Manufacturer's recommendation for electrical test

during initial comissioning, after maintenance or repair

EN

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Contents

1 Aims

These guidelines describe the electrical testing of MELAG devices. An obligation to test exists every time after the housing has been opened. This is to ensure the safety and functionality of the device and to determine any damage. In addition to the specified testing after repair, MELAG recommends performing the electrical test after the initial commissioning and after maintenance of the device. The test is performed in accordance with EN 50678 (VDE 0701).

2 Scope of application

These guidelines apply to all electrical devices that MELAG Medizintechnik markets or has marketed. The devices are tested to EN 50678 (VDE 0701). A test to DIN EN 62353 (DIN VDE 0751) is not necessary, as the devices are not used on patients. Comply with the valid national requirements when conducting the test; these take precedence over this document.

All MELAG devices must be setup outside the patient environment and in accordance with the applicable technical manual / installation instructions.

3 Test deadlines

The manufacturer cannot specify the test intervals for the recurrent test, as it is necessary to take into account the exterior influences that affect electrical devices. The device operator must use a hazard assessment (in Germany BetrSichV, §3) to determine the intervals at which the electrical device must be tested. EN 50699 (VDE 0702) applies to the recurrent tests of electrical equipment.

In other countries, comply with the corresponding national regulations.

4 Before the test

The person performing the test is responsible for safe working and the safety of persons on site during the test tasks. The test may be performed by qualified persons as defined by TRBS-1203. This person must have experience in testing electrical equipment, be able to use the test equipment and be familiar with the applicable national and international standards and laws.

⚠ WARNING

Danger of injury from electrical voltage

This can cause electrical current to flow through the human body, short circuit electric arcs and burns.

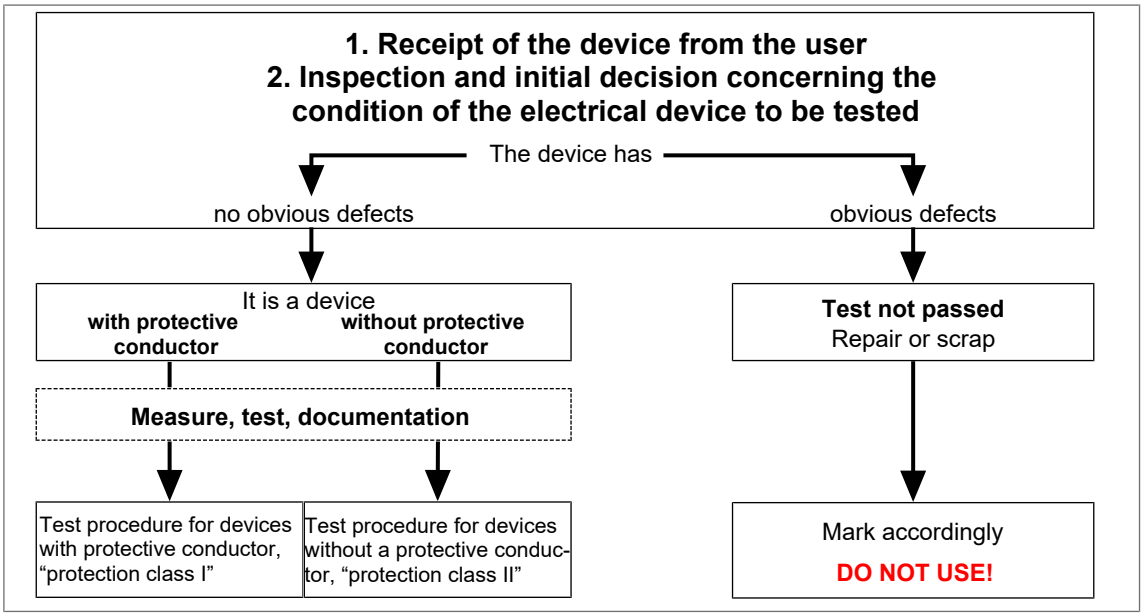
- For your own safety and to protect persons present during the electrical test, comply with the basic health and safety rules issued by the body responsible for accident insurance and prevention (Germany: Berufsgenossenschaften, in particular, “The 5 safety steps”. These rules take precedence over these guidelines.
- Only use test accessories which meet the requirements of IEC 61557-16 (VDE 0413-16) and EN 61010-1 (VDE 0411-1).
- Do not use any provisional test circuits.

