Instructions for USE

Isolating transformer for medical technology according to IEC / EN60601-1
REOMED 660/1120/1580/2000

Before putting the device into operation, please refer to the instructions for use

It is mandatory to read and apply.

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1.0 Hazard warnings

The following notices are for the personal safety of the operator as well as the safety of the described products and connected devices.

Warning!
Dangerous voltage
Non-observance can cause death, severe physical injury, or damage to property.

- To avoid the risk of electric shock, the isolation transformer may only be connected to a supply network with a protective conductor.
- Any interruption of the protective conductor inside or outside the device or disconnection of the protective contact can make the device a source of danger. Deliberate breaking of grounding is prohibited.
- The effectiveness of protective earthing must be checked regularly
- Disconnect the supply voltage before assembly or disassembly work, replacement of fuse or structural changes.
- Observe the accident prevention and safety regulations applicable in the specific case.
- Before commissioning, check whether the nominal voltage of the device corresponds to the local mains voltage.
- It is not permitted to operate the device in a flammable, potentially explosive atmosphere.
- The device presents a risk of fire and electric shock if the device is exposed to moisture or liquids.
- Anything containing water or any other fluid should not be placed on the unit, for example vases or bottles.
- Choose a safe location for the device.
- Do not remove the housing cover, risk of electric shock!
- Maintenance only by qualified personnel
- Defective and damaged devices must not be put into operation.
- This device must not be changed.
- It is not allowed to connect an additional multiple socket or an extension cable to the ME system.
- Multiple sockets intended for the ME system may only be used to power devices that are intended to be part of the ME system.
- Stacking of the device is not allowed
- Only the REOMED Isomonitor may be used to monitor the isolation transformer (insulation / temperature / load).
- Accessories other than those listed in this manual may adversely affect the EMC performance of the ME device.

- Portable RF communications equipment, including antennas, may not be used closer than 12 inches to any part of the ME or ME system, including cables specified by the manufacturer.
- Electromagnetic interference can interfere with the operation of the REOMED and REOMED Isomonitor and result in misbehaviour such as false alarms (Isomonitor) or malfunction of the switch-on current-limiter.

WARNING:

UNDER NO CIRCUMSTANCES CONNECT AND OPERATE THE UNIT WITH OTHER INPUT VOLTAGES AND INPUT FREQUENCIES OUTSIDE THOSE STATED ON THE RATING LABEL

1.1 Technical description

Toroidal transformers for medical technology with multiple socket (total unit portable), in a sturdy metal housing with an inrush current limiting and primary and secondary circuit breakers.

Product features:

⇒ Sturdy metal housing, floor standing unit with 4 integrated M6 mounting sockets
⇒ Touch current in normal operation <100 µA
⇒ Limiting earth leakage current at 127V/253V/50-60Hz <300/500 µA
⇒ Protected against short circuit and overload
⇒ Built-in temperature monitor in the primary circuit
⇒ Automatic circuit breaker in the primary circuit (2-pole)
⇒ Automatic circuit breaker in secondary circuit (1-pole)
⇒ ON / OFF - 2 line mains switch with green signal lamp
⇒ Inrush current limiting / half-wave failure detection or with NTC
⇒ Options with overvoltage protection and line filter
⇒ Equipotential bonding pin to DIN 42801 (POAG connector) (option: -M6 earthing pin)
⇒ The mains supply is provided by a 2m long flexible power cable with Schuko plug to IEC connector IEC60320-1
⇒ IEC device socket secondary (IEC320)
⇒ Approval IEC60601-1: 2005 / AMD1: 2012; ANSI / AAMIES 60601-1: 2005 / CR / 2012 CAN / CSA C22.2 no. 60601-1:14 (medical technology) USA and Canada IEC60601–1-2:2014(Partly); EN/IEC 61000-3-2:2014; EN 61000-3-3:2013
⇒ Conformity with the Low Voltage Directive 2014/35 / EU (2006/95 / EC)
⇒ Connection for temperature monitoring (option) by PTC according to DIN 44081 / DIN44082 and current transformer (CT option) for power monitoring.
⇒ Technical data (Annex)
⇒ Guidance and manufacturer's declaration (Annex)

