New since: 11.2004

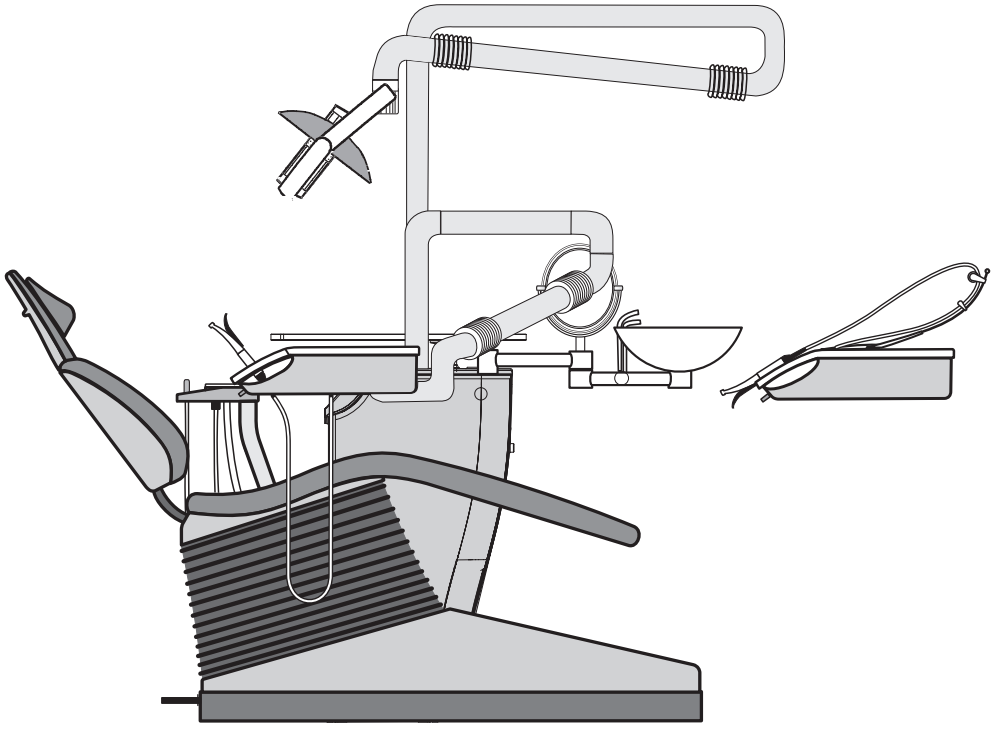
sirona
The Dental Company

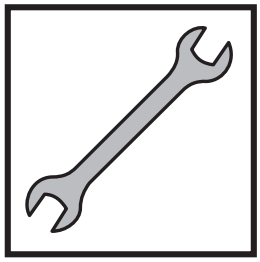
ProFeel+

Maintenance Manual

ProFeel+	
Model	Serial number Chair

English





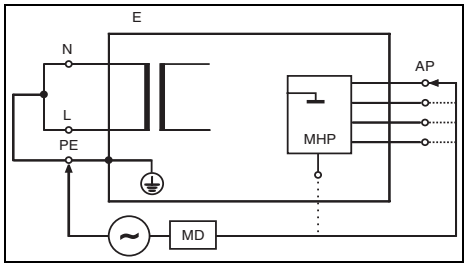


Table of Contents

1 General information

1.1 Purpose of the Maintenance Manual

In order to guarantee 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 predetermined 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.
Its realization and the measurement results are documented by the service engineer.
This document must be stored near the treatment center.

1.2 Work to be performed

By the service engineer:

1. Note the model and the serial number of the chair on the title page and the relevant pages (headers) of the Maintenance Manual.
2. Complete the “Installation Report / Warranty Passport” and file it after chapter 2.
3. Perform inspection and maintenance according to the Maintenance Certificate.
   Document their implementation in the “Installation Report / Warranty Passport".
4. Conduct the safety tests in accordance with chapter 3. Document the results.

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 noted down in addition 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 steps to be performed as well as the parts which must be replaced are specified in the document **"Maintenance Certificate"**. Their realization is documented there.