Ensure that the test area complies with the following important preconditions:

- Unauthorised persons are not granted access to the test area.
- The test area must be secured against unauthorised access.
- The surface of the test location may not be conductive, otherwise earth.
- Use a fault current circuit-breaker or alternatively a mobile fault current circuit-breaker. If the fault current circuit-breaker cannot be switched on at a socket, inform the system operator immediately. The circuit affected must be serviced by an electrician.

5 Test sequence

5.1 General test sequence



5.1.1 Inspect

The influence of various factors and every overload leave small traces which can often be determined by smell, hearing or touch. Electrical devices are inspected **when de-energized**. Interrupt the inspection upon the discovery of any defects. A defective device must be marked to prevent further operation. The device must be repaired or scrapped and fully tested again after repair.

1. Switch off the device and disconnect the power plug.
2. Inspect the electrical device for the characteristics listed in the following table.

Components	Inspect for the following:
	• Is a CE marking present? • Has an inventory been made? • Is the old test marking present? • What are the conditions in the place of use? • What is the device used for (type of use)? • Are tool marks observable? • Are there signs of heavy wear? • Can rattling noises be heard?
Device body	• Cracks, breakages, discolouration, signs of interference, overload, ageing, component stability
Installation opening	• IP protection class, damp, soiling
Ventilation slots	• IP protection class, soiling penetration, damp, grating, filter, components present / replacement necessary? Correct type?
Fixings	• Displaced, loose, incomplete, reliable?
Container	• State of the (water conducting) container, check for leaks
Handles etc.	• State, usable, is there a danger of injury?
Labels	• Understandable, legible?

▶ Perform a thorough manual inspection of the cables:

Electrical components	Inspect for the following:
Cable gland	• Loose, damaged, functional, IP protection class
Cable	• Strain relief, bend protection, state of the contacts
Plug housing	• Cracks, crushes, discoloured by heat/environment
Plug contacts	• Breakages, fixing
Contact bushings	• State, burn points, stability
Protective conductor contacts	• State, burn points, stability, resilience, transfer resistance to be expected

▶ Inspect the parts with which people can come into contact as follows:

Electrical components	Inspect for the following:
Parts with which people can come into contact	• Are these connected with the protective conductor or are they insulated?
Accessible parts	• State, IP protection class, fixing, operability, designation can be recognised?
Fusing	• Correct fittings?
Lights etc.	• Correct fittings?
Protective equipment	• Correct setting, operability, resetting possibility?

5.1.2 Measurement

Measurement is intended to discover any “internal” defects not detected during the inspection. It is necessary to check whether the performance characteristic limits are met.

Equipment (electrical devices) is divided into the following three protection classes:

Protection class I		The body of the equipment is connected to the protective conductor of the installed device.
Protection class II		Protection against indirect contact is achieved with an additional insulation for basic insulation
Protection class III		Equipment is operated with safety extra-low voltage (< 50 V AC or < 120 V DC)

Source: Prüfung elektrischer Geräte (K. Bödeker, M., Lochthofen, F. Bödeker), 3 ed, Hüthig & Pflaum Verlag, Munich, 2013

Comply with the following information when measuring:

- Identify the protection class of the device. If this cannot be determined from the type plate, try to identify it from the plug form (see table: “Plug forms of different protection classes”).
- Depending on the protection class, select the correct measurement procedure and method. If the protection class is unknown, the tester decides how the device should be tested.
- Before taking the measurement, wait until the test device has reached the ambient temperature.
- Carry out a measurement cable balance on the test device.

