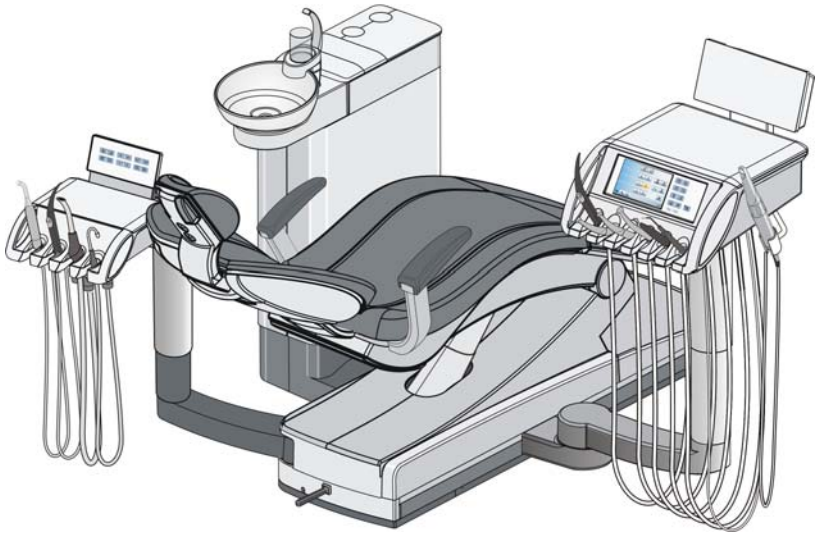
sirona
The Dental Company

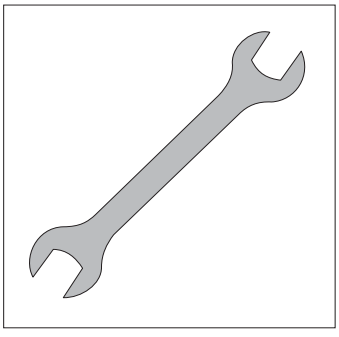
TENEO

Maintenance Manual

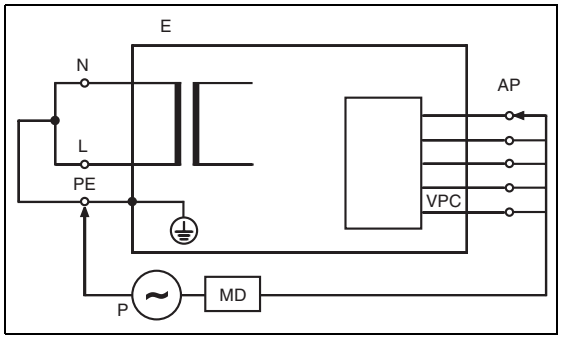
TENEO / D3509	
Model	Serial number

English





Inspection and maintenance



Safety checks

Contents

1 General information

1.1 Purpose of the Maintenance Manual

In order to ensure the operational safety and reliability of the system and to protect the health of patients, users and other persons, inspection and maintenance must be performed at scheduled intervals.

This includes:

- Inspection and maintenance (yearly)
  to prevent damage due to natural wear
- Safety tests (every 2 years)
  to ensure the technical safety of the system

This document describes the work to be performed by the service engineer.
The performance of the work and the measurement results are documented by the service engineer.
This document must be stored near the dental treatment center.

NOTE
*For systems with HF surgical equipment, this **Maintenance Manual** simultaneously serves as a **Medical Product Log**.*

1.2 Work to be performed

By the service engineer:

1. Write the serial number of the dental treatment center (see type label on the base of the patient chair) on the cover sheet and on the corresponding pages (header) of the maintenance log.
2. Complete the “Installation Report / Warranty Passport” after the initial installation and file it after chapter 2.
3. Perform inspection and maintenance according to the maintenance schedule.
   Document the performance of these in the “Installation Report / Warranty Passport".
4. Conduct the safety tests in accordance with chapter 3. Document the results.
5. For systems with HF surgical equipment (see section 4.1), carry out the documentation as specified in sections 4.2 and 4.3.

   Please inform the user of the obligation to carry out points 1 and 2 below.
6. Document comments and special issues regarding the dental treatment center in chapter 5.

By the user:

1. For systems with HF surgical equipment, carry out the documentation as specified in sections 4.2 and4.4 .
2. Document the reporting of incidents to authorities / manufacturers in chapter 5.

2 Installation Report / Warranty Passport

2.1 Master data of the unit

Complete the document **“Installation Report / Warranty Passport”** and file the “Customer Copy” after this page.

Unusual occurrences during installation can be additionally noted on the second page of the “Dealer Copy”.

2.2 Inspection and maintenance

To avoid damage due to natural wear, an inspection must be performed every year.

The dental treatment center automatically recognizes when the regular maintenance is due and indicates this in a timely manner on the user interface. You'll find more detailed information about the maintenance indicator in the user manual.

The steps to be performed as well as the parts which must be replaced are specified in the document **“Maintenance Schedule”**. The performance of these is documented there.

A separate maintenance schedule is produced for each maintenance event.

In addition, list the inspection and maintenance events under the maintenance overview in the **“Installation Report / Warranty Passport”**.

Attachment: Installation Report/Warranty Passport

3 Safety checks

Medical products are designed in such a way that the first occurrence of a fault does not create a hazard to the safety of the patient, the user or other persons. Hence it is important to detect such faults before a second fault occurs, which might then lead to safety hazards.