A separate Maintenance Certificate is produced for each maintenance event.

List the inspection and maintenance events also 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 start-up** (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 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 tests are in compliance with the standard **VDE 0751-1:2001***. It you use an automatic tester, you can program it according to this standard.*

- Type BF applied parts
- Permanently installed unit
- Protection class **I**
- The auxiliary measuring point (see 3.3) is treated like an applied part.

Sirona 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 applied parts	Micromotor Highspeed handpiece Ultrasound handpieces Polylight Sprayvit: no measurement necessarily ProSmile: no measurement necessarily
Type BF applied parts	Sirocam 3 Sirocam C: no measurement necessarily
Protective ground wire resistance	≤ 0.1 Ω
Earth leakage current	N.C. – 5mA S.F.C. – 10mA (permanent connection)
Patient leakage current	N.C. – 0.1mA S.F.C. – 0.5mA

NC. – normal condition

S.F.C. – single fault condition

During the measurements, the individual dental instruments **must be** operated **one after the other**.
Several measurements in succession may be required.

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 treatment center in accordance with the operating instructions.
  Are all functions present?
- Are all optical and acoustic warning signals functioning properly?
- Are all safety switches functioning?
- Are all housing parts safely attached and intact?
- Are all protective ground wire connections present, properly attached and intact?
- Does the treatment center have the right main fuse (1)? To check this, unscrew fuse and compare it to the label next to it.
- Are all labels according to the “Installation Report / Warranty Passport” affixed and legible?
- Are all operating instructions which belong to the treatment center available?
- In Germany:
  Is the Service Logbook of the amalgam separator (if applicable) available?

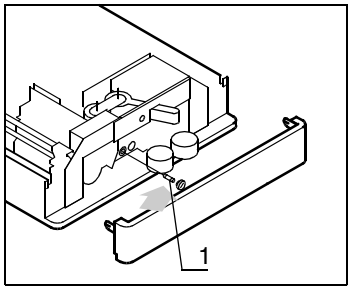


Fig. 3-1 Main fuse, chair

Test preparations

Before beginning with the tests described below, make the following preparations:

- The treatment center must be de-energized by means of the building installation
- For a video system connected to a PC:Pull the power plug of the PCs
- Open the cover of the connection box in the chair
- Disconnect all poles of the power connection (except protective ground wire PE) at the connection terminal

3.2 Protective ground wire test ProFeel+

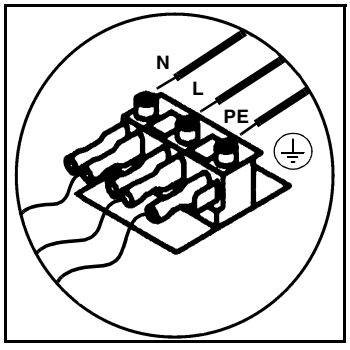


Fig. 3-2 Mains terminal

1. Measure the electrical resistance of electrically conductive parts connected to the protective ground wire on the treatment center against the protective ground wire on the mains terminal. When doing this, disconnect the power plug of the PC (with a video system).
2. Document the highest measured value.

The measured resistance must **not** exceed **0.3** Ω

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

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

The following measuring setup according to VDE 0751-1:2001 is used:

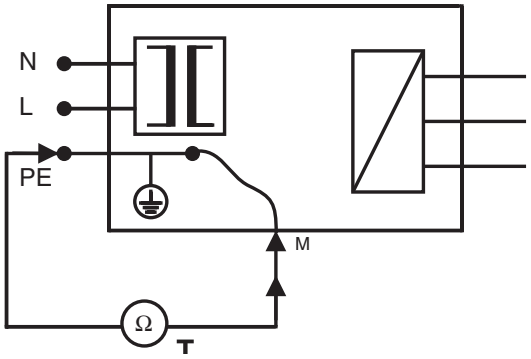


Fig. 3-3 Protective ground wire resistance measurement

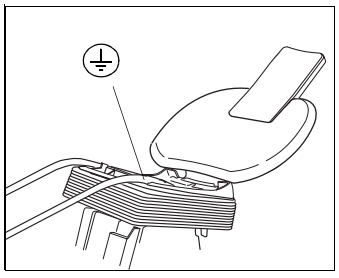


Fig. 3-4 Seat frame of chair

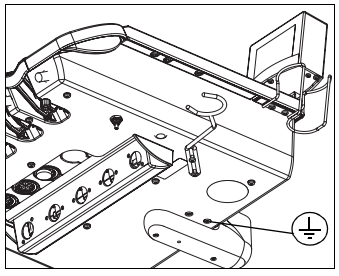


Fig. 3-5 Dentist element

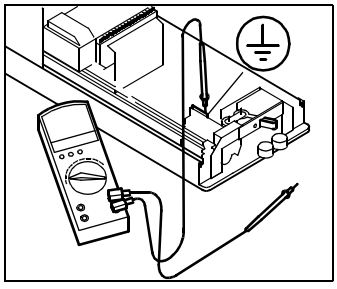


Fig. 3-6 Location of mains terminal
US version: Remove front sheet metal cover

The following list provides a selection of possible measuring points (M) if they are present on the treatment center:

Protective ground wire on the mains terminal against:

- Seat frame of the dental chair
- US version: sheet metal cover above the mains terminal
- Screw on the bottom of the dentist element
- Chassis of the water unit
- Connecting the protective ground wire of the monitor
- Protective ground wire connection of external PC on treatment centers with video system (PC power plug pulled)
- Foot switch of ProFeel+ – bottom and pedal
- Inlet connector for additional devices

NOTE

Support arm of the cuspidor do not measure.

Document the highest measured value obtained during initial start-up in section 3.4.

Document the highest measured value obtained during re-tests in section 3.5.

3.3 Measurement of equivalent leakage currents

Two different equivalent leakage currents are measured:

- Equivalent unit leakage current
- Equivalent patient leakage current

You need a high-resistance, power-frequency, sinusoidal measuring voltage source for the measurements. The no-load voltage corresponds to the nominal line 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 from the nominal line voltage. If you are not using an automatic tester, see the example on page 13.

The following measuring setup according to VDE 0751-1:2001 is used:

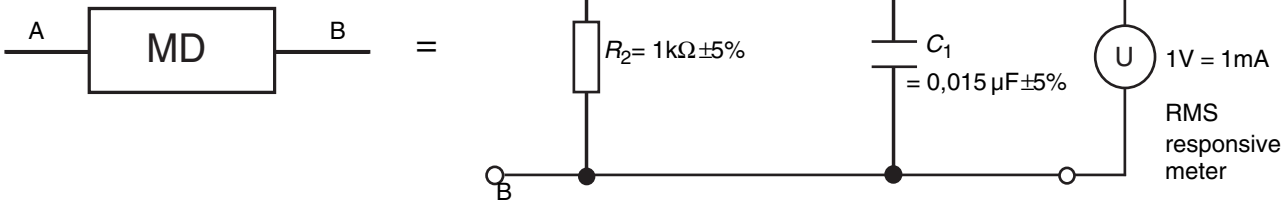


Fig. 3-7 Measuring setup (MD = measuring device)

R_1, R_2, C_1: Non inductive components

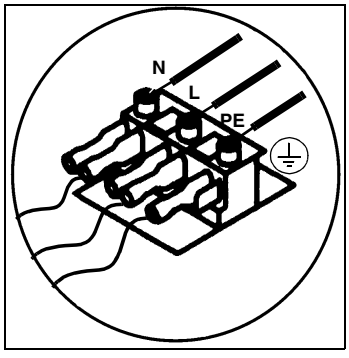


Fig. 3-8 Mains terminal

NOTE

The equivalent leakage current measurements also include the applied parts (dental instruments).
Since the treatment center is in a non-operating state, e.g. the motors of the dental instruments and their supply cables are disconnected by relays and therefore not connected to the potential of the patient circuit.
Hence, faults in the applied parts may not be detected.
For this reason, measurements against an auxiliary measuring point (MHP) in the connection box of the chair also performed during the following tests. It lies on the potential of the patient circuit. It is treated like an applied part.

