

| IMED |

Medical Isolating Transformers and accessories



*When performance matters.*



# IMED - Isolating Transformer for medical applications

The EC directive 93/42 EWG determines imperatively that medical devices and systems have to be constructed in such a way that patients, operating staff or other persons may not be harmed while having contact with these units. This applies particularly for electrical medical devices and systems, where – in accordance to EN 60601-1 and its complementary standards – high demands are made on the electrical safety.



Noratel is proud to introduce the IMED series which fulfil all requirements to a power supply for medical applications.

The IMED program and its accessories allow a safe and compliant installation of non-medical devices, like IT-equipment in medical surroundings. The combination of medical and non-medical devices is possible (i.e. combination of an ECG device with the IT-network) in combination of the IMED program.

IMED<sub>e</sub> has been developed for use in Europe. IMED<sub>e</sub> operate with a fixed primary and secondary voltage of 230 V.

IMED<sub>i</sub> can be used in regions for 115 V and 230 V AC voltages. The primary and secondary voltage can be switched separately.

IMED isolating transformers and accessories are approved by an accredited institution. This ensures that the standards for medical electrical devices in the whole EU are upheld and valid.



Using a medical IMED isolating transformer it is necessary to monitor the resistance of the isolated electrical safety circuit. This monitoring can be done by the Earth-Leakage Guard ELG, which detects and signals an isolating failure on the secondary circuit.

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## IMED Product features

Type	IMED <sub>e</sub> 150	IMED <sub>e</sub> 300	IMED <sub>e</sub> 600	IMED <sub>e</sub> 1000	IMED <sub>e</sub> 2000	IMED <sub>i</sub> 300	IMED <sub>i</sub> 600	IMED <sub>i</sub> 1000
Article number	9-059-000006	9-059-000003	9-059-000007	9-059-000004	9-059-000005	9-059-000001	9-059-000001	9-059-000002
230V input and output voltage	√	√	√	√	√			
115/230V selectable input / output voltage						√	√	√
50/60 Hz	√	√	√	√	√	√	√	√
Green LED operating indicator	√	√	√	√	√	√	√	√
Short-circuit and overload protected	√	√	√	√	√	√	√	√
PRI current limiting fuse + thermal switch	√	√	√	√	√	√	√	√
ON/OFF switch	√	√	√	√	√	√	√	√
In-rush current limiting design (NTC)	√	√	√	√	√	√	√	√
Construction class I	√	√	√	√	√	√	√	√
Type B equipment	√	√	√	√	√	√	√	√
Protection degree IP20	√	√	√	√	√	√	√	√
Test certificate; EC 93/42 EWG	√	√	√	√	√	√	√	√
Conformity; EN60601-1 & EN61558-2-4	√	√	√	√	√	√	√	√
Metal enclosure	√	√	√	√	√	√	√	√
Floor, table top, wall or stand-alone installation	√	√	√	√	√	√	√	√
CE Marking	√	√	√	√	√	√	√	√
Primary power cord	√	√	√	√	√	√	√	√
Varistor for peak voltage attenuation	√		√	√	√			
Earth bolt (POAG)	√	√	√	√	√	√	√	√
Multiple secondary contact plugs (IEC 320)	√ / 2	√ / 4	√ / 6	√ / 9	√ / 9	√ / 4	√ / 6	√ / 9
Power (VA)	150	300	600	1000	2000	300	300	2000
Weight (Kg)	3,0	4,5	9,0	14,0	21,0	4,5	9,0	14,0
Dimesions LxWxH (mm)	194x148x71	194x148x83	270x185x78	305x214x99	312x286x103	194x148x83	270x185x78	305x214x99

# Why IMED ?

## ***Indispensable add-ons to fulfill the safety requirements in medical safety areas***

For medical devices and systems many regulations according to the MDD need to be fulfilled from the supplier and planning-engineer, especially when power supplies are involved.

At the same time the product liability includes the supplier, service provider, and operator (doctor, dentist, etc.).

The usage of medical isolating transformers to power electrical devices in medical safety areas is a very economical way to fulfill the safety requirements of the MDD. A medical isolating transformer is the ideal solution to protect patients and operation staff.

