Safety of medical equipment MI 6601 MediTest



The MI 6601 Medi lest is a new Metrel tester for testing the electrical safety of medical equipment in the accordance with the IEC / EN 60601 standard in any stage of medical equipment life cycle. It is accurate enough for development work, offers detailed measurements for type testing, it can be embedded into the production line and is portable enough for recurrent testing in accordance with IEC 60601 or IEC 62353. In addition it can help with diagnosing problems in service departments or can be used for troubleshooting in the field.

The MI 6601 MediTest can be used as stand-alone tester without a PC or laptop in the field. For office and laboratory use, the tester can work in combination with Metrel Medical Electrical Safety Manager (MMESM). It supports creation and execution of test sequences in accordance with IEC/EN 60601 and asset management. Reports are created with integrated online services Metrel Cloud Reports and Metrel Cloud Storage. Compliance with IEC/EN 60601 is a widely accepted benchmark and a requirement for commercialisation of electrical medical equipment around the world. In Metrel we believe that our new MI 6601 MediTest is the fastest and easiest-to-use electrical safety compliance tester on the market, which entirely covers prescribed standard test procedures, without any compromises or simplifications.

MEASUREMENTS AND INSPECTIONS

- PE resistance with 200 mAac and 25 Aac;
- Insulation resistance with test voltage 250 V_{DC} or 500 V_{DC}
- All test configurations acc. to IEC 62353 are supported;
- Leakage current measurements with 1 μA resolution:
- AC, DC and TRMS value of leakage currents;
- All leakage current measurements as defined in IEC 60601-1 standard (patient, auxiliary, earth, touch);

- All leakage current measurements as defined in IEC 62353 (equipment and applied part; alternative, direct, differential method);
- Measurement according to portable appliance standards EN 50678 and EN 50699;
- Point-to-point, touch and mains voltage tests;
- Equipment power;
- IEC lead test;
- Pre-set or configurable visual and functional inspections.

KEY FEATURES

- The most complete IEC 60601 tester on the market;
- 10 universal configurable connections. They can be configured as applied parts, non-earthed parts, earthed parts:
- Dedicated test ports for connection to functional earthing and signal I/O connections;
- All possible configurations acc. to the IEC 60601 and IEC 62353 standards;
- Tests can be run on the instrument directly or via a PC;
- Fully automatic test flow with Auto Sequences®;
- Tests and limits are automatically set acc. to the set configuration of medical equipment;
- Test sequences are optimized for fastest work flow;
- Supports measuring by standards IEC/EN 60601 (2nd and 3rd editions), IEC/EN 62353, ANS/NZS 3551, EN 50678 and EN 50669;

- Use of single tests to diagnose problems easily:
- High current for testing continuity of PE connections: up to 25 A;
- AC and DC values of patient leakage and patient auxiliary current;
- Communication over USB, RS232 and Ethernet;
- Input data in any desired way: touchscreen, barcode/QR code scanner, wireless keyboard, PC SW;
- Optional printers or NFC writers for creating labels and tags;
- New subscription-based software solution including MMESM, Metrel Cloud Reports and Metrel Cloud storage;
- IP 40 case open, IP 65 case closed;
- · Carrying case and bag for accessories;
- Standard warranty 2 years.

APPLICATIONS

- Safety of medical equipment during development, production, service, periodic verification.
- Troubleshooting of medical equipment.
- Safety of standard portable appliances.
- Troubleshooting portable devices.