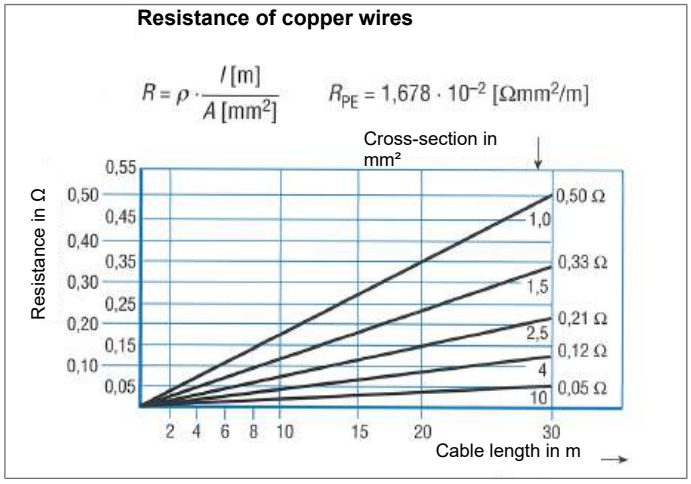
The plug forms of various protection classes

Examples of protection class I	Examples of protection class II
	

Resistance of copper wires of protection class I

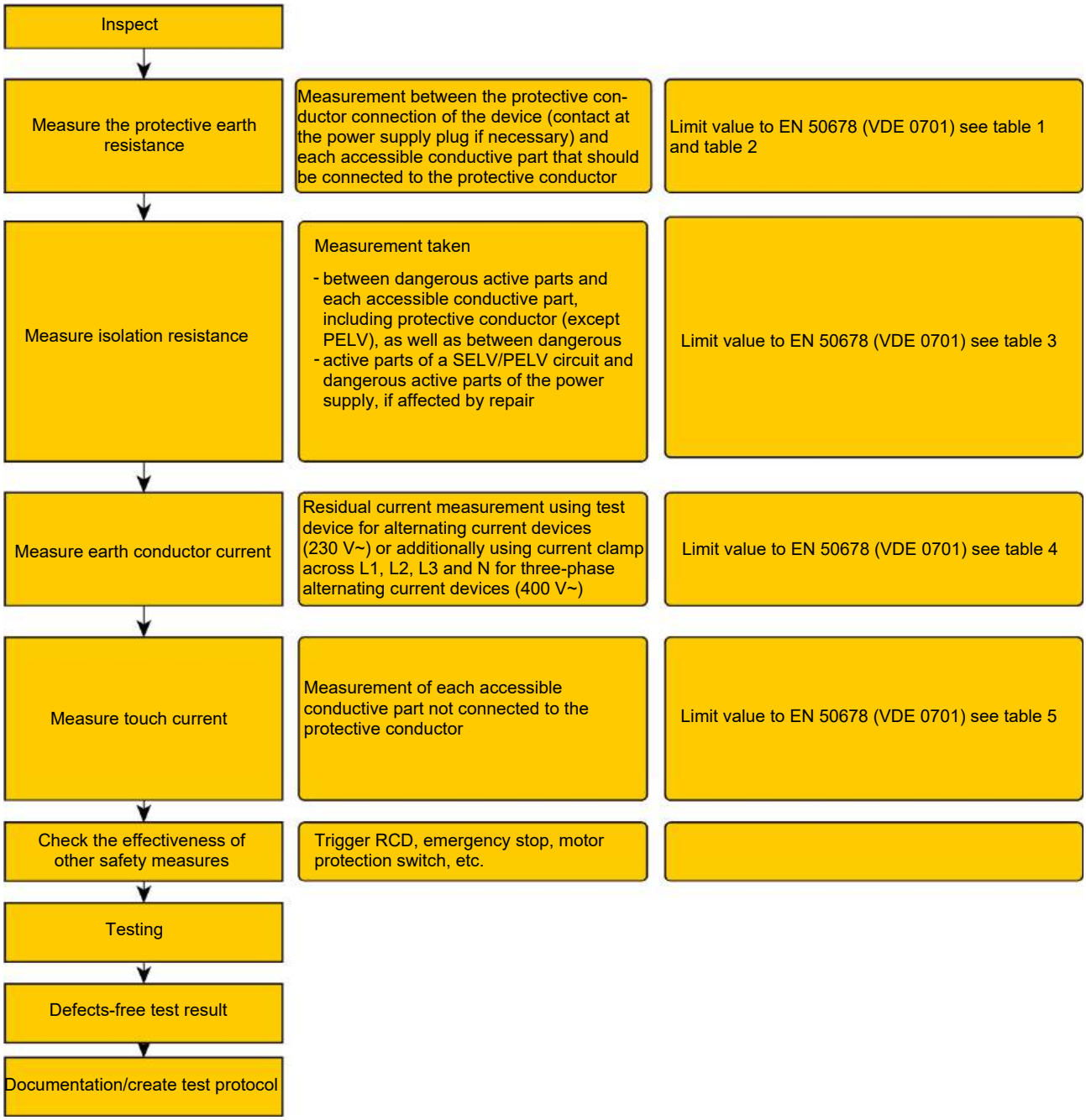
The resistance value to be expected for an intact protective conductor can be worked out using the length by consulting the following diagram.