1.2 Intended use

For use in series with the mains supply for medical electrical equipment and non-medical electrical equipment in patient environment and / or in medically used rooms. The unit provides safe galvanic isolation of input to output (double and reinforced insulation) and very low leakage current. The medical environment requires increased demands on air and creepage distances and these are achieved by using a special toroidal isolation transformer. This device safely complies with the required electrical limits for use in patient environment and / or in medically used rooms. The device can continue to be used where there is a requirement for very small leakage currents and in the reduction of the sum of the leakage currents of several individual devices in a supply circuit in the patient environment and / or in medical rooms.
For combinations of medical electrical appliances and non-medical electrical appliances in the patient environment and / or in medically used rooms, the appliance is connected upstream of the medical electrical appliances and / or the non-medical electrical appliances (e.g. Computer accessories such as a PC, screen, UPS system, printer, plotter, interfaces with medical electrical equipment and video equipment, diagnostic and security cameras, diagnostic, measuring and testing equipment and their combinations, etc.).

Additional equipment connected to the device's analogue and digital interfaces must be demonstrably compliant with their respective IEC or ISO standards (for example, IEC 60950 for data processing equipment). Furthermore, all configurations must comply with the regulatory requirements for medical systems (see IEC 60601-1-1 or Section 16 of 3.1 of IEC 60601-1, respectively). Anyone connecting additional equipment to medical electrical equipment is a system configurer and is responsible for ensuring that the system complies with the regulatory requirements for systems. It should be noted that local laws take precedence over the above normative requirements. If you have any questions, please contact your local dealer or the technical service.

The REOMED isolating transformer can be supplied with a number of options, for example with inrush current damping and half-wave failure detection or the basic option (NTC). It must be determined by the responsible system configurator and they also assume responsibility for the correct implementation in the ME system.

In the basic option, a failure of the input fuse is not a component failure, this can be reset by the operator to the previous state.

In order to function properly this device requires natural convection cooling.

The air must be able to circulate around the device freely, for this there must be a minimum distance of 30 mm. Place the unit in a stable place and ensure easy access to the power cord, in order to be able to disconnect the power cord quickly if necessary.
Standard operating position is horizontal!
Lateral wall mounting is possible. The base of the device should be fixed to the wall by means of mounting rails. The plug side must be on the side (left or right) to allow sufficient cooling. Other types of mounting require an individual approval.

1.3 Operating instructions

Check if there is a secure power connection and turn off the whole system **(OFF = 0)** before connecting further terminals to the output of the device. Please note the output voltage of the **REOMED** and check whether the following devices can be operated with the set voltage.

Please pay attention to earthed connections (sockets) for the power supply of the **REOMED**.

Make sure all terminals are OFF **(OFF = 0)** before connecting them to the **REOMED**.

In addition, the isolating transformer has a standardized grounding connection **(POAG plug as equipotential bonding pin in accordance with DIN 42801)**, which can be used for connection to appropriate equipotential bonding devices. The isolating transformer can thus be combined with other medical devices, provided they also comply with the requirements of EN60601-1. (Option: additional grounding bolt)

Now connect the desired devices with the **REOMED** (output). When the **REOMED** is now switched on **(ON = I)**, voltage is present at the output. The devices connected to the **REOMED** can now be switched on (please observe the regulations and the requirements for the supply lines and connecting cables), please note the safe and secure fit of all supply and connection cables.

The total output of the **REOMED** is equal to the sum of the individual performance of the terminals connected to the **REOMED** which are in use at the same time. It is essential to ensure that the required total power of the terminals does not exceed the maximum total power indicated on the nameplate of the unit at the same time. The performance data of the available **REOMED** series are shown in the table below.

If the **REOMED** isolating transformer is overloaded, it automatically shuts off. Only when the isolation transformer has cooled to 55 ° C, can the isolation transformer be put into operation again.

Attention: Only for devices with NTC as inrush current limiter

After switching off the device, a "waiting time" of approx. **1 minute** is recommended. If this is not observed, then the automatic circuit breakers in the input area of the **REOMED** or even the circuit breaker of the mains connection can be triggered.

