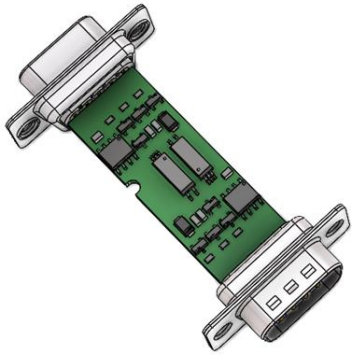
RS232 Medical Isolator

Product Datasheet

Serial interface isolator, with and without plastic housing

RS232 Medical Isolator E1



RS232 Medical Isolator I1

1 FEATURES AND ADVANTAGES

- Suitable for use in medical supply units with supply voltages up to 250 V AC
- Dielectric strength of 4.0 kV AC or 8.5 kV DC
- Designed and tested in accordance with IEC 60601-1 and IEC 60601-1-2
- Data transfer speeds up to 576 kbaud (576 kbit/s)
- UL Recognized Component
- No additional power supplies necessary
- Supports both polar and unipolar signalling
- Level matching at data receiver
- RoHS compliant
- 100% quality control testing

2 GENERAL DESCRIPTION

The RS232 Medical Isolator disconnects every electrically conducting connection (specifically the data and shield conductors) between devices connected together via a serial interface cable. The isolator prevents current flow resulting from differences in electrical potentials, and also protects connected devices and their users from stray external voltages and power surges which may be directly or inductively coupled onto the network lines by causes such as installation errors, lightning, switching operations, and electrostatic discharge.

When used in conjunction with a medical terminal or peripheral device, the RS232 Medical Isolator facilitates the safe operation of this device in the patient environment. The RS232 Medical Isolator satisfies all construction requirements of IEC 60601-1 in the formation of two means of patient protection (MOPP) within the serial interface, thereby eliminating the risk of electrical shocks arising from such stray external voltages at the network connection. Thanks to its UL certification, the RS232 Medical Isolator is also approved for the Canadian and US markets.

No additional power supply is needed for the isolator, as all required energy is provided by the connected devices. This applies both to the input as well as the output (see *Figure 6: Schematic diagram*), and therefore it is not possible to connect multiple isolators in series.

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3 APPLICATIONS

3.1 PATIENT PROTECTION

Electrical separation of serial interfaces of medical electrical (ME) devices and systems, where patients must be protected from dangerous leakage currents, in conformity with applicable standards.

3.2 EQUIPMENT PROTECTION

Applications, in which valuable devices or those requiring special protection need to be protected against ripple, mains hum, and surge voltages from the serial periphery.

3.3 MEASUREMENT TECHNOLOGY

Electrical measuring and monitoring equipment, which needs to be protected against external voltages and interference voltages arising from the serial periphery.

4 DRAWINGS

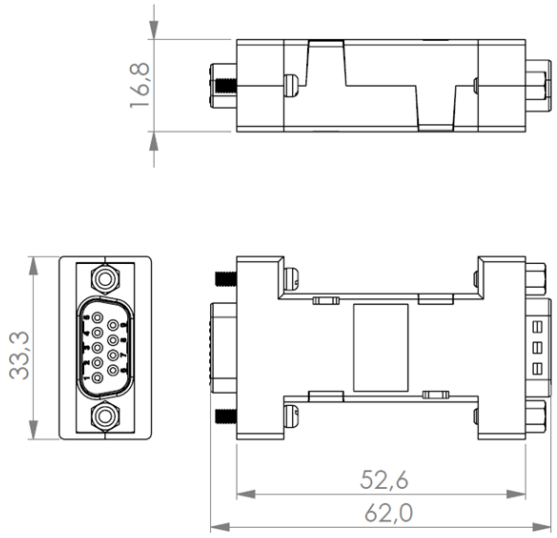

Figure 1: Physical dimensions of RS232 Medical Isolator E1. All dimensions are in millimetres.

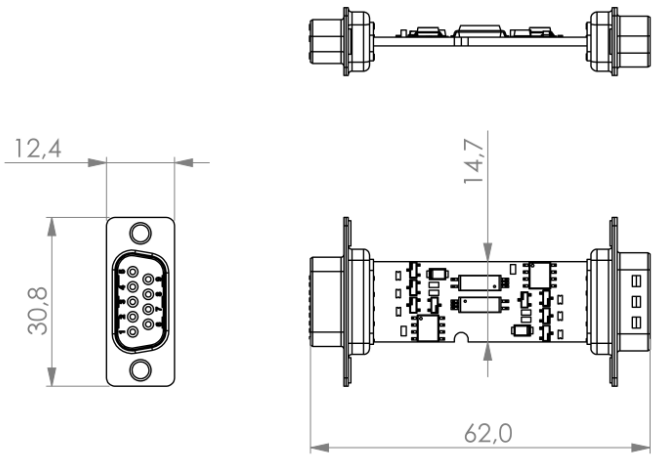

Figure 2: Physical dimensions of RS232 Medical Isolator I1. All dimensions are in millimetres.