Resistance of copper wires



Source: Prüfung elektrischer Geräte (K. Bödeker, M., Lochthofen, F. Bödeker), 3 ed, Hüthig & Pflaum Verlag, Munich, 2013

5.1.2.1 Test procedure for devices with a protective conductor: “protection class I”



Measure the protective conductor resistance

Table 1: Limit value for a conductor cross-section of up to 1.5 mm²

Description	Value
up to 5 m connection length	0.3 Ohm
for each additional 7.5 m length plus	+ 0.1 Ohm
permissible maximum value	1.0 Ohm

The limit value for conductor cross-sections above 1.5 mm² is determined with the following formula:

$$R = p\frac{l}{A} + 0{,}1\Omega \quad \text{or} \quad R = \frac{l}{kA} + 0{,}1\Omega$$

R the electrical resistance (Ω)
p the specific resistance ((Ω mm²)/m) for the metal of the protective conductor [Copper, at 20 °C: 0.0178 (Ω mm²)/m]
l the length of the conductor (m)
A the cross-section of the conductor (mm²)
k the electrical conductivity (m/(Ω mm²)) [Copper: 56 m/(Ω mm²)]

PLEASE NOTE: The value of 0.1 Ω in the equation takes into account the influence of the contact resistance.

Table 2: Examples of the protective conductor resistances determined for MELAG devices

Device	Cross-section	Cable length		
		2 m	3 m	3.9 m
Vacuclave 105/305	1.5 mm²	0.3 Ohm	--	--
Vacuclave 118/318		0.3 Ohm	--	--
Vacuclave 123/323		0.3 Ohm	--	--
Vacuclave 118 S/123 S		0.3 Ohm	--	--
SteriHero Beauty/Vet/Speed+		0.3 Ohm	--	--
SteriHero Podo 18 S/Vet 23 S		0.3 Ohm	--	--
Vacuclave 118/318 (200 V)	2 mm²	0.118 Ohm	--	--
MELAtronic 23 (110V)		0.118 Ohm	--	--
Euroklav 29 VS+ (100V)		0.118 Ohm	--	--
Vacuklav 31 B+ (200V)		0.118 Ohm	--	--
MELAtherm 10 DTA	2.5 mm²	--	0.121 Ohm	--
MELAtherm 10 DTB		--	0.121 Ohm	--
MELAtherm 10 Evolution DTA		--	0.121 Ohm	--
MELAtherm 20		--	0.1 Ohm	--
Cliniclave 45/45 D with star connection		--	3.5 m: 0.125 Ohm	--
Vacuquick 13-B / 14-B		0.114 Ohm	--	--
Vacuklav 40 B+/44 B+		0.114 Ohm	--	--
Vacuklav 41 B+/43 B+		0.114 Ohm	--	--
Careclave 618		0.114 Ohm	--	--
Vacuclave 550		0.114 Ohm	--	--
Cliniclave 45 M/MD with star connection	4 mm²	--	--	0.117 Ohm
Cliniclave 45/45 D with delta connection	6 mm²	--	3.5 m: 0.109 Ohm	--
Cliniclave 45 M/MD with delta connection	10 mm²	--	--	0.107 Ohm

Measure insulation resistance

Table 3: Limit value for insulation resistance

Description	Value
Insulation resistance - general information	> 1.0 MOhm
for accessible conductive parts of equipment not connected to PE	> 2.0 MOhm
Devices with heating elements	> 0.3 MOhm
SELV, PELV	> 0.25 MOhm

Measure protective conductor current

MELAG recommends use of the residual current method of measurement.