For that reason it is essential to perform safety tests aimed particularly at detecting electrical faults **every 2 years**. All inspections and measurements are performed by the authorized service engineer. They are specified in the following.

Safety tests are performed on the following occasions:

- **initial startup** (section 3.4)
- **regularly every 2 years**
- **after extensions/upgrades (conversion)** of the treatment center
- **after repair work**

You must document the measured values in section 3.4 and/or 3.5.

CAUTION

When taking measurements, please observe that hazardous voltages might be present on the system under test.

CAUTION

*If the dental treatment center does not pass the safety tests, it must **not** be operated any longer!*
You must advise the user of this fact in your capacity as service engineer. Corresponding repair work by an authorized service engineer is required before putting the system into service again.

NOTE

*The safety checks correspond to the standards **IEC 62353:2007** and/or **VDE 0751-1:2001**.*
If you use an automatic tester, you can program it according to these standards.
– Application components Type BF
– Permanently attached unit
*– Protection Class **I***

The measurements to be performed are complex and time-consuming. Sirona therefore explicitly recommends using an automatic tester.

Measurement according to IEC 60601-1

If you have no possibility of performing the measurements according to VDE 0751-1:2001, you may also perform them according to IEC 60601-1.

For details on how to perform the measurements, please refer to the standard IEC 60601-1 and the documents on your measuring device.

NOTE

*This type of measurement is **not** recommended by Sirona due to its complexity.*

When taking measurements, please observe the following:

Type B application components	Micromotors SL, BL BL ISO or BL implant Turbine Ultrasonic handpiece Curing light Mini-LED Sprayvit
Type BF application parts	HF surgery handpiece SiroCam digital (does not require any testing)
Protective ground wire resistance	$\leq$ 0.1W
Earth leakage current	N.C. – 5 mA S.F.C. – 10 mA (permanent connection)
Patient leakage current	N.C. – 0.1 mA S.F.C. – 0.5 mA

N.C. – normal condition

S.F.C. – single fault condition

When the measurements are performed, the individual treatment instruments must be operated **one after the other**. However, the HF surgical instrument must be measured in an inactive state.
Thus several measurements must be performed one after the other.

Make a note in Section 3.4 or 3.5 stating that you have performed the measurements according to IEC 60601-1 and correct the specified limiting values.

Document the highest measured values.

3.1 Visual inspection

Check the following points:

- Perform a functional test of the dental treatment center in accordance with the operating instructions.
  Are all functions present?
- Are all optical and acoustic warning signals functioning properly?
- Are all housing parts safely attached and intact?
- Are all labels specified in the “Installation Report / Warranty Passport” affixed and legible?
- Are all operating instructions which belong to the treatment center available?
- Is the “Maintenance Manual” for the dental treatment center, which also serves as the Medical Device Log for systems with HF surgical equipment, available?
- In Germany:
  Is the Service Log of the amalgam separator (if applicable) available and properly maintained?
- Are all safety switches functioning?
  - Press a key to move the patient chair, e.g. a program key.
  - While the patient chair is moving, actuate all safety switches one after the other and check whether a corresponding error message appears on the user interface. The positions for triggering the safety switches are shown in the diagram below.
  - Perform the following actions:
    1 - Elevate backrest
    2 - Elevate footrest
    3 - Push rear right and left facing upwards
    4 - Push rear right and left elevation frame upwards
    5 - Push front right and left elevation frame upwards
    6 - Push front right and left manual switch bar on seat support upwards
    7 - Push rear right and left manual switch bar on seat support upwards
    8 - Swivel armrest on the dentist element side outwards
    9 - Push the head of the assistant element and pull it upwards
    10 - Cuspidor bowl (see below for test)

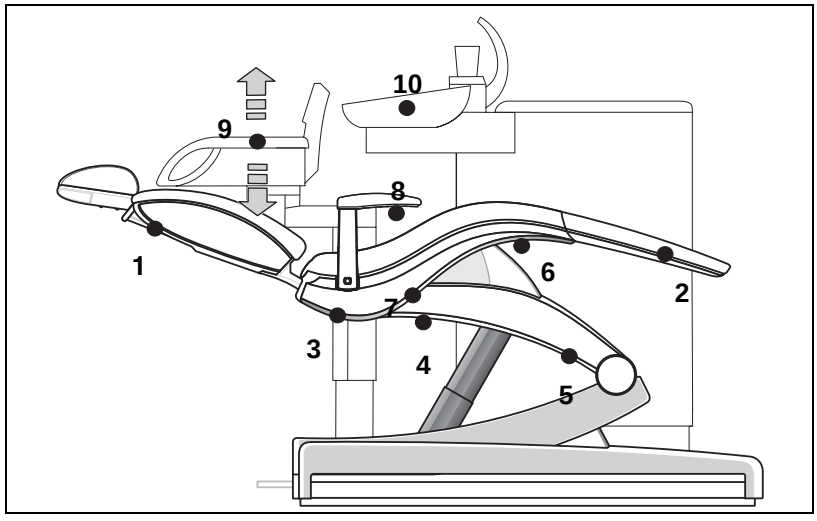


Fig. 3-1 Trigger points for the safety switches

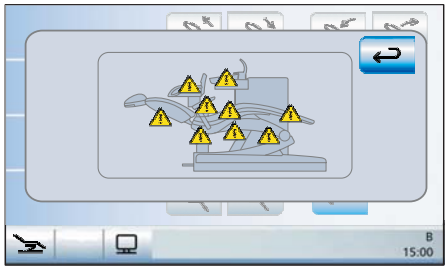


Fig. 3-2 Display on the EasyTouch user interface

– When a safety switch is triggered, the following events occur:
  • an acoustic signal sounds
  • the patient chair stops moving; a corrective movement in the opposite direction may take place.
  • the triggered safety switch is displayed on the user interface of the touchscreen

• Does the safety switch of the cuspidor bowl (10) work?
  – Move the patient chair to the lowest position.
  – Swivel the cuspidor bowl towards the patient chair.
  – Move the patient chair upwards.

