

# User Manual

## Medical USB Isolation

Type: MUI V1.4

Galvanic USB Isolation for  
medical electrical devices and systems according to  
*EN 60601-1:2006/AC:2010/A1:2013,*  
*EN 60601-1-2:2015*



### **WARNING**

***Prior to commission / operation of the MUI,  
the user has to make himself familiar with the functionality  
of the MUI by careful reading of this instruction manual!***

## 1 General safety instructions

The MUI must be used solely for the purpose specified in chapter 2 Purpose of determination. The MUI must be installed and put into operation only by persons who qualify for operating personnel according to the medical devices operator ordinance (MPBetreibV) §5.

The case of the MUI may not be opened! There are no user-serviceable parts inside the MUI. Do not perform any repairs or modifications to the MUI yourself! Otherwise, the correct functioning of the MUI and the security may be endangered. Opening or modifying the MUI voids the warranty.

The DeMeTec GmbH reserves the right to modify the device without prior notice.

Before using the MUI, contact the manufacturer of your medical device/system, whether by using the MUI there are any special safety instructions to be observed!

### 1.1 Application area and location

Note that the MUI is not protected against the effects of greater mechanical force and the penetration of liquids. The MUI is not intended for operation in combustible atmospheres!

### 1.2 Functional safety

When the electrical consumers are connected to the MUI, make sure that the following points are met:

- Only data interfaces according to the USB standard may be connected to the device
- Only the supplied AC adapter may be used as power supply. Otherwise, the electrical safety is not guaranteed, the device can take damage, and there is a danger for people!

### 1.3 Maintenance

#### Warning

The MUI must be periodical inspected and maintained by persons who are qualified in accordance with the medical devices operator ordinance (MPBetreibV) §5. Repair of the MUI must be executed only by persons referred to above, to ensure a hazard-free operation.

See also chapter 5 Safety inspection / control (STK). If in doubt, please contact your supplier or the manufacturer, DeMeTec GmbH.

### 1.4 Environmental protection / disposal



The DeMeTec GmbH is aware of its responsibility towards the environment. The MUI may not be disposed together with household waste!

According to the WEEE, the DeMeTec GmbH takes back all equipment, which was put into circulation by the DeMeTec GmbH since 2015-08-13, for the purpose of proper disposal.

Please contact us in this regard if required and inform your customers when reselling.

## 1.5 Instructions to suppliers / manufacturer of medical electrical devices and -systems

The MUI is a electrical device that was designed specifically for the use in medical technology, developed for various ME-Devices / -Systems.

The existing insulation distances in the MUI meet the requirements of the standard:

EN 60601-1 *Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance.*

The isolation chart is available upon request from the manufacturer of the MUI.

Basically, the supplier / manufacturer of the ME-devices / -systems has to consider the requirements of the Medical Device Regulation (MDR) and the following standards when combining devices:

- EN 60601-1 (IEC 60601-1) Medical electrical Equipment - Part 1: General requirements for basic safety and essential performance
- EN 60601-1-2 (IEC 60601-1-2) Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

Please refer to chapter 3 Connection and commissioning!

### 1.6 Declaration of symbols

	Refer to documentation
	Must not be disposed together with household waste!

## 2 Purpose of determination

The device „Medical USB Isolation“ (MUI) is especially designed for usage in the medical technology.

The MUI is an accessory for active medical devices. It is used, in accordance with relevant electrical safety standards EN 60601-1 and EN 60601-1-2, for galvanic isolation of all wires within an USB cable, which correspond to the USB standard.

Please note chapter 1 General safety instructions!

## 3 Connection and commissioning

The MUI may only be installed and put into operation by qualified personnel. Please contact your medical-technical section or manufacturer.

Because of the special safety concept within the development of the MUI, it can be applied universal for the galvanic isolation of an USB interface. This means it does not care on which side the medical device with patient contact is connected. Both directions are considered and are approved by the manufacturer.

Make sure to turn off all devices, that you wish to connect to the MUI, before installing it. Connect all cables and the power supply to the MUI before you plug the adapter into the main socket!

Take account of the safety instructions in chapter 1.2 Functional safety!

According to the operation purpose the following installation is advised:

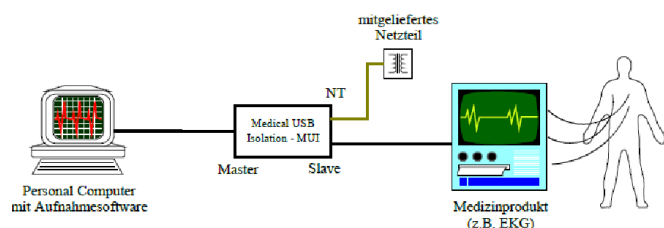


Figure 1: Typical use

### 3.1 Connection

The MUI will be recognized as a “generic USB Hub”, when connected to a PC. Due to the internal structure a speed of up to USB 2.0 full speed (12Mbit/s) is possible.