This measurement on the MHP is possible only if the second transformer for the power supply of the electric dental instruments is built-in.

The MHP is located in the connection box of the chair (see Fig. 3-9).

The MHP is fuse F1 on board SF (REF 54 47 573).
This board is mounted on transformer T2.

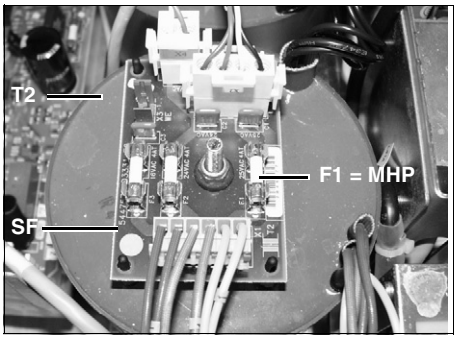


Fig. 3-9 MHP C8+

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

Extrapolating the leakage current for the nominal line voltage

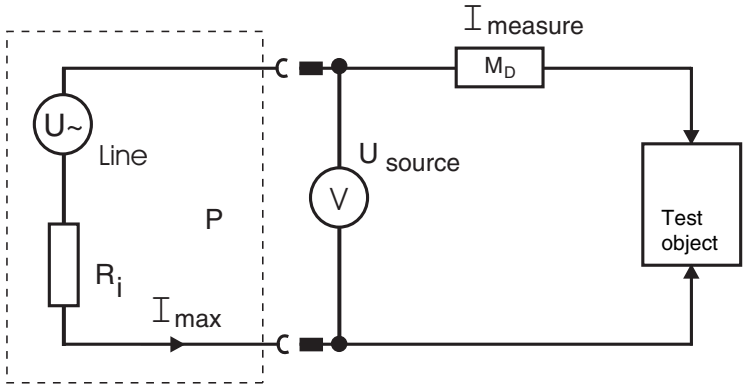


Fig. 3-10 Measuring voltage source

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 kΩ

Selected: R_i = 68 kΩ

Case 1: Measured:

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

Leakage current:

I_{leak} = 230V / 162V = 1.42 x 1mA = 1.42mA

Case 2: Measured:

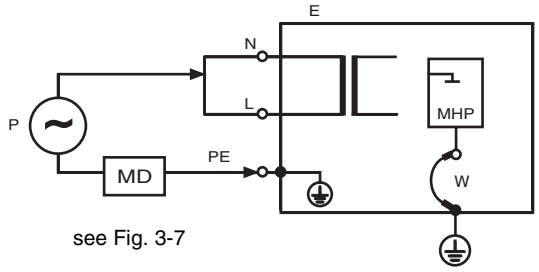
U_{source} = 26V, $I_{measure}$ = 3mA

Leakage current:

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

3.3.1 Equivalent unit leakage current

The following measuring setup according to VDE 0751-1:2001 is used:



see Fig. 3-7

→ – 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
MHP – Auxiliary measuring point (potential of patient circuit - F1 on board SF)
W – Measuring wire

Fig. 3-11 Measuring circuit for equivalent unit leakage current

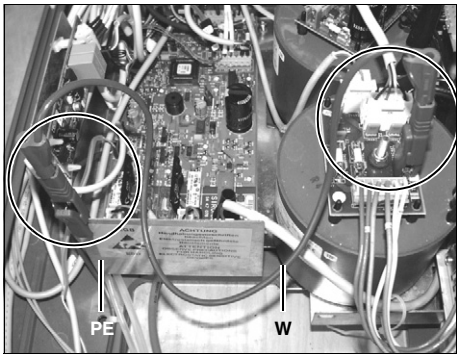


Fig. 3-12 Measuring wire W ProFeel+

The mains supply of the treatment center is disconnected at all poles (except PE).

The main switch on the chair must be **ON**.