- **Circuit breaker:**
  If an automatic circuit breaker triggers in the event of an overload or short circuit, the mains switch must be in the "OFF = 0" position. In addition, disconnect the mains cable from the device.
  After removing the fault, reset the circuit breaker on the reset button.
  The device is now ready for use again.

- **Device supply line, device connection cables:**

  Input: The supplied power cable is designed to be connected to the power supply (outlet).

  Output: All equipment connection cables must comply with the relevant standards and regulations of the individual countries in which the REOMED is used, e.g. UL / CSA / VDE / SEMKO / CHAR> etc. In the US and Canada, a special connection cable is required for use in hospitals. The connecting cables that are used must all have a protective conductor connection (3-pole!).

- **Cleaning:**
  Disconnect the power cord from the mains before cleaning the unit.
  Clean the device with a slightly damp cloth.
  Do not use liquid cleaners or sprays.

- **Water and moisture:**
  Do not use the device near water, such as next to sinks, washing tubs, bathtubs or in an area which may become wet. No water should come into contact with either the input and output plugs and the housing cooling vents. It must be ensured that no liquids are able to penetrate inside the **REOMED** housing.

- **Precautionary inspection:**
  The device is maintenance-free.

- **Safety checks:**
  Should be carried out at intervals no longer than 24 months. A visual inspection of the power cable and the housing for damage as well as a check of the protective conductor connection and to carry out and document a leakage current measurement test is to be performed.

1.4 Transport, storage and disposal

For transport and storage periods of up to 15 weeks, the following storage conditions apply

Temperature:	- 10°C	... + 50°C
Relative humidity:	10%	... 90% (non-condensing)
Air pressure:	264hPa	...1060hPa
Height:	10000 m	(Transport only)
Thereafter, the values of the operating conditions apply		
Temperature:	+ 0°C	... + 40°C
Relative humidity:30%	...75%	(non-condensing)
Air pressure:	700hPa	...1060hPa
Height:	3000 m	

The **REOMED** should only be stored indoors the original packaging. Condensation must be prevented. Do not expose the device to impacts at any time.
To ensure compliance with the terms of warranty any device returned to the manufacturer or its agent must be in the original box or on a small pallet.

Disposal:

- The device packaging is sent for recycling.
- The metal parts of the device are sent to for scrap metal disposal.
- The plastic parts, electrical components and printed circuit boards are disposed of as electronic scrap.
- Disposal must be carried out in accordance with the respective national legal regulations.
- Appropriate disposal companies are to be consulted.
- Consult your local authority for waste management advice.

1.5 Versions and models

Model	Article number + Option	Power consumption (VA)	Input Voltage (V)	Output Voltage (V)	Output current (A)	Machines rated current (A) /250Vac
						F1;F2 / F3
REOMED 660	65B8107A+xx	660	230	230	2.80	4 / 3
REOMED 1120	65B8108A+xx	1120	230	230	4.70	6 / 5
REOMED 1580	65B8109A+xx	1580	230	230	6.70	8 / 7
REOMED 2000	65B8110A+xx	2000	230	230	8.40	12 / 10

Options label:

+ = Execution	+	Place holder
	LC	without static shield winding (standard)
	++	with static shield winding (option)
xx = Option	10	NTC
	50	Electronic switch-on current limiter
	01	Surge protection
	02	Mains filter
	03	Surge protection + mains filter
xx - = Option	B	PTC-probe connection
	C	CT-for power monitoring

Example: 65B8110ALC50BC without static shield winding + electronic switch-on current limiter + PTC + CT-connection

1.6. Technical options for medical transformers

Option 10: NTC

Is possible at low power without internal by-pass circuit, however, as the NTC resistor is not cooled when the power is turned on again quickly, there is the danger here that, despite the NTC resistance, that the inrush current limiter does not work in instances of rapid mains cycling. This option requires a waiting time before resetting the unit.

Option 50: Electronic switch-on current limiter

Provides a controlled switching without excessive inrush current.

