter

- If no filter is inserted, all indicator lights flash simultaneously.
- In reserve mode (yellow light on) and with suction power deactivated, it is possible to determine the number of hours remaining by pressing and holding the START/STOP + SELECT buttons simultaneously. The yellow light will start flashing and the display will show the hours available.

FOOT SWITCH

The device can be activated via an optional foot pedal, which can be connected to the corresponding port on the front panel.

REAR PANEL



1. Mains socket
2. Power switch
3. Fuse holder
4. Equipotential socket

DEVICE POWER MODULE

The device's power supply module is the connection point for the power supply to the internal electronics. Includes mains connection, circuit breaker and line fuses.

CAUTION: Before switching on the device, the operator should ensure that the mains voltage indicated on the type plate corresponds to the voltage to which it is connected.

MECHANICAL POWER SWITCH

The mechanical power switch is used to turn the device on or off. To turn the device on, press the switch to position 1 (up). When the device is turned on, the front panel lights up. Pressing the switch to position 0 turns off the power supply. This process can also be used as an emergency switch in the event of a fault.

TECHNICAL SPECIFICATIONS / PERFORMANCE DATA

Description	EickTron EVAC
Device code	EKM10200.10 Clock
Maximum suction flow	1000 LPM (35 CFM)
Maximum suction pressure	250 mbar (83 inches H_2W)
Filter type	ULPA with activated carbon
Filter efficiency	99.999X%
Diameter of filtered particles	0.12 µm
Dimensions (W × H × D)	370 × 144 × 319 mm
Weight	4 kg
Supply voltage	230 V alternating current – 50/60 Hz
Input	800 VA
Fuses	2 × T 4AL, 250 V (5 × 20 mm)
Electrical class	I CF

MAINTENANCE

GENERAL MAINTENANCE NOTES

There are no user-adjustable parts inside the device for calibration or maintenance. The device housing must not be opened – unauthorised tampering with the device will void the warranty. In the event of repair or adjustment, the entire device should be sent to the EICKEMEYER® service centre together with a description of the fault. User maintenance mainly consists of cleaning and sterilising the accessories and checking the device before each use. Functional and safety checks to verify the parameters are carried out by specialised technical personnel.

CLEANING THE HOUSING

Switch off the device completely and disconnect it from the mains before cleaning. Wipe the outside of the housing with a damp cloth. Do not use solvents or chemical components. A mild, non-abrasive cleaning agent may be used.

REPLACING CONSUMABLES AND ACCESSORIES

Accessories such as hoses and filters should be disposed of in accordance with hospital waste control procedures.

To replace filters:

- Switch off the device.
- Remove all outlet pipes connected to the filter.
- Press on the sides of the filter to remove it.

TROUBLESHOOTING GUIDE

If you encounter a problem, you must first check that you have installed and prepared the accessories correctly.

Problem	Probable cause	Solution
The device cannot be switched on	No mains voltage or interruption in the mains voltage	- Check that the mains cable is connected correctly. - Check the condition of the fuses and replace them with the correct type.
All LEDs (green, yellow and red) are lit	Filter not inserted correctly	- Insert a new filter. - If already inserted, remove it and repeat the process.
Red filter status LED is lit	Filter out of stock	Replace the filter with a new one.

REPAIRS

Filters and pipes cannot be repaired. Always replace a defective part with a new one.

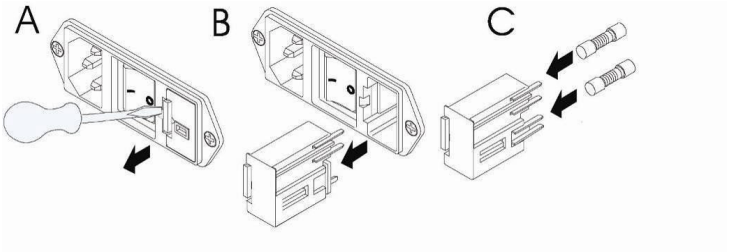
REPLACING THE FUSES

DISCONNECT THE DEVICE FROM THE POWER SUPPLY BEFORE REPLACING THE FUSES.

To replace the fuses, use 5x20 type fuses and proceed as follows: (A-B) Remove the fuse boxes from the power supply module using a small screwdriver.

(C) Insert the fuses, referring to the following:

Voltage 220 – 240 V Time-delay fuses 2x T4AL, 250 V / 5 x 20 mm



CHECK THE DEVICE BEFORE USE

Each time the device is programmed, the most important safety conditions must be checked, taking the following points into account:

- Check the integrity of the cables and connections and inspect them for broken wires.
- Ensure that all electrical equipment is properly grounded.
- Ensure that all necessary accessories are available and sterilised.
- Check the charge level of the filter to assess whether it will last long enough for the procedure to be performed.

SAFETY CHECKS AND MEASUREMENTS

The Department of Bioengineering or other specialists must schedule inspections and measurements of the equipment at least once a year, including the following items:

1. **Condition of cables and power plugs**
   Check cables and plugs for visible damage and proper functioning.
2. **Visual inspection of isolating protective devices**
   Check that all mechanical protective devices are intact and in working order.
3. **Protection against hazards caused by spillage and ingress of liquids** Check the device for protection against liquids, drops, moisture, hygiene products and disinfectants.
4. **Operating instructions**
   Ensure that the operating instructions are available and up to date.
5. **Measuring the resistance of the earth connection**
   Measure the resistance of the earth connection to ensure that the earthing system is functioning properly and that electrical safety is maintained.

Information on the disposal of this product (applies in countries with separate collection systems)	
	At the end of its life cycle, this product must not be disposed of as municipal waste, but must be disposed of in a separate collection system. If the product is disposed of improperly, some parts of the product (e.g. some batteries) may be harmful to the environment and human health. The symbol on the side (crossed-out wheelie bin) indicates that the products should not be disposed of in household waste bins, but should be disposed of separately. Penalties may be imposed for improper disposal of this product.

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