  ↳ The chair can be moved.
  However, when the patient chair moves near the cuspidor bowl, the latter swivels inwards.

Test preparations

Before beginning the safety tests described below, carry out the following preparations:

- Move the dental treatment center to a middle height so that the connection box is easily accessible.
- Shut off the mains power connection to the dental treatment center.
- Remove the seat upholstery (leave the backrest upholstery in place).
- Open the cover of the connection box of the patient chair.
- If a PC is connected: Disconnect the power supply of the PC and remove all other connections (e.g. shielded signal cables) which ground the PC.

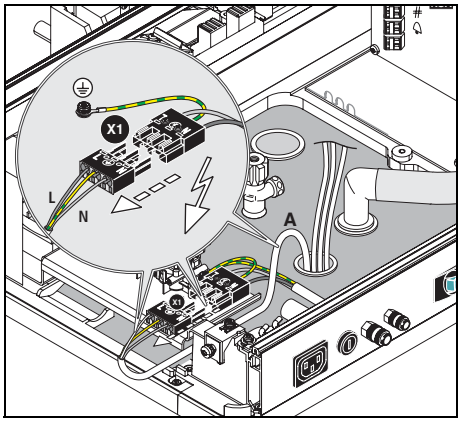


Fig. 3-3 Disconnect the power supply connector.

- Disconnect the power supply connector of the dental treatment center from the building mains (Figure 3-3).

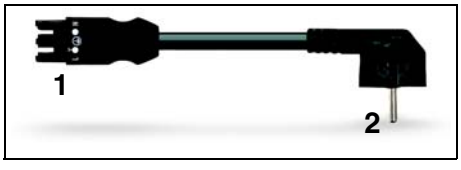


Fig. 3-4 Test cable

- Replace it with the special test connector (1) of the test cable [1] (Figure 3-4).
- Plug the grounded plug (2) into the test unit.

NOTE

If you use an automatic tester, it may be necessary to bring the application components into contact with the unit before the following protective ground wire test. Proceed according to section 3.3.1.

1. You can order the test cable, consisting of the test connector, power cable (2 m) and grounded plug, under Article No. 771-9993/306-201 from WAGO Kontakttechnik GmbH Co. KG, Postfach 2880, 32385 Minden, Germany, www.wago.com.
You can obtain this test cable free of charge when you attend a training session for service engineers.

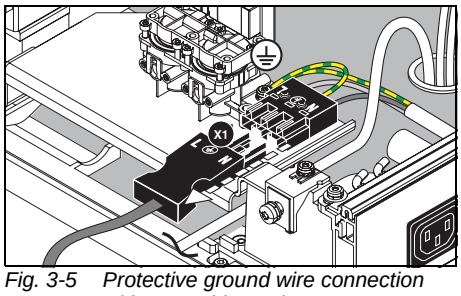


Fig. 3-5 Protective ground wire connection with test cable on the power connection terminal

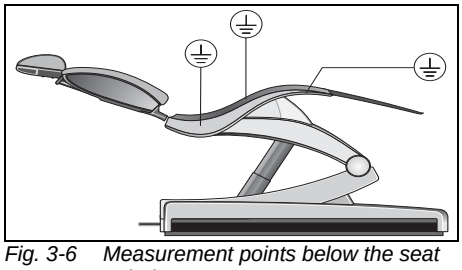


Fig. 3-6 Measurement points below the seat upholstery

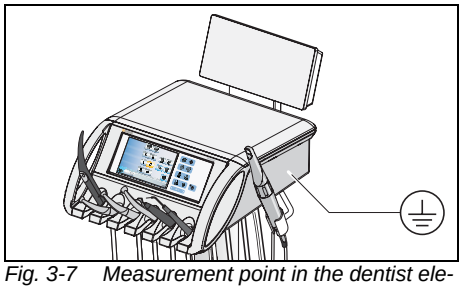


Fig. 3-7 Measurement point in the dentist element

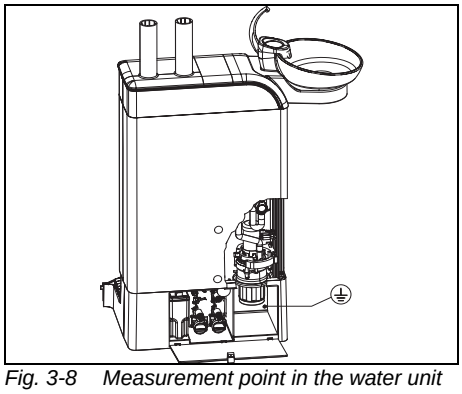


Fig. 3-8 Measurement point in the water unit

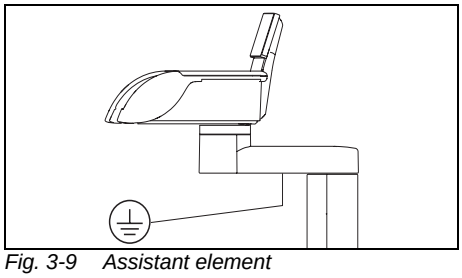


Fig. 3-9 Assistant element

3.2 Protective ground wire test

Before beginning the protective ground wire test, ensure that all protective ground wire connections are present, firmly attached and intact.

