

User Manual

Medical RS232 Isolation

Type Rsl V1.2

Galvanic serial interface isolation for
medical electrical devices and systems according to

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

EN 60601-1-2:2007/AC:2010

EC Directive 93/42/EEC, MDD



WARNING

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

1 General Safety Instructions

The Rsl must be used solely for the purpose specified in chapter 2 Purpose. The Rsl must be installed and put into operation only by persons who qualify for operating personnel according to MPBetriebV §2(2) (Medical Devices Operator Ordinance).

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

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

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

1.1 Application area

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

1.2 Functional safety

When electrical devices are connected to the Rsl, make sure that the following points are met:

- Only serial data interfaces according to the standard "TIA/EIA-232-F" may be connected to the Rsl.
- Only the supplied AC adapter is used as the power supply. Otherwise, the electrical safety is not guaranteed, the device can take damage, and there is a danger of people!

1.3 Maintenance

Warning

The Rsl must be periodically inspected and maintained by persons who are qualified in accordance with the MPBetriebV (Medical Devices Operator Ordinance), §6(4). Repair of the Rsl must be executed only by persons referred to above, to ensure a hazard-free operation.

See also chapter 5 Safety Technical Inspection / Control STC. If in doubt, please contact your supplier or the manufacturer.

1.4 Environmental protection / disposal



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

According to the WEEE, DeMeTec GmbH takes back all equipment, which put into circulation by DeMeTec GmbH since 2005-08-13, for the purpose of proper disposal.

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

1.5 Instruction to suppliers / manufacturer of medical Electrical Device and -system

Networking:

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

Basically, the supplier / manufacturer of the ME-Devices / -Systems at device combinations has to consider the requirements of the Medical Devices Act and the following standards:

- *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*

1.6 Declaration of symbols

	Refer to documentation
	Serial connector „Serial A“ (usually for the medical device, eg. EEG)
	Serial connector „Serial B“ (usually for the non-medical device, eg. Computer)
	Socket „NT“ for the supplied power adapter for power supply
	Must not be disposed together with household waste!

2 Purpose

The device „Medical RS232 Isolation“ (Rsl) is especially designed for usage in the medical technology.

The Rsl is an accessory for active medical devices. It is used, in accordance with the relevant electrical safety standards IEC 60601-1 and IEC 60601-1-2 and EC-Directive 93/43/EEC, for galvanic isolation of all data lines (RxD, TxD, CTS, DSR, DCD, RI, RTS, DTR) of 9-pin serial interfaces, which correspond to the TIA/EIA-232-F (RS-232) standard.

Please take note of chapter 1 General Safety Instructions!

3 Connection and commissioning

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

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

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

According to the operation purpose, the following installations is advised:

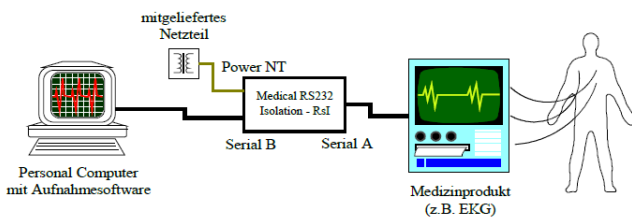


Figure 1: Typical application

3.1 Connection

The data and control lines are routed 1:1 through the Rsl, so you can simply “loop” the device into the serial line. The assignment of the connecting sockets can be found in chapter 8 Technical Description.

Note: The installation of the Rsl should be as close to the medical device as possible.

Figure 1 shows the typical use of the Rsl. Simply connect the side market “Serial B” D-sub connector to the non-medical (eg. Computer to record the ECG) and the marked “Serial A” D-sub connector to the isolated medical device (eg. An ECG amplifier).

Be sure to tighten the screws of the D-sub connector, so that the data lines do not accidentally loosen.

If your application requires, you can connect the medical device to the socket “Serial B” and the non-medical device with “Serial A”.

3.2 Connection to the power supply

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

Then plug the power cord of the power adapter into the power outlet (230V).

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

The Rsl may only be used with the supplied AC adapter. For a replacement power supply, please contact the manufacturer.

4 Cleaning and Disinfection

Attention!