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5 SPECIFICATIONS

5.1 GENERAL

Category	Standards or Test Criteria	Property	
Designation		RS232 Medical Isolator E1	RS232 Medical Isolator I1
Article Number		A10315	A10316
Housing colour		Black	-
Housing Material		Plastic (ABS, UL94 V-0)	None
Data Interface	Device is functionally symmetrical	RS-232	
Input / Output Interface		D-Sub-9 Socket D-Sub-9 Plug	
Weight		approximately 25 g	approximately 13 g
Protection rating	EN 60529	IP40	IP40*
Mating cycles	D-Sub-9 plug in D-Sub-9 socket	> 500 cycles	
Mean Time To Failure (MTTF) at 25°C	SN 29500 Standard Duty cycle: 100% (24 hours, 7 days)	450 years	
MTTF at 40°C		290 years	

5.2 SIGNALLING

Parameter		Minimum	Typical	Maximum	Unit
Input	High Level (V_{IH})	2.4†	-	15.0	V
	Low Level (V_{IL})	-15.0	-	1.5‡	V
Output	High Level (V_{OH})	V_{IH} – 2.0	V_{IH} – 1.0	V_{IH}	V
	Low Level (V_{OL})	V_{IL} + 0.3	-	V_{IL} + 0.5	V
Latency		10	40	60	ns
Data Rate (limited by cable length)		-	-	576	kbaud

5.3 ELECTRICAL

Category	Standards or Test Criteria		Property
AC Dielectric Strength	at 50 Hz, for 60 seconds		4.0 kV
DC Dielectric Strength	for 60 seconds		8.5 kV
Reinforced Isolation	IEC 60601-1		✓
Total Leakage Current	275 V AC at 50 Hz	Typical:	0.4 µA
		Maximum:	0.8 µA

* *IP40 achievable when installed in a suitable device.*

† *For unipolar signals, V_{IH} must be 5.0 V or greater.*

‡ *For polar signals, V_{IL} must be -3.3 V or less.*

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5.4 OPERATING CONDITIONS

Category	Standards or Test Criteria		Property
Pollution Degree*	IEC 61010		2
Overvoltage Category	IEC 60664-1		III
Maximum Working Voltage†	Maximum mains voltage of the connected devices, in accordance with IEC 60601-1		250 V AC 300 V DC
Temperature		Minimum:	10°C
		Maximum:	50°C
Air Humidity	Non-condensing	Minimum:	10%
		Maximum:	90%
Air Pressure		Minimum:	700 hPa
		Maximum:	1,060 hPa
Altitude		Maximum:	3,200 m

5.5 STORAGE AND TRANSPORT ENVIRONMENTAL CONDITIONS

Category	Standards or Test Criteria		Property
Temperature		Minimum:	-40°C
		Maximum:	+70°C
Air Humidity	Non-condensing	Minimum:	10%
		Maximum:	90%
Air Pressure		Minimum:	500 hPa
		Maximum:	1,060 hPa

5.6 CERTIFICATIONS

Category	Property
UL Recognized Component	✓
UL File No.	E362969
IEC 60601-1	✓
IEC 60601-1-2	✓
ANSI/AAMI ES 60601-1	✓
CAN/CSA-C22.2 No. 60601-1	✓
Low Voltage Directive	✓
EMC Directive	✓
RoHS Directive	✓

The versions of the cited standards and directives to which our products comply with can be found in our Declaration of Conformity and our UL certificate on our website "Standard Conformity and Certificates".