Table 4: Limit value for protective conductor current

Description	Value
Protective conductor current	< 3.5 mA
Devices with heating elements with power > 3.5 kW	1.0 mA/kW, max. 10 mA

Measure touch current

PLEASE NOTE: Measure the touch current of each accessible (exposed) conductive part of the device that is not connected to the protective conductor (if such parts are present).

Table 5: Limit value for touch current

Description	Value
Touch current	< 0.5 mA

5.1.2.2 Test procedure for devices without a protective conductor, “protection class II”

5.1.3 Testing

The test includes the following functional checks:

- Switch on the device and perform a test run in the Quick-Program.
- Listen for vibrations and running noises.
- If the device is equipped with an automatic switch off function, test it.
- Examine the device for leaks, especially at water-carrying points.
- Check latching of all switch positions.
- Check whether the power plug can be plugged in and unplugged using a normal degree of force.
- Test the residual current device, EMERGENCY OFF button, EMERGENCY STOP button and motor protection test.

Example of safety test 1LT during a functional test

5.2 Recommended test sequence for MELAG alternating current devices with earthed safety plug 230 V~

Test device	Description	Example
Test device to DIN EN 61557-16/ EN 61010 for safety check of alternating current loads to VDE 0701	Protective earth resistance R_{PE} Insulation resistance R_{ISO} Protective conductor current I_{SL} with residual current measurement I_{DIF} or equivalent leakage current measurement I_{EA} (only alternative method) Touch current I_B Power supply voltage and voltage Current and power Integrated automatic fault current tripping > 20 mA	

Test procedure

1. Inspect the device to be tested, see Inspect [▸ page 4].
2. Carry out a measurement cable balance on the test device.
3. Measure the protective earth resistance with a test current of 200 mA of all accessible conductive parts:
   - Connect the device to be tested to the test device.
   - Position the test probe at the measuring points and start the R_{PE} measurement.
   - During the measurement, move the connection cable to identify cable breaks, see Examples for measuring points of one protective earth resistance [▸ page 14].
4. After the protective earth resistance measurement has been passed, switch on the device at the main switch.
5. Start the insulation measurement (R_{ISO} measurement) with 500 V direct voltage at the test device.
6. Perform a functional test, see Testing [▸ page 10].

During the functional test, take the protective conductor current measurement with residual current measurement and touch current measurement as follows:

7. **Protective conductor current measurement with residual current measurement**
   - Start the ID measurement at the test device.
   - Briefly activate all device components using the Diagnosis menu/Diagnosis program.
   Make sure that the heating element does not run dry.
   - Note the highest residual current value.

   PLEASE NOTE: Use the alternative method of protective conductor current measurement (previously “equivalent leakage current method measurement” I_{EA} measurement and device de-energised) only if the insulation resistance lies within the normal range and there are no voltage-dependent switches in the device. Do not use the method of protective conductor current measurement for voltage-dependent switches (e.g. contactors) and switch mode power supply parts in the device. Do not use the direct protective conductor current measurement with current clamp around the PE conductor if, in addition to the protective conductor, the device has a connection to the earth potential, e.g. water connection.
8. **Touch current measurement**
   - With the device switched on, hold the I_B measuring probe at all accessible conductive parts without protective conductor connection (determined in step 3).
   - Document the highest value.
9. Document all measured values and, if possible, enter them in a test protocol, see Documentation [▸ page 16].
10. Option: Fill out the test sticker and stick it onto the device.
11. Sign and save the test protocol.
12. Hand over a copy or printout of the test protocol to the operator.