#### Note

The installation of the MUI should be as close to the medical device as possible.

If a USB device is connected, which could use a faster connection, this will be displayed as a message in the operating system. This is not an error message.

The green LED indicates the correct and functioning connection to a master (host).

### 3.2 Connection to the power supply

Connect the included power adapter to the jack „NT“.

Then plug the power supply into the power outlet (230V).

A green LED indicates that the MUI is ready for use.

The MUI may only be operated with the supplied power supply. For a replacement power supply, please contact the manufacturer.

## 4 Cleaning and disinfection

#### Attention

Switch off the ME-device / -system before cleaning! Disconnect the MUI from the mains supply before cleaning!

To clean the device you should use a cloth moisturised with a mild cleaning agent! You can also use clinical cleaning and disinfection agents (Vol. Alcohol <70%). Scouring agents or aggressive cleaning agents are not suitable.

You should also take care that no liquids get into the MUI! The MUI is not protected against liquid entry!

## 5 Safety inspection / control (STK)

#### Caution

Maintenance and service of the MUI can not be subjected while the device is used on a patient!

#### Note

A regular maintenance and safety check should be performed by a person who meets the requirements of the medical devices operator ordinance (MPBetreibV) §5.

The following steps have to be performed to ensure the continued safe use of the MUI:

- Visual inspection: Visual inspection for external damage (housing, power cables / connectors, readable labels, dirt, etc.) and availability and completeness of documentation
- Functional test: Check the correct operation of the device using the manual
- Verification of electrical safety according to EN 60601-1: Measurement of isolation resistance between signal input and signal output. The resistance has to be higher than 50MΩ.

If in doubt, contact your supplier or manufacturer.

## 6 EU Declaration of Conformity



**DeMeTec GmbH**

Lützelwiesen 5, D-35428 Langgöns (Germany)

We hereby declare in sole responsibility that the product

**Medical USB-Isolation – MUI V1.4**

(item no. FG-292)

with the serial numbers 71292nnnnn

complies with the relevant regulations of the Low Voltage Directive 2014/35/EU (LVD), the Electromagnetic Compatibility (EMC) Directive 2014/30/EU as well as those of Directive 2011/65/EU (RoHS-II) on the restriction of the use of certain hazardous substances in electrical and electronic equipment. Applicable changes at the time of the declaration are included.



Meeting the following standards:

EN 60601-1:2006/AC:2010/A1:2013  
EN 60601-1-2:2015

Langgöns, 2021-12-06

Manager,  
Head of Development Department

Quality Management Officer,  
Regulatory Affairs

## 7 Manufacturer / contact

If you have any questions or problems, please contact your local dealer or the manufacturer:

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Lützelwiesen 5  
D-35428 Langgöns  
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Home page: <http://www.DeMeTec.de>

## 8 Technical description

<b>Medical USB-Isolation - MUI V1.4</b>	
mains voltage	100-240V AC (via included power supply)
mains frequency	50-60Hz typical (via included power supply)
power consumption	3W (via included power supply)
<b>classification</b>	
Protection against electric shock	II
IP Classification: Protection against harmful ingress of solids or water	IP30
Sterilization	not applicable
Suitability for use in oxygen-enriched ambient	not applicable
operating mode	continuous operation
operating conditions	ambient temperature: +32°F to 122°F / 0°C to +50°C relative humidity: 10% to 90% (non-condensing) air pressure: 70kPa to 106kPa
storage conditions	ambient temperature: -13°F to +185°F / -25°C to +85°C relative humidity: 10% to 95% (non-condensing) air pressure: 50kPa to 106kPa
dimension (L×W×H)	(90×50×25) mm <sup>3</sup>
weight	approx. 180g (including power supply & 1m USB-cable)
Specification of data connections	USB 1.1 (1.5Mbps), USB 2.0 Full-Speed (up to 12Mbps)
	The MUI behaves USB compliant as self-powered USB Hub
Voltage endurance between the connectors	4kV
rated voltage	230V AC
Insulation distance	2 x MOPP
Air clearance	> 8mm
Creepage distance	> 8mm
connectors	<ul style="list-style-type: none"> <li>• USB-A</li> <li>• USB-B</li> <li>• power supply</li> </ul>
<b>Accessory</b>	<ul style="list-style-type: none"> <li>• Power supply, Co. MEAN WELL, type: GSM06E05 (euro plug)</li> <li>• Alternative power supply with 4 plug adapters, Co. MEAN WELL, type: GEM12I05</li> <li>• AC plug "Euro"</li> <li>• AC plug "US"</li> <li>• AC plug "UK"</li> <li>• AC plug "Australia"</li> </ul>