* *Normally only nonconductive pollution occurs. Temporary conductivity caused by condensation is to be expected.*
† *The RS232 Medical Isolator can be permanently exposed to this voltage level.*

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5.7 ISOLATION DIAGRAM

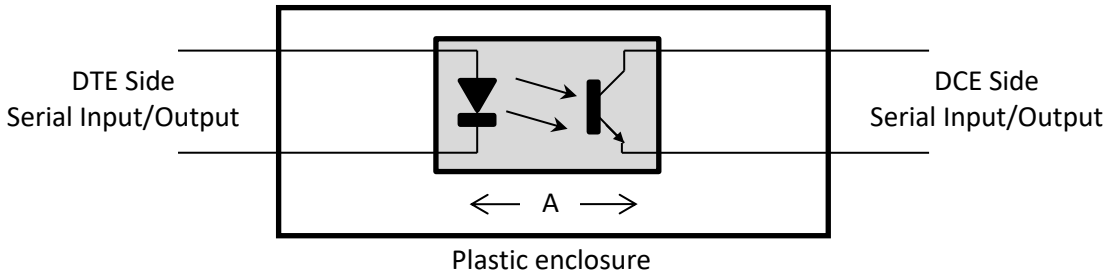

Figure 3: Isolation diagram for RS232 Medical Isolator E1

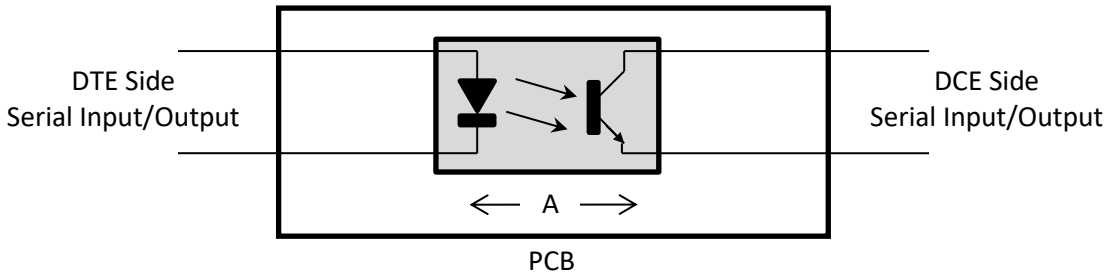

Figure 4: Isolation diagram for RS232 Medical Isolator I1

Area	Number and type of Means of Protection	Material Group (from CTI)	Maximum Operating Voltage		Required creepage distance (mm)	Required clearance distance (mm)	Measured creepage distance (mm)	Measured clearance distance (mm)
			V AC	V_{peak}				
A	2 MOPP *	IIIb †	250	353	8.0	5.0	8.2	8.2

* *MOPP = Means of Patient Protection*

† *Materials in the Material Group IIIb have a Comparative Tracking Index (CTI) value between 100 and 175.*

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5.8 REQUIRED ISOLATION DISTANCES FOR RS232 MEDICAL ISOLATOR I1

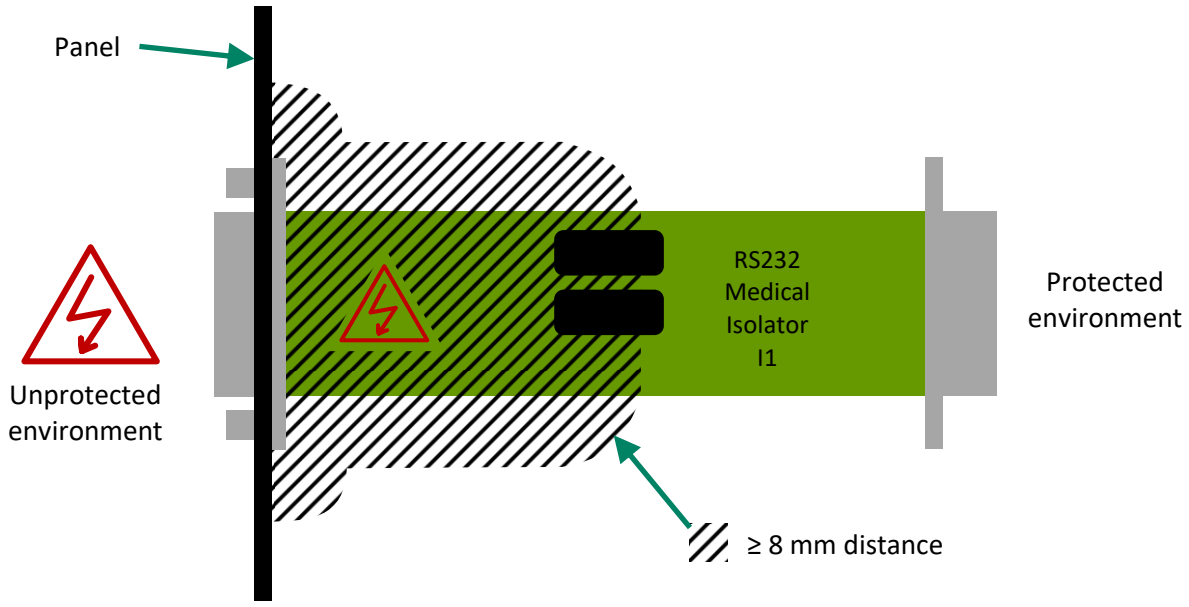

Figure 5: Required isolation distances for RS232 Medical Isolator I1 when built into devices. (Not to scale.)