Switch off before cleaning the ME-Device / -System! Disconnect the Rsl 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 Rsl!

5 Safety Technical Inspection / Control STC

We recommend that you periodical perform a STC by persons who qualify for operating personnel according to MP-BetriebV §6(4). This includes the following steps:

- Visual inspection for external damage (housing, power cables / connectors, readable labels, dirt, etc.), availability and completeness of documentation
- Measurement of isolation resistance between signal input and signal output. The measured value has to be higher than 50M Ohm.

If in doubt, contact your supplier or manufacturer.

6 EC Declaration of Conformity for medical devices

(as defined by directive for medical devices 93/42/EEC, MDD 2007, Annex VII)



DeMeTec GmbH

Lützelwiesen 5, 35428 Langgöns (Germany)

We hereby declare, that the product

Medical RS232 Isolation – Rsl Version 1.2

was manufactured in harmony with the technical documentation as defined by Annex VII, section 3 of the medical device directive and that it corresponds to the requirements of the following directive:

Medical Device Directive 93/42/EEC

Meeting the following standards: **EN 60601-1:2006/AC:2010/A1:2013**
EN 60601-1-2:2007/AC:2010

As well the following guideline will be followed:

Directive 2011/65/EU (RoHS-II)

In compliance with the national Electrical and Electronic Equipment fabric Regulation



Langgöns, 2018-05-22

Harald Hellmann

Manager
Head of Development Department

C. Ennisk

Quality Management Officer
Regulatory Affairs

7 Contact, Manufacturer

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

DeMeTec GmbH
Lützelwiesen 5
35428 Langgöns (Germany)
Tel.: 06403-7874-0
Fax: 06403-7874-30
email@DeMeTec.de
<http://www.DeMeTec.de>