For critical ME systems, use REOMED isolating transformers > = 300VA with electronic switch-on current limiters and half-wave failure detection

Option 01: Surge protection

The surge protection protects against voltage surges in the network.

Option 02: Mains filter

The EMC filter is used to reduce the conduction rfi interference.

Option 03: Surge protection + mains filter (combi-filter)

This is a combination of option 01 and option 02.

Option B: PTC Sensor connection

This is a PTC sensor element which is installed directly in the isolating transformer and connected to a plug or socket mounted on the front.

The REO-ISOMONITOR can be connected to allow the temperature of the REOMED to be monitored to ensure that it is not overheated at any time.

Option C: Power display connection

This is a built-in current transformer in the output line, which is connected to a front-mounted plug or socket.

The REO-ISOMONITOR (Option - Power Display) can be connected to allow the power of the REOMED to be monitored to ensure that it is not overloaded at any time.

Inrush current limiting options

The REOMED models can be optionally equipped with an NTC or an electronic inrush current limiter; With the NTC, waiting times of up to 5 minutes have to be allowed before switching on again.

Accessories:

- REO ISOMONITOR for direct connection to the REOMED output socket and sensor connection socket (device option).
- Trigger protection for output plugs according to IEC320

2.0 Technical specifications REOMED 660/1120/1580/2000VA

Mechanical data: **Dimensions / weight**

Model	H (mm)	W (mm)	D (mm)	Weight (kg)
REOMED 660	115 (122*)	235	325	7.7
REOMED 1120	115 (122*)	235	325	13,0
REOMED 1580	115 (122*)	235	325	17,6
REOMED 2000	115 (122*)	235	325	18,0

* =Height with rubber feet

MEDICAL ISOLATING TRANSFORMER

Model	**REOMED 660**
Article-No	**BV65B8107A+xx**
Supply voltage	**230V**
Frequency	**50 / 60 Hz**
Power input	**660 VA**
Thermal circuit breaker	**F1; F2 4A**
Thermal circuit breaker	**F3 3A**
Rated output voltage	**230V by 6 Outputs**
Rated output current	**2,80 A**
Sensorconnector	**PTC**
Case protection	**IP 20**
Protection class	**I**

MADE IN GERMANY

MEDIZINISCHER TRENNTRANSFORMATOR

Modell	**REOMED 660**
Artikel-Nr	**BV65B8107A+xx**
Eingangsspannung	**230V**
Frequenz	**50 / 60 Hz**
Leistungsaufnahme	**660 VA**
Sicherungsautomat	**F1; F2 4A**
Sicherungsautomat	**F3 3A**
Ausgangsspannung	**230 V an 6 Ausgängen**
Ausgangsstrom	**2,80 A**
Sensorkontakt	**PTC**
Schutzart	**IP 20**
Schutzklasse	**I**

MEDICAL ISOLATING TRANSFORMER

Model	**REOMED 1120**
Article-No	**BV65B8108A+xx**
Supply voltage	**230V**
Frequency	**50 / 60 Hz**
Power input	**1120 VA**
Thermal circuit breaker	**F1; F2 6A**
Thermal circuit breaker	**F3 5A**
Rated output voltage	**230V by 6 Outputs**
Rated output current	**4,70 A**
Sensorconnector	**PTC**
Case protection	**IP 20**
Protection class	**I**

MADE IN GERMANY

MEDIZINISCHER TRENNTRANSFORMATOR

Modell	**REOMED 1120**
Artikel-Nr	**BV65B8108A+xx**
Eingangsspannung	**230V**
Frequenz	**50 / 60 Hz**
Leistungsaufnahme	**1120 VA**
Sicherungsautomat	**F1; F2 6A**
Sicherungsautomat	**F3 5A**
Ausgangsspannung	**230 V an 6 Ausgängen**
Ausgangsstrom	**4,70 A**
Sensorkontakt	**PTC**
Schutzart	**IP 20**
Schutzklasse	**I**