5.3 Recommended test procedure for MELAG three-phase alternating current devices with CEE plug 400 V~

The following is a list of test devices and adaptors required to perform the electrical test to EN 50678 (VDE 0701) for MELAG three-phase alternating current devices 400 V~ with protection class I.

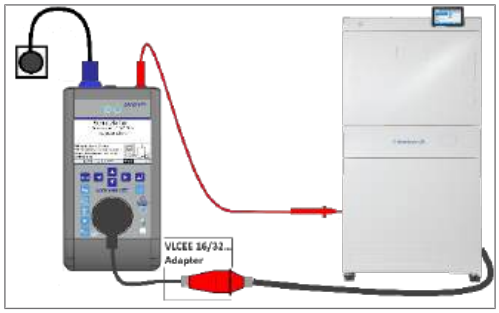
Table 6: Test devices and adapters

No.	Test device/adapter	Description	Example
1	Test device to DIN EN 61557-16/EN 61010	Protective earth resistance R_{PE} Insulation resistance R_{ISO} Protective conductor current I_{SL} with residual current measurement I_{DIF} or equivalent leakage current I_{EA} (only alternative method) Touch current I_B Power supply voltage and voltage Current and power Integrated automatic fault current tripping > 20 mA	
2	Current clamp/residual current clamp	Non-contact measurement of currents and residual current measurement to DIN EN 61557-14 for correct assessment of the harmonics in three-phase alternating current devices	
3	Measuring adapter for three-phase alternating current devices up to 16 A	Measurement of R_{PE}, R_{ISO} and I_{EA} with test device Earthed safety plug 230 V~ on CEE coupling 400 V~/16 A	
4	Measuring adapter for three-phase alternating current devices > 16 A up to 32 A	Measurement of R_{PE}, R_{ISO} and I_{EA} with test device Earthed safety plug 230 V~ on CEE coupling 400 V~/32 A	

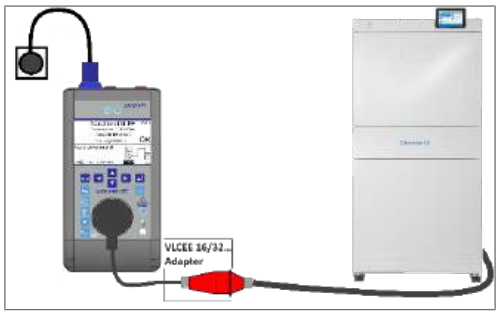
No.	Test device/adapter	Description	Example
5	CEE measuring adapter for three-phase alternating current devices up to 16 A	Measurement of differential, protective conductor and load currents using current clamp. CEE plug 400 V~/16 A on CEE coupling 400 V~/ 16 A, conductors can be tapped individually	
6	CEE measuring adapter for three-phase alternating current devices > 16 A up to 32 A	Measurement of differential, protective conductor and load currents using current clamp. CEE plug 400 V~/32 A on CEE coupling 400 V~/ 32 A, conductors can be tapped individually	

Test procedure

1. Inspect the device to be tested, see Inspect [▸ page 4].
2. Carry out a measurement cable balance on the test device.
3. Measure the protective earth resistance with a test current of 200 mA of all accessible conductive parts:
   - Connect the device to be tested to the test device using the respective measuring adapter (see table “Test devices and adapters”).
   - For permanently connected devices, connect the test device to a socket near the device to be tested.
   - Position the test probe at the measuring points and start the R_{PE} measurement.
   - During the measurement, move the connection cable to identify cable breaks, see Examples for measuring points of one protective earth resistance [▸ page 14].



4. After the protective earth resistance measurement has been passed, switch on the device at the main switch.
5. Start the insulation measurement (R_{ISO} measurement) with 500 V direct voltage at the test device. **PLEASE NOTE:** It is not possible to measure the insulation resistance of permanently connected devices with the test device.