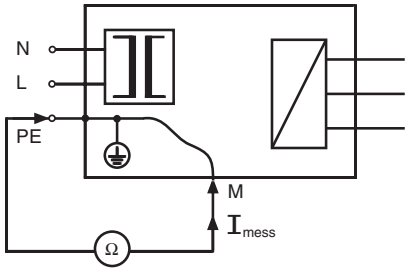
1. Measure the electrical resistance of electrically conductive parts and parts connected to the protective ground wire on the dental treatment center to the protective ground wire connected to the power connection terminal (deduct the resistance of the test cable, Figure 3-5).
   Remove the power supply connector of the PC connected to the dental treatment center and any other network connections that ground the PC.
2. Document the highest measured value.

The measured resistance **must not exceed 0.3** W .

The measuring current (I_{meas}) must be between **0.2 A** and **25 A**.

The no-load voltage must be between **4 V min.** and **24 V max.**

Measurements must be performed in accordance with the following measuring set-up as per IEC 62535:2007 or VDE 0751-1.



NOTE

If you use an automatic tester as specified in IEC 62353 or VDE 0751, the aforementioned parameters are automatically guaranteed. Plug the connector of the test cable into the tester and carry out the measurement in accordance with the operating instructions for the tester.

The following list provides a selection of possible measuring points (M):

- plate in the connection box on which the power supply connection is installed
- plate on the base of the patient chair in which the power switch is installed
- elevation frame and seat support below the seat upholstery (Figure 3-6)
- backrest support (Figure 3-6)
- screw on the underside of the dentist element (Figure 3-7)
- floor plate of the cable foot control
- screw behind the amalgam separator rotor (open cover, Figure 3-8)
- protective ground wire connection of the monitor (if present)
- cold unit plug socket for additional devices (if present)
- assistant element, screw below the transverse arm (Figure 3-9)
- protective ground wire connection of the external PC on dental treatment centers with PCs (PC power plug disconnected)

Document the measuring results obtained during initial startup in section 3.4.

Document the measuring results obtained during re-tests in section 3.5.

3.3 Measurement of equivalent leakage currents

Two different equivalent leakage currents are measured:

- Equivalent device leakage current
- Equivalent patient leakage current

NOTE

Sirona recommends using an automatic tester that complies with standard IEC 62353:2007 or VDE 0751 to perform the measurements.
If you do not use an automatic tester, please comply with the instructions on page 13.

Use of the VPC measuring point

NOTE

The equivalent leakage current measurements also include the applied parts (treatment instruments).
Since the treatment center is in a non-operating state, the motors of the treatment instruments, their supply cables and lamps are disconnected via relays and therefore not connected to the potential of the patient circuit.
Thus, under the circumstances insulation defects in the patient circuit may not be detected.
The following measurements are therefore also measured against the potential of the patient circuit (measuring point in the voltage patient circuit [VPC]).
This circuit is treated like an application component.

The VPC measurement point is located in the head of the dentist element.
Proceed as follows to establish contact:

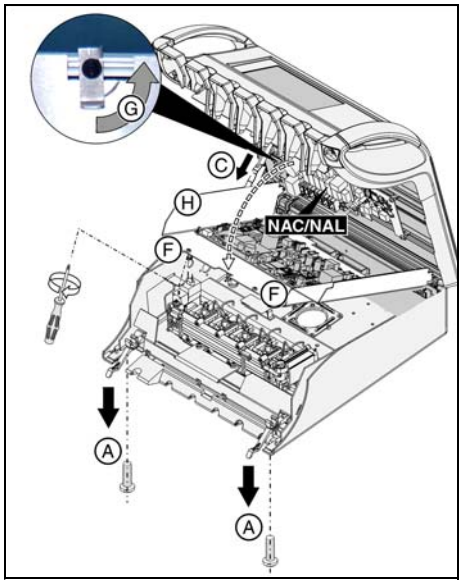


Fig. 3-10 Opened dentist element

1. Open the dentist element by flipping the two locking brackets (A) downwards and removing the two screws with a screwdriver (Figure 3-10).
2. Flip the cover of the dentist element head with the instrument holder upwards and secure the housing cover with pin **C**. The instruments remain in the holder.
3. Remove the two screws (F) on the cover plate.
4. Flip the locking bracket **(G)** upwards.
5. Now fold the plate **(H)** downwards.
6. Attach the test terminal to the VPC measuring point (see Figure 3-11, 3-12).
7. The VPC measuring point is located on the upper board.
8. Connect the test terminal to the tester like an application component.