TECHNICAL SPECIFICATION

FUNCTION		MEASURING RANGE	RESOLUTION	ACCURACY
Continuity / Protective earth resistance		0.00.0 40.00.0	0.01.0	(2.0) 5 11 2.0)
¹Continuity	R	0.00 Ω 19.99 Ω 20.0 Ω 99.9 Ω	0.01 Ω 0.1 Ω	±(2 % of reading + 2 D) ±3 % of reading
		100.0 Ω 199.9 Ω	0.1 Ω	±5 % of reading
Insulation Resistance (Riso, Riso-S)		200 Ω 999 Ω	1Ω	Indicative
² Insulation resistance, Insulation resistance –S (250 V, 500 V)	Riso	0.00 ΜΩ 19.99 ΜΩ	0.01 Ω	±(3 % of reading + 2 D)
	Riso-S	20.0 MΩ 99.9 MΩ 100.0 MΩ 199.9 MΩ	0.1 Ω 0.1 Ω	±5 % of reading ±10 % of reading
² Output voltage	Um	0 V 600 V	1 V	±(3 % of reading + 2 D)
Sub-Leakage Current, Substitute Leakage Current - S				(5.0) (5.0)
³ Substitute leakage current, Substitute leakage current - S	Isub Isub-S	0.00 mA 1.99 mA 2.00 mA 19.99 mA	0.01 mA 0.01 mA	±(3 % of reading + 3 D) ±5 % of reading
Differential Leakage current				<u> </u>
⁴ Differential leakage current	ldiff	0.000 mA 1.999 mA 2.00 mA 19.99 mA	1 μΑ 0.01 mA	±(3 % of reading + 3 D) ±5 % of reading
⁴ Power (active)	Р	0 W 999 W	1W	±(5 % of reading + 5 D)
		1.00 kW 3.70 kW	10 W	±5 % of reading
PE leakage current SPE leakage current	lpe	0.000 mA 1.999 mA	1μΑ	±(3 % of reading + 3 D)
		2.00 mA 19.99 mA	0.01 mA	±5 % of reading
^s Power (active)	Р	0 W 999 W 1.00 kW 3.70 kW	1 W 10 W	±(5 % of reading + 5 D) ±5 % of reading
Touch leakage current				
⁶ Touch leakage current	lpe	0.000 mA 1.999 mA 2.00 mA 19.99 mA	1 μΑ 0.01 mA	±(3 % of reading + 3 D) ±5 % of reading
⁶ Power (active)	Р	0 W 999 W	1 W	±(5 % of reading + 5 D)
Power		1.00 kW 3.70 kW	10 W	±5 % of reading
Power (active)	Р	0 W 999 W	1 W	±(5 % of reading + 5 D)
Power (apparent)	S	1.00 kW 3.70 kW 0 VA 999 VA	10 W 1 VA	±5 % of reading ±(5 % of reading + 5 D)
		1.00 kVA 3.70 kVA	10 VA	± 5 % of reading
Power (reactive)	Q	±(0 VAr 999) VAr ±(1.00 kVAr 3.70) kVAr	1 VAr 10 VAr	±(5 % of reading + 5 D) ±5 % of reading
Power factor	PF	0.00i 1.00i	0.01	±(5 % of reading + 5 D)
Total Harmonic Distortion (voltage)	THDU	0.00c 1.00c 0.0 % 99.9 %	0.1 %	±(5 % of reading + 5 D)
Total Harmonic Distortion (current) Cosinus fi	THDI Cos fi	0.00 A 16.00 A 0.00i 1.00i	0.01 A	±(3 % of reading + 5 D)
Cosilius II	C05 11	0.00c 1.00c	0.01	±(5 % of reading + 5 D)
Current Voltage	l U	0.00 A 16.00 A 0.0 V 199.9 V	0.01 A 0.1 V	±(3 % of reading + 5 D) ±(3 % of reading + 10 D)
		200 V 264 V	1 V	±3 % of reading
Leak's & Power ⁷ Power (active)	Р	0 W 999 W	1 W	±(5 % of reading + 5 D)
		1.00 kW 3.70 kW	10 W	±5 % of reading
⁷ Touch leakage current	ltou	0.000 mA 1.999 mA 2.00 mA 19.99 mA	1 μΑ 0.01 mA	±(3 % of reading + 3 D) ±5 % of reading
Differential leakage current	ldiff	0.000 mA 1.999 mA	1μΑ	±(3 % of reading + 3 D)
Power (apparent)	S	2.00 mA 19.99 mA 0 VA 999 VA	0.01 mA 1 VA	±5 % of reading ±(5 % of reading + 5 D)
Power (reactive)	Q	1.00 kVA 3.70 kVA ~(0 VAr 999) VAr	10 VA 1 VAr	± 5 % of reading ±(5 % of reading + 5 D)
Fower (reactive)		~(0 VAI 353) VAI ~(1.00 kVAr 3.70) kVAr	10 VAr	±5 % of reading
Power factor	PF	0.00i 1.00i 0.00c 1.00c	0.01	±(5 % of reading + 5 D)
Total Harmonic Distortion (voltage)	THDU	0.0 % 99.9 %	0.1 %	±(5 % of reading + 5 D)
Total Harmonic Distortion (current) Cosinus fi	THDI Cos fi	0.00 A 16.00 A 0.00i 1.00i	0.01 A 0.01	±(3 % of reading + 5 D) ±(5 % of reading + 5 D)
Comment		0.00c 1.00c	0.01 A	
Current Voltage	U	0.00 A 16.00 A 0.0 V 199.9 V	0.1 V 1 V	±(3 % of reading + 5 D) ±(3 % of reading + 10 D)
Claren aussant		200 V 264 V		±3 % of reading
Clamp current *Clamp current	ldiff	0.10 mA 9.99 mA	0.01 mA	±(5 % of reading + 10 D)
·	lp	10.0 mA 99.9 mA 100 mA 999 mA	0.1 mA 1 mA	±(5 % of reading + 5 D) ±(5 % of reading + 5 D)
		1.00 A 9.99 A	0.01 A	±(5 % of reading + 5 D)
Inculation Pocistance		10.0 A 24.9 A	0.1 A	±(5 % of reading + 5 D)
Insulation Resistance RISO LN-PE, LN-NEP, LN-AP, AP-PE, AP-NEP RISO	Riso	0.00 MΩ 19.99 MΩ	0.01 ΜΩ	±(3 % of reading + 2 D)
⁹ Output voltage	Um	20.0 MΩ 199.9 MΩ 0 V 600 V	0.1 MΩ 1 V	±5 % of reading ±(3 % of reading + 2 D)
Equipment leakage (alternative, direct, differential)				
¹⁰ Equipment leakage current (direct, differential, alternative) ¹⁰ Ulpe (direct, differential, alternative)) leq Ulpe	0.000 mA 1.999 mA 2.00 mA 19.99 mA	1 μΑ 0.01 mA	±(3 % of reading + 3 D) ±5 % of reading
¹⁰ Power (direct, differential)	Р	0 V 299 V	1 V	±(2 % of reading + 2 D)
		0 W 999 W 1.00 kW 3.70 kW	1 W 10 W	±(5 % of reading + 5 D) ±5 % of reading
Applied Part leakage (alternative, direct)				<u> </u>
"Applied Part leakage current (direct, alternative)	lap	0.000 mA 1.999 mA 2.00 mA 19.99 mA	1 μΑ 0.01 mA	±(3 % of reading + 3 D) ±5 % of reading
"Uap (direct, alternative)	Uap	0 V 299 V	1 V	±(2 % of reading + 2 D)
¹¹ Power (direct)	Р	0 W 999 W 1.00 kW 3.70 kW	1 W 10 W	±(5 % of reading + 5 D) ±5 % of reading