To ensure that creepage and clearance distances of at least 8 mm are respected for the entire isolator, no other materials (conductive or otherwise) may be present inside the hatched area (including above and below the device).

The dimensions of these areas are based upon requirements for realising two means of patient protection (2 MOPP) for medical electrical (ME) devices with nominal operating voltages of up to 250 V AC.

However, the actual requirements for the clearance and creepage distances vary with device and application, which must be determined and verified. The assembly of the RS232 Medical Isolator I1 in a manner that satisfies requirements and relevant standards is the responsibility of the device manufacturer.

6 SCHEMATIC DIAGRAM

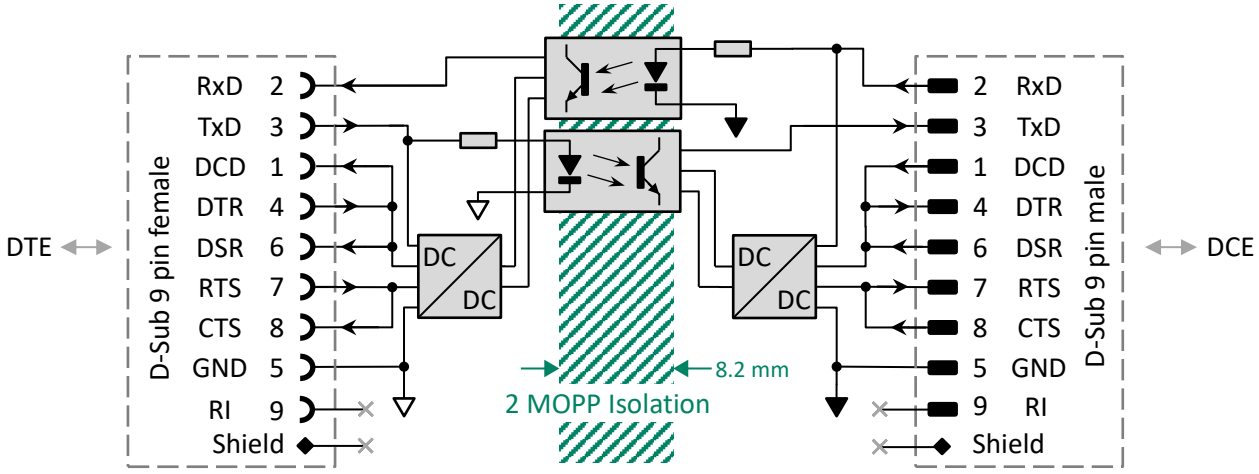

Figure 6: Schematic diagram for RS232 Medical Isolator E1 and RS232 Medical Isolator I1

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7 PRODUCT MARKINGS

CE	Through this mark, the conformity of the product with all applicable EU Directives is confirmed.
c UL us E362969	Designates the product as a UL "Recognised Component"; File № E362969.
	The product may not be disposed of in domestic rubbish.
RoHS compliant	This product meets the requirements of EU Directive concerning the limitation of the use of certain hazardous substances in electric and electronic equipment.

8 SCHEDULED MAINTENANCE

When used as directed, this medical isolator is maintenance-free.

9 QUALITY

EMO Systems operates a certified quality management system for development and production in accordance with ISO 9001 and ISO 13485. Prior to delivery, each isolator is subjected to a comprehensive quality inspection. This inspection ensures, among other factors, that the attained values for leakage currents, dielectric withstand strengths, and data transfer rates all meet the specified requirements.

10 CONTACT AND SUPPORT

Please find our up-to-date contact details on our website: www.emosystems.de/en/contact

Or send us an email at the following address: support@emosystems.de

11 LEGAL NOTICE

The information provided in this datasheet has been compiled with all due care, and it is believed to be accurate and reliable. However, we cannot guarantee that the information contained is completely free of errors.

The end user is responsible and liable for the proper use of this product; EMO Systems assumes no liability. We reserve the right to make changes to this datasheet without notice.

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