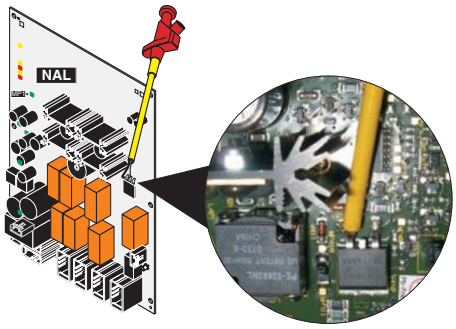


Fig. 3-11 NAL board - V 410, pin 3

VPC measuring point on the SL motor:

NAL board - pin 3 of V 410

or

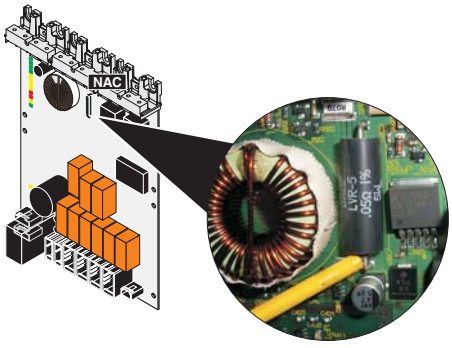


Fig. 3-12 NAC board - R533

VPC measuring point on the BL, BL ISO, BL Implant motors

NAC board - R533

Measurement without an automatic tester

If you're using an automatic tester, you can skip this page 13 and 14 .

Test conditions

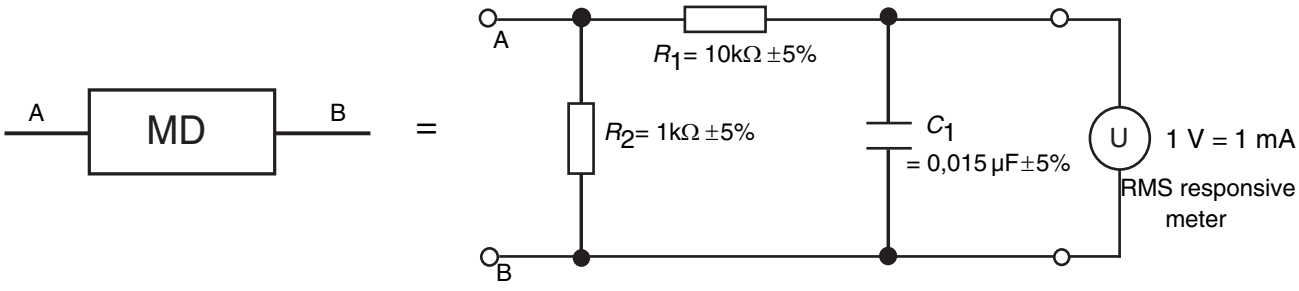
If you are not using an automatic tester, please comply with the following specifications:

You need a high-resistance, power-frequency, sinusoidal measuring voltage source for the measurements. The no-load voltage corresponds to the nominal mains voltage.

The short-circuit current **must not exceed 3.5 mA** (protection of persons).

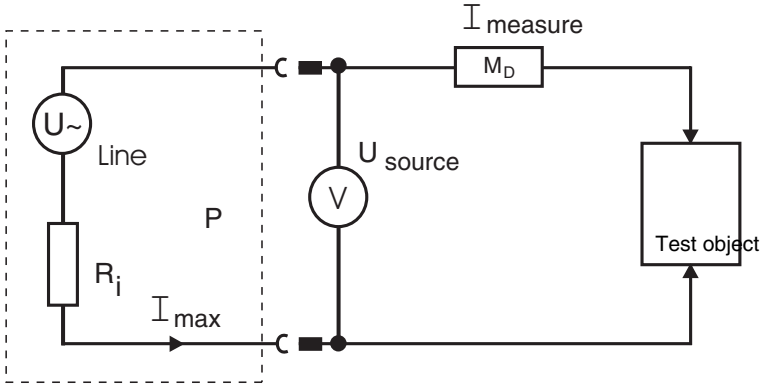
Since equivalent leakage currents of up to 10mA are permissible, the voltage of the measuring voltage source must also be monitored during the measurements, and the leakage current must be extrapolated to the nominal line voltage. Please pay attention to the following examples.

Measurements must be performed with the following circuitry in accordance with IEC 62353:0751 or VDE 1-1



R_1, R_2, C_1: Noninductive components

Extrapolating the leakage current for the nominal line voltage



U_{Line} – Line voltage

R_i – Internal resistance of measuring voltage source

P – Power-frequency measuring voltage source

U_{source} – Measured source voltage

I_{max} – Maximum measuring current 3.5mA

$I_{measure}$ – Measured current

I_{leak} – Leakage current of test object

Example:

U_{line} = 230V AC, I_{max} = 3.5 mA

R_i = 230V / 3.5 mA = 65.71 kW

Selected: R_i = 68 kW

Case 1:

Measured:

U_{source} = 162V, $I_{measure}$ = 1mA

Leakage current:

I_{leak} = 230 V / 162 V = 1.42 x 1 mA = 1.42 mA ⇨ O. K.