Touch current, Touch current NEP -NEP				
Touch current	ltou	0.000 mA 1.999 mA 2.00 mA 19.99 mA	1 μA 0.01 mA	±(3 % of reading + 3 D) ±5 % of reading
Patient leakage				
Patient leakage (Vext on SIO), Total patient leakage (Vext on SIO)	ltou	0.000 mA 1.999 mA	1μΑ	±(3 % of reading + 3 D)
		2.00 mA 19.99 mA	0.01 mA	±5 % of reading
Patient leakage (Vext on NEP), Total patient leakage (Vext on NEP)	ltou	0.000 mA 1.999 mA	1 μA	±(3 % of reading + 3 D)
		2.00 mA 19.99 mA	0.01 mA	±5 % of reading
Patient leakage (Vext on AP), Total patient leakage (Vext on AP)	ltou	0.000 mA 1.999 mA	1 µA	±(3 % of reading + 3 D)
		2.00 mA 19.99 mA	0.01 mA	±5 % of reading
Patient leakage, Total patient leakage	ltou	0.000 mA 1.999 mA	1 µA	±(3 % of reading + 3 D)
		2.00 mA 19.99 mA	0.01 mA	±5 % of reading
Patient auxiliary leakage	ltou	0.000 mA 1.999 mA	1 µA	±(3 % of reading + 3 D)
, 2		2.00 mA 19.99 mA	0.01 mA	±5 % of reading

0.08 በ ... 199.9 በ
0.2 A, 25 A
> 0.2 A at R < 2 D /
> 25 A into short circuit at 230 V
< 9 VAC
0.08 MW ... 199.9 (999) MW
250 V, 500 V (-0 %, +10 %)
max. 2.0 mA
0.02 mA ... 199.9 mA
230 VAC, 110 VAC ¹Operating range (acc. to EN 61557-4) Test currents Current source (at nominal mains voltage, use of standard accessories)