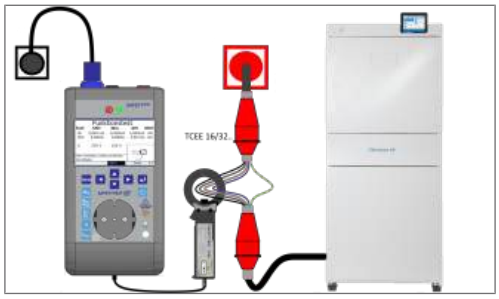


6. **Swapping the measuring adapter**
   - Switch off the device at the main switch.
   - Swap the measuring adapter (see table “Test devices and adapters”).
   - Switch on the device at the main switch.
   - In case of permanently connected devices, prepare all active conductors gripping around with the residual current clamp, either in the device or at the connection socket.
7. If possible, connect the residual current clamp to the test device.
8. Grip around all active conductors (L1, L2, L3 and N) of the device with the residual current clamp.

9. Perform a functional test, see Testing [▸ page 10].

During the functional test, take the protective conductor current measurement with residual current measurement and touch current measurement as follows.

10. **Protective conductor current measurement with residual current measurement**
- Start the ID measurement at the test device.
- Briefly activate all device components using the Diagnosis menu/ Diagnosis program.
Make sure that the heating element does not run dry.
- Note the highest residual current value.



11. **Touch current measurement**
- With the device switched on, hold the I_B measuring probe at all accessible conductive parts without protective conductor connection (determined in step 3).
- Document the highest value.

12. Document all measured values and, if possible, enter them in a test protocol, see Documentation [▸ page 16].

13. Option: Fill out the test sticker and stick it onto the device.

14. Sign and save the test protocol.

15. Hand over a copy or printout of the test protocol to the operator.

5.4 Examples for measuring points of one protective earth resistance

The following overview provides examples of possible measuring pointsfor determining the protective conductor resistance on different types of devices.

Vacuklav 40 B+, 41 B+, 43 B+, 44 B+, incl. *Evolution*
DAC Premium Plus
Vacuklav 40-B, 41-B, 43-B, 44-B
Vacuquick 13-B, 14-B

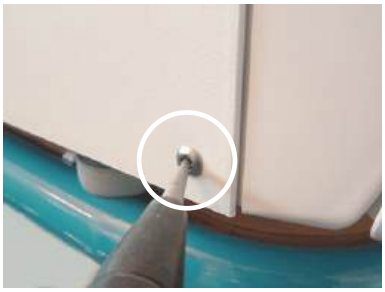
Vacuklav 23 B+, 24 B+, 24 BL+, 30 B+, 31 B+
Vacuvet 23 B+
DAC Professional
Vacuklav 23-B, 24-B, 24-B/L, 30-B, 31-B
Euroklav 23 VS+, 29 VS+, 23 S+
Euroklav 23V-S, 29V-S, 23-S, 29-S

MELAtronic 15 EN+
MELAtronic 15 EN, 17 EN, 23 EN
MELAtronic 15, 17, 23

MELAquick 12+, 12+ p

Cliniclave 45

Cliniklav 25



Careclave 618

Vacuclave 550

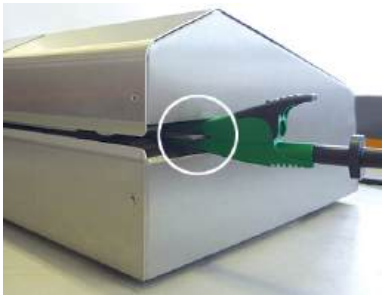
Vacuclave 118/318
Vacuclave 123/323
SteriHero Beauty/Vet