8 Technical Description

Medical RS232 Isolation - Rsl V1.2																																																																							
Insulating gap / rated voltage	2 × MOPP / 230V AC																																																																						
Voltage endurance between the RS232-connectors	4kV																																																																						
Air gap and creepage	> 8mm / > 8mm																																																																						
Classification	Protection class	II																																																																					
	Protection against penetration of liquids	IP30																																																																					
	Protection class of applied part against electric shock	Not applicable																																																																					
	Protection class against discharge of de-fibrillators	Not applicable																																																																					
	Operation mode	Continuous operation																																																																					
	Classification according to appendix IX, MDD	Class I																																																																					
Operating conditions	temperature	+32°F to 122°F / 0°C to +50°C																																																																					
	relative humidity	10% bis 90% (non-condensing!)																																																																					
Storage conditions	temperature	-13°F to 185°F / -25°C to +85°C																																																																					
	relative humidity	10% bis 95% (non-condensing!)																																																																					
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)																																																																						
Dimension (L×W×H)	(150 × 80 × 30) mm ³																																																																						
Weight	510g (including power supply)																																																																						
Specification of data connections	Connection according to TIA/EIA-232-F and ITU V.28 standard																																																																						
Maximum data transfer rate	230kBd																																																																						
ESD resistance of the RS232 connections	±15kV (IEC / HBM)																																																																						
Sockets	1 × D-sub plug (Serial A) 1 × D-sub socket (Serial B) 1 × panel jack 5,5 × 1,0 mm („NT“)																																																																						
Assignment D-sub connector (serial A)	Assignment D-sub socket (serial B)																																																																						
<p style="text-align: center;">RS232 Device A (ECG)</p> <table border="0"> <thead> <tr> <th>high level/low level</th> <th>Signalname</th> <th></th> <th></th> </tr> </thead> <tbody> <tr> <td>data carrier detect/no carrier</td> <td>→ DCD</td> <td>1</td> <td></td> </tr> <tr> <td>data set ready/not ready</td> <td>→ DSR</td> <td>6</td> <td></td> </tr> <tr> <td>Start, /Data, /Stop, /Idle</td> <td>→ /RxD</td> <td>2</td> <td></td> </tr> <tr> <td>request to send/stop to send</td> <td>← RTS</td> <td>7</td> <td></td> </tr> <tr> <td>Start, /Data, /Stop, /Idle</td> <td>← /TxD</td> <td>3</td> <td></td> </tr> <tr> <td>clear to send/stop to send</td> <td>→ CTS</td> <td>8</td> <td></td> </tr> <tr> <td>data terminal ready/not ready</td> <td>← DTR</td> <td>4</td> <td></td> </tr> <tr> <td>ring indicator/not ringing</td> <td>→ RI</td> <td>9</td> <td></td> </tr> <tr> <td>Signal ground</td> <td>↔ Gnd</td> <td>5</td> <td></td> </tr> </tbody> </table> <p>Inputs default to low level if unconnected D-sub-9-male View from outside on pins of male connector.</p>	high level/low level	Signalname			data carrier detect/no carrier	→ DCD	1		data set ready/not ready	→ DSR	6		Start, /Data, /Stop, /Idle	→ /RxD	2		request to send/stop to send	← RTS	7		Start, /Data, /Stop, /Idle	← /TxD	3		clear to send/stop to send	→ CTS	8		data terminal ready/not ready	← DTR	4		ring indicator/not ringing	→ RI	9		Signal ground	↔ Gnd	5		<p style="text-align: center;">RS232 Device B (PC)</p> <table border="0"> <thead> <tr> <th></th> <th>Signalname</th> <th>high level/low level</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>DCD →</td> <td>data carrier detect/no carrier</td> </tr> <tr> <td>6</td> <td>DSR →</td> <td>data set ready/not ready</td> </tr> <tr> <td>2</td> <td>/RxD →</td> <td>Start, /Data, /Stop, /Idle</td> </tr> <tr> <td>7</td> <td>RTS ←</td> <td>request to send/stop to send</td> </tr> <tr> <td>3</td> <td>/TxD ←</td> <td>Start, /Data, /Stop, /Idle</td> </tr> <tr> <td>8</td> <td>CTS →</td> <td>clear to send/stop to send</td> </tr> <tr> <td>4</td> <td>DTR ←</td> <td>data terminal ready/not ready</td> </tr> <tr> <td>9</td> <td>RI →</td> <td>ring indicator/not ringing</td> </tr> <tr> <td>5</td> <td>Gnd ↔</td> <td>Signal ground</td> </tr> </tbody> </table> <p>D-sub-9-female Inputs default to low level if unconnected View from outside into holes of female connector.</p>		Signalname	high level/low level	1	DCD →	data carrier detect/no carrier	6	DSR →	data set ready/not ready	2	/RxD →	Start, /Data, /Stop, /Idle	7	RTS ←	request to send/stop to send	3	/TxD ←	Start, /Data, /Stop, /Idle	8	CTS →	clear to send/stop to send	4	DTR ←	data terminal ready/not ready	9	RI →	ring indicator/not ringing	5	Gnd ↔	Signal ground
high level/low level	Signalname																																																																						
data carrier detect/no carrier	→ DCD	1																																																																					
data set ready/not ready	→ DSR	6																																																																					
Start, /Data, /Stop, /Idle	→ /RxD	2																																																																					
request to send/stop to send	← RTS	7																																																																					
Start, /Data, /Stop, /Idle	← /TxD	3																																																																					
clear to send/stop to send	→ CTS	8																																																																					
data terminal ready/not ready	← DTR	4																																																																					
ring indicator/not ringing	→ RI	9																																																																					
Signal ground	↔ Gnd	5																																																																					
	Signalname	high level/low level																																																																					
1	DCD →	data carrier detect/no carrier																																																																					
6	DSR →	data set ready/not ready																																																																					
2	/RxD →	Start, /Data, /Stop, /Idle																																																																					
7	RTS ←	request to send/stop to send																																																																					
3	/TxD ←	Start, /Data, /Stop, /Idle																																																																					
8	CTS →	clear to send/stop to send																																																																					
4	DTR ←	data terminal ready/not ready																																																																					
9	RI →	ring indicator/not ringing																																																																					
5	Gnd ↔	Signal ground																																																																					
Accessory	<ul style="list-style-type: none"> • Medical Power Supply, Fa. Egston, Type: P2CFMW3 6W-5V • AC plug "Euro" • AC plug "US" • AC plug "UK" • AC plug "Australia" 																																																																						