TECHNICAL SPECIFICATION

Mains supply				
Supply voltage, frequency	110 V / 230 V AC, 50 Hz / 60 Hz			
Supply voltage tolerance	±10 %			
Max. power consumption	300 VA (without load on test socket)			
Max. load	10 A continuous, 16 A short duration, 1.5 kW motor			
Mains supply overvoltage category	CAT II / 300V			
Altitude	≤ 2000 m			
Measuring categories				
Instrument	CAT II / 300 V			
Test socket	CAT II / 300 V			
Plug test cable	CAT II / 300 V			
Altitude	≤ 2000 m			
Leakage current measurements				
Measuring device (MD)	Comply to IEC 60601 and IEC 61557-16 requirements			
Measurement type	AC, DC or True RMS, as per IEC 60601, IEC 61557-16 requirements			
Protection classifications				
Power supply	Class I			
Pollution degree	2			
Degree of protection	IP 40			
3 '	IP 20 (mains test socket)			
Case	Shock proof plastic/portable/IP 65			
Display				
Display	Colour TFT display, 4.3 inch, 480 x 272 pixels			
Touch screen	Capacitive			
Communication				
Memory	Depends on microSD card size			
RS-232 interfaces	3			
USB 2.0	Standard USB Type B			
Bluetooth	Class 2			
Ethernet	Dynamic IP (DHCP)			
Reference conditions				
Reference temperature range	15 °C 35 °C			
Reference humidity range	35 % 65 % RH			
Operation conditions				
Working temperature range	0 °C +40 °C			
Maximum relative humidity	85 % RH (0 °C 40 °C), non-condensing			
Storage conditions	-10 °C +60 °C			
Temperature range	90 % RH (-10 °C +40 °C)			
Maximum relative humidity	80 % RH (40 °C 60 °C)			
Fuses				
F1, F2	T 16 A / 250 V / 32 mm x 6.3 mm / 1500 A			
General				
Dimensions (w×d×h)	42 cm x 33 cm x 18 cm			
Weight	8.1 kg			

Accuracies apply for 1 year in reference conditions. Temperature coefficient outside these limits is 0.2 % of measured value per °C plus 1 digit, otherwise noted.

OPTIONAL ACCESSORIES

Photo	Part No.	Description	Photo	Part No.	Description
	A 1758	Test lead, black, 1 m	0	A 1579	Leakage current clamp
	A 1759	Test lead, brown, 1 m		A 1488	BT Able printer, (battery or mains operated)
O	A 1760	Test lead, green, 1 m		A 1489	Label printer Able, with power and data cables, (battery or mains operated)
	A 1761	Test lead, yellow, 1 m		S 2062	BT label printer set, (mains operated)
	A 1762	Test lead, violet, 1 m	18	A 1628	Spare label roll for S 2062
-	A 1014	Test probe, black		A 1450	Spare label roll for S 2062
	A 1298	Test probe, brown		A 1520	Labels for ABLE printer, (250 labels per roll)
	A 1062	Test probe, green		A 1105	Barcode scanner
*	A 1013	Crocodile clip, black		A 1105 2D	Barcode scanner 2D RS232 connection
*	A 1297	Crocodile clip, brown		A 1571	NFC reader / writer
*	A 1309	Crocodile clip, green	06	A 1572	NFC tags, fi 34mm self- stick 50 pcs
	A 1546	Crocodile clip, yellow		A 1573	NFC labels, fi 29 mm self- stick 50 pcs

ORDERING INFORMATION



Standard set MI 6601

- Instrument MI 6601 MediTest
- A 1080 Mains cable
- A 1758 Test lead, black, 1 m
- A 1759 Test lead, brown, 1 m
- A 1760 Test lead, green, 1 m
- A 1761 Test lead, yellow, 1 m
- A 1762 Test lead, violet, 1 m
- A 1014 Test probe, black
- A 1298 Test probe, brown
- A 1062 Test probe, green
- A 1013 Crocodile clip, black, 2pcs
- A 1297 Crocodile clip, brown
- A 1309 Crocodile clip, green
- A 1546 Crocodile clip, yellow
- A 1727 USB cable
- A 1017 Communication cable RS232
- A 1500 Bag for accessories
- Subscription to Metrel Medical Software solution:
- Metrel Medical ES Manager
- Metrel Cloud Reports
- Metrel Cloud Storage

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