Vacuclave 105/305
SteriHero Speed+

MELAtherm 10 DTA/DTB
MELAtherm 10 Evolution EDTA/EDTB

MELAtherm 20

MELAseal 300



MELAseal Pro

MELAseal 100+, 200
SteriHero Sealer
SiroSeal Professional, Premium

Sterilizer 75, 205, 255

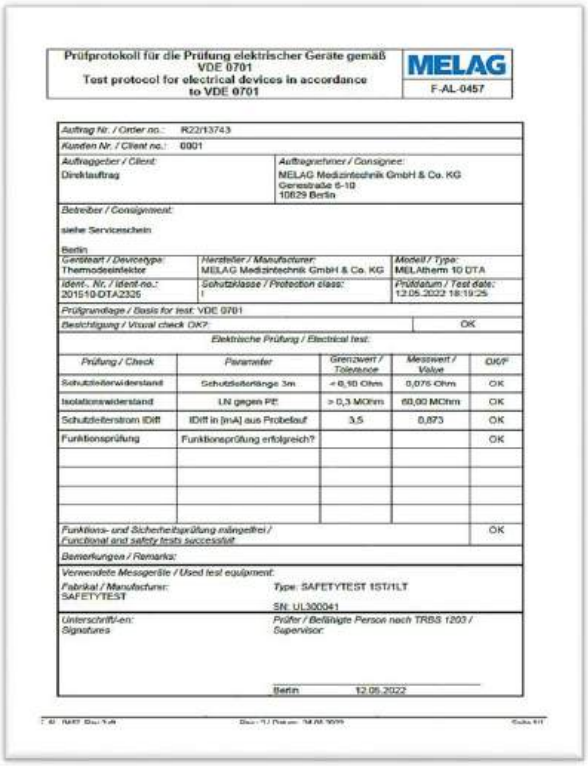
6 Documentation

Test protocol

Document all test results and hand over the results to the operator, e.g. in the form of a test protocol. The test protocol is produced automatically, e.g. by a safety test device. Save the following information in the documentation/test protocol:

- Identification of the tested device (device type, model, ID no.)
- Measured values
- Time and date of the test
- Name of the tester
- Test result
- Test equipment used
- Tester's comments

Sign and save the test protocol. Hand over a copy or a printout to the operator.



Prüfprotokoll für die Prüfung elektrischer Geräte gemäß VDE 0701
Test protocol for electrical devices in accordance to VDE 0701

MELAG F-AL-0457

Auftrag Nr. / Order no.: R22/13743
Kunden Nr. / Client no.: 0001
Auftraggeber / Client: Direktauftrag
Auftragnehmer / Consignee: MELAG Medizintechnik GmbH & Co. KG, Geneststraße 5-10, 10829 Berlin
Betreiber / Consignment: siehe Serviceschein, Berlin
Gerätteart / Devicetype: Thermodesinfektor
Hersteller / Manufacturer: MELAG Medizintechnik GmbH & Co. KG
Modell / Type: MELAtherm 10 DTA
Ident-. Nr. / Ident-no.: 201510-DTA2326
Schutzklasse / Protection class: I
Prüfdatum / Test date: 12.05.2022 18:19:25
Prüfgrundlage / Basis for test: VDE 0701
Besichtigung / Visual check OK?: OK

Elektrische Prüfung / Electrical test:

Prüfung / Check	Parameter	Grenzwert / Tolerance	Messwert / Value	OK/F
Schutzleiterwiderstand	Schutzleiterlänge 3m	< 0,10 Ohm	0,076 Ohm	OK
Isolationswiderstand	LN gegen PE	> 0,3 MOhm	60,00 MOhm	OK
Schutzleiterstrom IDiff	IDiff in [mA] aus Probelauf	3,5	0,873	OK
Funktionsprüfung	Funktionsprüfung erfolgreich?			OK

Funktions- und Sicherheitsprüfung mängelfrei / Functional and safety tests successful: OK
Bemerkungen / Remarks:
Verwendete Messgeräte / Used test equipment:
Fabrikat / Manufacturer: SAFETYTEST
Type: SAFETYTEST 1ST/1LT
SN: UL300041
Unterschrift/-en: Signatures
Prüfer / Befähigte Person nach TRBS 1203 / Supervisor:
Berlin 12.05.2022

Example test protocol

Test sticker

If possible, and if the test is passed, stick a test sticker on the device with marking of the test date.

Example test sticker

Test sticker of the German Berufsgenossenschaft (BG ETEM, available free of charge to members)

MELAG test sticker