MEDICAL ISOLATING TRANSFORMER

Model	**REOMED 1580**
Article-No	**BV65B8109A+xx**
Supply voltage	**230V**
Frequency	**50 / 60 Hz**
Power input	**1580 VA**
Thermal circuit breaker	**F1; F2 8A**
Thermal circuit breaker	**F3 7A**
Rated output voltage	**230V by 6 Outputs**
Rated output current	**6,70 A**
Sensorconnector	**PTC**
Case protection	**IP 20**
Protection class	**I**

MADE IN GERMANY

MEDIZINISCHER TRENNTRANSFORMATOR

Modell	**REOMED 1580**
Artikel-Nr	**BV65B8109A+xx**
Eingangsspannung	**230V**
Frequenz	**50 / 60 Hz**
Leistungsaufnahme	**1580 VA**
Sicherungsautomat	**F1; F2 8A**
Sicherungsautomat	**F3 7A**
Ausgangsspannung	**230 V an 6 Ausgängen**
Ausgangsstrom	**6,70 A**
Sensorkontakt	**PTC**
Schutzart	**IP 20**
Schutzklasse	**I**

MEDICAL ISOLATING TRANSFORMER

Model	**REOMED 2000**
Article-No	**BV65B8110A+xx**
Supply voltage	**230V**
Frequency	**50 / 60 Hz**
Power input	**2000 VA**
Thermal circuit breaker	**F1; F2 12A**
Thermal circuit breaker	**F3 10A**
Rated output voltage	**230V by 6 Outputs**
Rated output current	**8,40 A**
Sensorconnector	**PTC**
Case protection	**IP 20**
Protection class	**I**

MADE IN GERMANY

MEDIZINISCHER TRENNTRANSFORMATOR

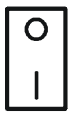
Modell	**REOMED 2000**
Artikel-Nr	**BV65B8110A+xx**
Eingangsspannung	**230V**
Frequenz	**50 / 60 Hz**
Leistungsaufnahme	**2000 VA**
Sicherungsautomat	**F1; F2 12A**
Sicherungsautomat	**F3 10A**
Ausgangsspannung	**230 V an 6 Ausgängen**
Ausgangsstrom	**8,40 A**
Sensorkontakt	**PTC**
Schutzart	**IP 20**
Schutzklasse	**I**

3.0 Guidance and manufacturer's declaration

EMC testing was performed according to the following standards:

Emission tests	**Compliance**
RF emissions CISPR 11 (Radiated and Conducted Emission)	Class B, Group 1
Harmonic emissions IEC 61000-3-2,	Class A
Voltage fluctuations/flicker emissions IEC 61000-3-3	Passed
Immunity tests	**Compliance**
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: ± 8 kV Air: ±2 kV, ± 4 kV, ± 8 kV, ± 15 kV
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV 100 kHz repetition frequency
Surge IEC 61000-4-5	± 0,5 kV, ± 1 kV, ± 2 kV
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0° and 0 % U_T; 250/300 cycle
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 & 60 Hz
Conducted RF IEC 61000-4-6	10 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz
IMMUNITY to proximity fields from RF wireless communications equipment IEC 61000-4-3	28 V/m 450 MHz, 50% PM at 18 Hz 810 MHz, 50% PM at 18 Hz 870 MHz, 50% PM at 18 Hz 930 MHz, 50% PM at 18 Hz 1720 MHz, 50% PM at 217 Hz 1845 MHz, 50% PM at 217 Hz 1970 MHz, 50% PM at 217 Hz 2450 MHz, 50% PM at 217 Hz 27 V/m 385 MHz, 50% PM at 18 Hz 9 V/m 710 MHz, 50% PM at 217 Hz 745 MHz, 50% PM at 217 Hz 780 MHz, 50% PM at 217 Hz 5240 MHz, 50% PM at 217 Hz 5500 MHz, 50% PM at 217 Hz 5785 MHz, 50% PM at 217 Hz

4.0 Symbols



O = Power off I = Power on

Potential equalization

Protective conductor connection

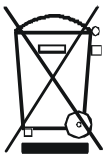
Alternating current

F

Fine fuse or circuit breaker

T

Slow acting fuse



Not household waste

Conformity marking

Warning / Caution

Follow instructions for use / instructions for use

Approval mark

RQS

REO-Quality-Assurance (serial number)

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