Case 2:

Measured:

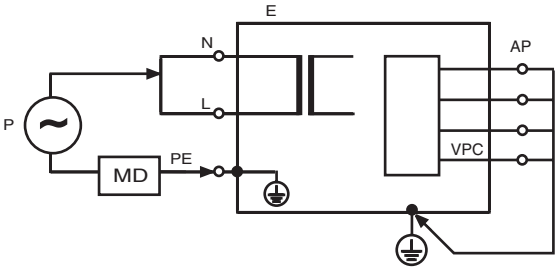
U_{source} = 26V, $I_{measure}$ = 3mA

Leakage current:

I_{leak} = 230 V / 26 V = 8.85 x 3 mA = 26.55 mA ⇨ Error

3.3.1 Equivalent device leakage current

Measurements must be performed in accordance with the following measuring set-up as per IEC 62353 or VDE 0751-1



→	–	Connections of measuring device
L, N	–	Phase, neutral conductor on mains terminal
PE	–	Protective ground wire on mains terminal
P	–	Power-frequency measuring voltage source
E	–	Accessible conductive parts (housing) at protective ground potential
VPC	–	Measuring point (potential of patient circuit)
AP	–	Application components

The dental treatment center is disconnected from all pins of the main power supply.

The power switch at the base of the patient chair must be switched **ON**.

CAUTION

*The measured leakage current **must not exceed 10 mA**.*

CAUTION

If the measured value deviates considerably from the one obtained during the first measurement (see section 3.4), find the cause and correct the problem if necessary.

With automatic tester

Fig. 3-13 Sprayvit contacting

Fig. 3-14 Establishing contact to the heating cartridge

1. Using measuring cables, connect all metallic application components and the VPC measuring point with the tester connections provided.

- Sprayvit heating cartridge on the dentist and assistant side
  1. Pull off the sheaths of the Sprayvit.
  2. Attach a test terminal to the heating cartridge
  (Figures 3-13 and 3-14)
- Housing of the SL, BL, BL ISO, BL Implant micromotors
- Turbine housing
- Tip of the US handpiece
- Tip of the HF surgery handpiece
- MiniL.E.D curing light housing
- VPC measuring point on NAL or NAC board
  contacting VPC, see section 3.3, Fig. 3-11 or Fig. 3-12.

NOTE

The camera is not tested.

2. Connect the power supply connector of the test cable with the tester.

3. Program the tester for the following conditions:
- Type BF application components
- Permanently attached unit
- Protection class **I**

NOTE

Make sure that the tester is programmed for a permanent connection (and not for 1 mA) (a 10 mA leakage current is permissible).

4. Perform the measurements according to the operating instructions of the tester.

NOTE

All cables remain on the tester for the measurement of the replacement patient circuit (see section 3.3.2).

Document the value measured during initial startup in Section 3.4.
Document the values measured during re-tests in Section 3.5.

Without automatic tester

Fig. 3-15 Sprayvit contacting

Fig. 3-16 Establishing contact to the heating cartridge

Fig. 3-17 Establishing contact of the application components to the protective ground wire

1. Using measuring cables, connect all metallic application components and the VPC measuring point with the protective ground wire (Figure 3.17).

   – Sprayvit heating cartridge on the dentist and assistant side
     1. Pull off the sheaths of the Sprayvit
     2. Attach a test terminal to the heating cartridge
     (Figures 3.15 and 3.16)
   – SL, BL, BL ISO, BL Implant micromotor housing
   – Turbine housing
   – Tip of the US handpiece
   – Tip of the HF surgery handpiece
   – MiniL.E.D curing light housing
   – VPC measuring point on NAL or NAC board
     To establish contact with the VPC, see section 3.3, Fig. 3-11 or Fig. 3-12

NOTE

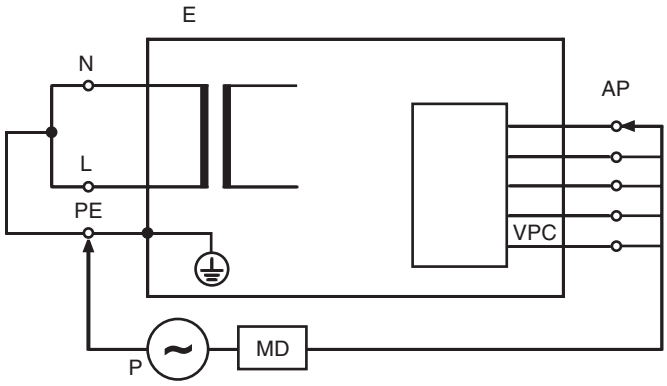
The camera is not tested.

2. Insert the measuring device between the short-circuited mains connections (L and N) and the protective ground wire (PE) connection of the mains terminal.
3. Measure the current flowing across the insulation and MD (1 V = 1 mA).
4. Remove the connections to the protective ground wire after taking this measurement.
5. Calculate the leakage current as described on page 13.

Document the value measured during initial startup in Section 3.4.
Document the values measured during re-tests in Section 3.5.

3.3.2 Equivalent patient leakage current

The following measuring set-up according to IEC 62353 or VDE 0751-1.



→ – Connections of measuring device
L, N – Phase, neutral conductor on mains terminal
PE – Protective ground wire on mains terminal
P – Power-frequency measuring voltage source
E – Accessible conductive parts (housing) at protective ground potential
VPC – Measuring point (potential of patient circuit)
AP – -Applied parts (type BF)

The dental treatment center is disconnected from all pins of the main power supply.
The power switch at the base of the patient chair must be switched **ON**.

CAUTION
*The measured leakage current **must not exceed 5 mA**.*

CAUTION
If the measured value deviates considerably from the one obtained during the first measurement (see section 3.4), find the cause and correct the problem if necessary.

With automatic tester

- The application components, VPC measurement point and the power supply connector of the test cable are already connected to the tester as described in section 3.3.1 "With automatic tester" ..