1. Connect auxiliary measuring point MHP (fuse F1) to protective ground wire PE with a measuring wire (W).
   Protective ground wire PE:
   ProFeel+ – Metal plate on which PC board SB is mounted

NOTE
If you use an automatic tester, the auxiliary measuring point must be treated like an applied part.
If the tester connects the applied part to the protective ground wire during this measurement, the measuring wire (W) can be omitted.

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 measuring wire W after taking this measurement.

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

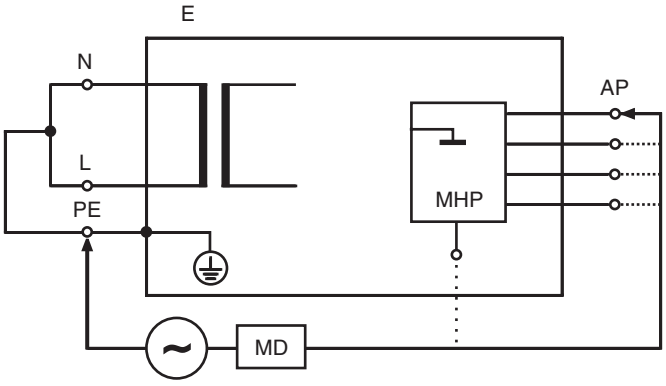
NOTE
Make sure that the tester is programmed for a permanent connection (and not for 1mA) (a 10mA leakage current is permissible).

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

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.

3.3.2 Equivalent patient leakage current

The following measuring setup according to VDE 0751-1:2001 is used:



→ – 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
MHP – Auxiliary measuring point (potential of patient circuit - F1 on board SF)
AP – -Applied parts (type BF)

Fig. 3-13 Measuring circuit for equivalent patient leakage current

The mains supply of the treatment center is disconnected at all poles (except PE).

The main switch on the chair must be **ON**.

1. Connect the short-circuited mains wires (L and N) to the protective ground wire (PE).
2. Successively connect the measuring device between PE and the different applied metal parts. Applied metal parts include:
   - Micromotor housing
   - Highspeed handpiece housing
   - Tip of the US handpiece
   - Housing of the Sirocam 3
   - Other applied parts
   - Auxiliary measuring point (MHP) in the connection box (see section 3.3)
3. Measure the current flowing across the insulation and MD (1 V = 1 mA).

CAUTION

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

Document the value measured during initial start-up in Section 3.4.
Document the highest value measured during re-tests in Section 3.5.

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.

NOTE

If you use an automatic tester, the auxiliary measuring point must be treated like an applied part.

3.4 Safety check (Initial test after initial start-up)

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

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

Model	ProFeel+	Serial number chair	

3 Safety checks

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

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

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

Visual inspection	Protective ground wire resist. ($\leq 0.3\Omega$)	Equiv. device leakage curr. ($\leq 10mA$)	Equiv. patient leakage current ($\leq 5mA$)	Safety maintained?
☐ OK ☐ Faults	Ω	mA	mA	☐ yes ☐ no
Remarks / Particularities:				
Date	**Name of engineer**	**Depot**		**Signature**

Visual inspection	Protective ground wire resist. ($\leq 0.3\Omega$)	Equiv. device leakage curr. ($\leq 10mA$)	Equiv. patient leakage current ($\leq 5mA$)	Safety maintained?
☐ OK ☐ Faults	Ω	mA	mA	☐ yes ☐ no
Remarks / Particularities:				
Date	**Name of engineer**	**Depot**		**Signature**

Visual inspection	Protective ground wire resist. ($\leq 0.3\Omega$)	Equiv. device leakage curr. ($\leq 10mA$)	Equiv. patient leakage current ($\leq 5mA$)	Safety maintained?
☐ OK ☐ Faults	Ω	mA	mA	☐ yes ☐ no
Remarks / Particularities:				
Date	**Name of engineer**	**Depot**		**Signature**

Model	ProFeel+	Serial number chair	

3 Safety checks

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

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

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

4 Remarks / particularities regarding the treatment center

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

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Sirona Dental Systems GmbH

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www.sirona.de

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