## ***In which rooms or areas are the increased regulations of the MDD necessary ?***

In hospitals, surgery (doctors and dentists) and other medical safety areas, such as sickrooms, laboratories, consulting rooms, waiting rooms; anywhere patients have contact to IT-equipment.

## ***What devices in medical safety areas with the reinforced isolation are necessary according to the MDD / EN 60601-1 ?***

### **All equipment without approval according to MDD**

The approval may be recognized with the CE sign; an appended 3-digit number of the test-house (so called notified body) or the availability of an explicit declaration of conformity issued from an accredited institution for medical technology.

Devices which are only labeled with a CE sign normally do not have a MDD approval.

### **Especially all devices without MDD-approval when connected with medical devices which are approved according to MDD, e.g. printers, PCs and monitors in combination with an ECG device**

All electrical connections going from the medical safety area to external devices have to be isolated, e.g. by the use of LAN-Isolators like ELG.

### **All IT-devices and coupled devices without MDD-approval inside the medical safety area (see above, e.g. servers, workstations, screens, network devices, UPS, etc.)**

Attention should be paid that computers, which are connected with a wired network, have to be considered a part of the complete system in the safety area. Therefore isolating measures are absolutely necessary.

### **Several medical devices which are combined to a complete workgroup; when the leakage current exceeds the limit of 100 $\mu$ A (patient leakage current) according to MDD**

An example may be a medical cart system where several devices (with and without approval) are combined.

# IMED - Accessories

## ELG - Earth-Leakage Guard

The Noratel ELG monitors the dielectric resistance between the two isolated energized pins of the output jack and its neutral conductor.

The commonly in households used protective equipment like residual-current-operated protective devices (RCD) are, because of the galvanic isolation in principle not able to recognize an insulation failure on the secondary side of the IMED transformer. If an insulation defect occurs in the power supply of a medical system it normally would not be detected and generates a high potential risk for the patient and staff.

The earth leakage guard eliminates this security vulnerability. In case of defect the ELG signals an optical and acoustic warning.

The resistance is monitored. If the minimum level of 50 kOhm is short fallen, an optical (LED) and acoustic (Beeper) signal is triggered.

The ELG is directly connected to one of the output plugs of the IMED transformers. Its function is solely to signal isolating failures.



The ELG is exclusively approved in combination with the Noratel IMED transformers.

### Technical Data ELG:

- Dimension (LxWxH): 193x33x56 mm
- Protection class: Class I / IP 40
- Medical grade: Class I, Type B
- Ambient temp.: ta 40 °C/B
- Conformity acc. to.: EN 60601-1, 60601-1-1, 60601-1-2, EN 60601-1-4, EN 14971, MDD93/42EWG

## MLI - Medical LAN isolator

The Noratel MLI solves a serious problem in wired IT-networks within medical safety zones.

All IT-devices (computers, printers, servers, etc) which are connected together with Ethernet cables have a direct electrical connection with other IT-devices within the network structure. This connection happens through the shielding of the network-cable.

To operate IT-devices within the medical safety area – especially when they are connection with medical electrical devices – it is necessary, besides using an IMED isolating transformer, to separate the 10/100 MBit network connection galvanically from the rest of the IT network.

Between the network beyond the medical safety range and the medical safety area itself the MLI builds up an isolation barrier with 4 kV AC isolation strength. In this way harmful residual currents are kept away from the patient.

From a safety aspect the LAN connection is very often underestimated, the risk for the patient is high. Therefore the isolation barrier on the LAN connections is absolutely necessary.

The MLI is delivered with a patch cable with 0.5m length to make the loop-connection as uncomplicated as possible.

Regarding datatransfer the MLI is absolutely neutral and needs no software or driver installation.



### Technical Data MLI:

- Isolation resistance: >4 kV
- Insertion loss TX/RX : <1,5 dB (10 MBit)  
<4 dB (100 Mbit)
- Max. cablelength: 80 m (to next switch/hub)
- Connectors: 2x RJ45 sockets (8P/8C)
- Conformity acc. to : EN 60601-1, 60601-1-1, 60601-1-2, MDD93/42/EWG





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