▶ Perform the measurements according to the operating instructions of the tester.

Document the value measured during initial startup in Section 3.4.
Document the values measured during re-tests in Section 3.5.

Without automatic tester

1. Connect the short-circuited mains wires (L and N) to the protective ground wire (PE).
2. **Successively** connect the test device between PE and the different metal application components. Applied metal parts include:
   - The Sprayvit heating cartridge on the dentist and assistant element side
   - Housing of the SL, BL, BL ISO, BL Implant micromotors
   - Turbine housing
   - Tip of the US handpiece
   - Tip of the surgical handpiece
   - Mini-LED curing light housing
   - VPC measuring point on the NAL/NAC board (see Section 3.3)

3. Measure the current flowing across the insulation and MD (1 V = 1 mA).
4. Calculate the maximum leakage current as described on page13.

Document the values measured during initial startup in Section 3.4.
Document the values measured during re-tests in Section 3.5.

3.3.3 Final work

The safety checks have now been completed!

- Remove the measuring equipment.
- Reattach all covers to the dentist element and close the cover.
- Plug in the power supply connector again.
- Close the connection box cover.
- Switch on the current of the building mains again.
- Complete the documentation.

3.4 Safety check (Initial test after initial startup)

The values measured during initial startup are documented so that they can be compared with the values measured during the re-tests.

Visual inspection	**Protective ground wire resistance (≤ 0.3 W)**	**Equivalent device leakage current (≤ 10 mA)**	**Equivalent patient leakage current (≤ 5 mA)**	**Safety maintained?**
☐ OK ☐ Faults	W	mA	mA	☐ yes ☐ no
Remarks / Particularities:				

Date	**Name of engineer**	**Depot**	**Signature**

3.5 Safety check (re-tests)

The results of the re-tests are documented on these forms.

Visual inspection	Protective ground wire resistance (≤ 0.3 W)	Equivalent device leakage current (≤ 10 mA)	Equivalent patient leakage current (≤ 5 mA)	Safety maintained?
☐ OK ☐ Faults	W	mA	mA	☐ yes ☐ no
Remarks / Particularities:				
Date	**Name of engineer**	**Depot**		**Signature**

Visual inspection	Protective ground wire resistance (≤ 0.3 W)	Equivalent device leakage current (≤ 10 mA)	Equivalent patient leakage current (≤ 5 mA)	Safety maintained?
☐ OK ☐ Faults	W	mA	mA	☐ yes ☐ no
Remarks / Particularities:				
Date	**Name of engineer**	**Depot**		**Signature**

Model	TENEO / D 3509	Serial number	

3 Safety checks

Visual inspection	Protective ground wire resistance (≤ 0.3 W)	Equivalent device leakage current (≤ 10 mA)	Equivalent patient leakage current (≤ 5 mA)	Safety maintained?
☐ OK ☐ Faults	W	mA	mA	☐ yes ☐ no
Remarks / Particularities:				
Date	**Name of engineer**	**Depot**		**Signature**

Visual inspection	Protective ground wire resistance (≤ 0.3 W)	Equivalent device leakage current (≤ 10 mA)	Equivalent patient leakage current (≤ 5 mA)	Safety maintained?
☐ OK ☐ Faults	W	mA	mA	☐ yes ☐ no
Remarks / Particularities:				
Date	**Name of engineer**	**Depot**		**Signature**

Visual inspection	Protective ground wire resistance (≤ 0.3 W)	Equivalent device leakage current (≤ 10 mA)	Equivalent patient leakage current (≤ 5 mA)	Safety maintained?
☐ OK ☐ Faults	W	mA	mA	☐ yes ☐ no
Remarks / Particularities:				
Date	**Name of engineer**	**Depot**		**Signature**

Model	TENEO / D 3509	Serial number	

3 Safety checks

Visual inspection	Protective ground wire resistance (≤ 0.3 W)	Equivalent device leakage current (≤ 10 mA)	Equivalent patient leak-age current (≤ 5 mA)	Safety maintained?
☐ OK ☐ Faults	W	mA	mA	☐ yes ☐ no
Remarks / Particularities:				
Date	**Name of engineer**	**Depot**		**Signature**

Visual inspection	Protective ground wire resistance (≤ 0.3 W)	Equivalent device leakage current (≤ 10 mA)	Equivalent patient leak-age current (≤ 5 mA)	Safety maintained?
☐ OK ☐ Faults	W	mA	mA	☐ yes ☐ no
Remarks / Particularities:				
Date	**Name of engineer**	**Depot**		**Signature**

Visual inspection	Protective ground wire resistance (≤ 0.3 W)	Equivalent device leakage current (≤ 10 mA)	Equivalent patient leak-age current (≤ 5 mA)	Safety maintained?
☐ OK ☐ Faults	W	mA	mA	☐ yes ☐ no
Remarks / Particularities:				
Date	**Name of engineer**	**Depot**		**Signature**

Model	TENEO / D 3509	Serial number	

3 Safety checks

Visual inspection	**Protective ground wire resistance (≤ 0.3 W)**	**Equivalent device leakage current (≤ 10 mA)**	**Equivalent patient leakage current (≤ 5 mA)**	**Safety maintained?**
☐ OK ☐ Faults	W	mA	mA	☐ yes ☐ no

Remarks / Particularities:

Date	**Name of engineer**	**Depot**	**Signature**

Visual inspection	**Protective ground wire resistance (≤ 0.3 W)**	**Equivalent device leakage current (≤ 10 mA)**	**Equivalent patient leakage current (≤ 5 mA)**	**Safety maintained?**
☐ OK ☐ Faults	W	mA	mA	☐ yes ☐ no

Remarks / Particularities:

Date	**Name of engineer**	**Depot**	**Signature**

Visual inspection	**Protective ground wire resistance (≤ 0.3 W)**	**Equivalent device leakage current (≤ 10 mA)**	**Equivalent patient leakage current (≤ 5 mA)**	**Safety maintained?**
☐ OK ☐ Faults	W	mA	mA	☐ yes ☐ no

Remarks / Particularities:

Date	**Name of engineer**	**Depot**	**Signature**

4 Treatment centers with HF surgical equipment

4.1 General information

In Germany, medical equipment is subject to the provisions of the Ordinance on the Installation, Operation and Use of Medical Equipment (Medizinprodukte-Betreiberverordnung – MPBetreibV) of June 29, 1998.

According to Section 6, safety tests are required for systems with HF surgical equipment.

According to Section 7, a “Medical Product Log” must be kept, in which the measured values as well as the tests conducted must be documented.

These tests for systems with HF surgical equipment are identical to the safety tests described in chapter 3.

They must be performed **every 2 years**.

The **Maintenance Manual** thus simultaneously acts as **Medical Product Log**.

The system owner is obliged to keep this Medical Product Log.

Upon request, the Medical Product Log must be made available to the competent authority for inspection purposes at any time.

The Medical Product Log must be safekept for a period of at least 5 years after putting the system out of service.

In order to comply with the provisions of the Ordinance on the Installation, Operation and Use of Medical Devices (MPBetreibV), the following documentation must be maintained for dental treatment centers with HF surgical equipment in Germany:

By the service engineer:

- Safety tests conducted (see chapter 3)
- Repair work performed on the HF module (see section 4.3)
- Personnel who have been trained in the use of the HF surgical equipment according to Section 5 of the MPBetreibV (see section 4.2)

By the user (system owner):

- Personnel who have been trained in the use of the HF surgical equipment according to Section 5 of the MPBetreibV (see section 4.2)
- Effects of malfunctions and repeated, similar operator errors (see section 4.4)
- Reporting of incidents to authorities and manufacturers (see chapter 5)

NOTE

As a system user outside of Germany, you must observe the legal requirements of your country.

4 Treatment centers with HF surgical equipment

4.2 List of trained personnel

The treatment center with HF surgical equipment must be operated only by personnel who have been trained in its use by the manufacturer or supplier. Trained personnel may train other personnel.

The relevant trainings are documented in the table below.

Date	Name, trainer	Depot	Signature	Name, person trained	Signature

4.3 Repair work on the HF module

Repair work on the HF module must be performed by authorized service engineers only. After repair, a safety test must be performed and documented in section 3.5.

The nature of the repair measures must be documented below.

Description of the repair work performed:				
Date	**Name of engineer**	**Depot / performing agency**	**Safety test passed?**	**Signature**
			☐ yes	

Description of the repair work performed:				
Date	**Name of engineer**	**Depot / performing agency**	**Safety test passed?**	**Signature**
			☐ yes	

Description of the repair work performed:				
Date	**Name of engineer**	**Depot / performing agency**	**Safety test passed?**	**Signature**
			☐ yes	

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Description of the repair work performed:				
Date	**Name of engineer**	**Depot / performing agency**	**Safety test passed?**	**Signature**
			☐ yes	

Description of the repair work performed:				
Date	**Name of engineer**	**Depot / performing agency**	**Safety test passed?**	**Signature**
			☐ yes	

Description of the repair work performed:				
Date	**Name of engineer**	**Depot / performing agency**	**Safety test passed?**	**Signature**
			☐ yes	

4.4 Effects of malfunctions and repeated, similar operator errors on the HF module

The nature and effects of malfunctions and repeated, similar operator errors must be documented here **by the user**.

NOTE

In addition, please comply with the obligation to report incidents according to chapter 5.

Type of fault:		
Date	**Name of operator**	**Signature**

Type of fault:		
Date	**Name of operator**	**Signature**

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Type of fault:		
Date	**Name of operator**	**Signature**

Type of fault:		
Date	**Name of operator**	**Signature**

Type of fault:		
Date	**Name of operator**	**Signature**

Type of fault:		
Date	**Name of operator**	**Signature**

5 Reporting of incidents to authorities / manufacturers

Incidents which have led or might have led to the death or a serious deterioration in the state of health of a patient, user or other person must be immediately reported **by the user** to the competent authority (according to Section 3 of the MPBetreibV).

In addition, reports to the manufacturer can be documented here as well. These reports must be documented below.

Description of incident:		
Report submitted to:		
Date	**Name**	**Signature**

Description of incident:		
Report submitted to:		
Date	**Name**	**Signature**

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5 Reporting of incidents to authorities / manufacturers

Description of incident:		
Report submitted to:		
Date	**Name**	**Signature**

Description of incident:		
Report submitted to:		
Date	**Name**	**Signature**

6 Remarks / special issues with regard to the dental treatment center

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6 Remarks / special issues with regard to the dental treatment center

We reserve the right to make any alterations which may be required due to technical improvements.

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