New since: 04.2005

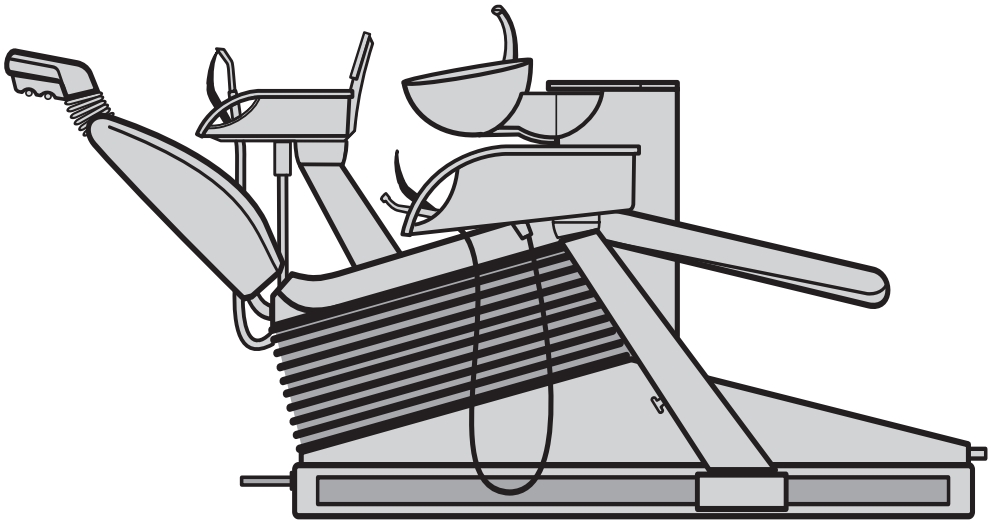
sirona
The Dental Company

C1+– C5+, C5+Turn , M1+

Maintenance Manual

☐ C _____+ ☐ M1+	
Model	Serial No. of Chair

English



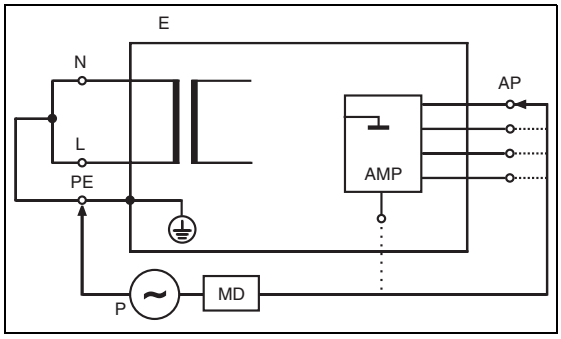


Table of Contents

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 avoid damage due to natural wear
- Safety tests (every 2 years)
  to ensure the tecical 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.

NOTE
*For units with HF surgery equipment, this **Maintenance Manual** simultaneously acts as **Medical Product Log**.*

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 in accordance with the Maintenance Certificate.
   Document their realization on the “Installation Report / Warranty Passport”.
4. Conduct the safety tests in accordance with chapter 3. Document the results.
5. On units with HF surgery equipment, maintain the documentation required in section 4.2 and 4.3.
6. Document additional remarks and particularities regarding the treatment center in chapter 5.

By the user:

1. On units with HF surgery equipment, maintain the documentation required in section 4.2 and 4.4.
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 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 treatment center independently recognizes the necessity of regular maintenance and displays this in due time.
You will find further information concerning the maintenance display in the Operating Instructions.

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.

For each maintenance event, a separate Maintenance Certificate is produced.

List the inspection and maintenance events also under the maintenance overview in the **"Installation Report/Warranty Passport"**.

Appendix: Installation Report / Warranty Passport

3 Safety tests

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 **every 2 years** which aim particularly at detecting electrical faults. 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.

ATTENTION

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

ATTENTION

*If the treatment center does not pass the safety tests, it may **no** longer be operated!*
In your capacity as service engineer, you must advise the user of this fact. 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 (peak)
Type BF applied parts	Sirocam 3 SIROCAM C (no measurement required) HF surgery - handpiece
Protective ground wire resistance	≤0.1Ω
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.

You measure HF surgery however in the inactive condition.
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 details:

- 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?
- Is the document “Care and Maintenance by the Practice Team” available?
- Is the “Maintenance Manual”, serving also as Medical Product Log on units with HF surgery equipment, available?
- In Germany:
  Is the Service Logbook of the amalgam separator (if applicable) available?

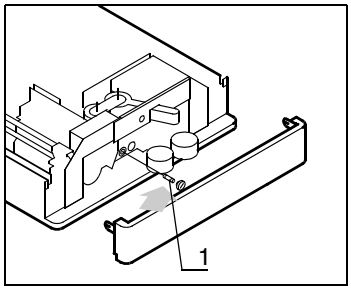


Fig. 3-1 Main fuse

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
- Open the cover of the connection box in the chair
- For a video system connected to a PC:Pull the power plug of the PCs
- Disconnect all poles (also PE) of the mains supply at the connection terminal (except protective ground wire PE)

3.2 Protective ground wire test

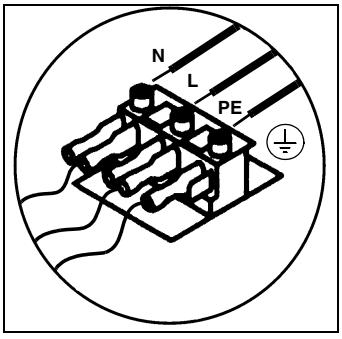


Fig. 3-2 Mains terminal

1. Measure the electrical resistance between the electrically conductive, grounded parts on the treatment center and the protective ground wire at the mains terminal.
   The power plug of the PC (with video system) must be disconnected for that purpose.
2. Document the highest measured value.

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

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.**

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

.

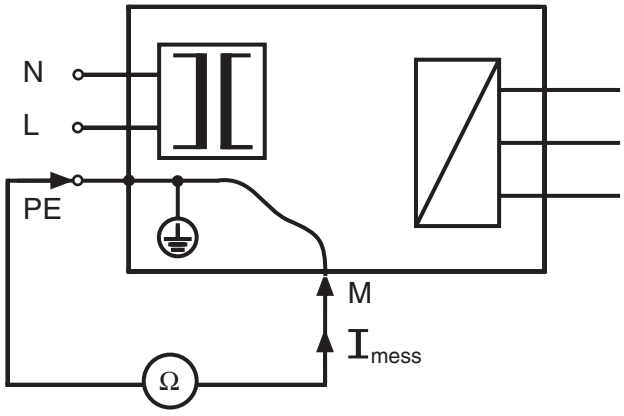


Fig. 3-3 Protective ground wire resistance measurement

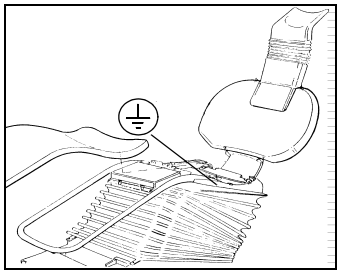


Fig. 3-4 Seat frame of chair

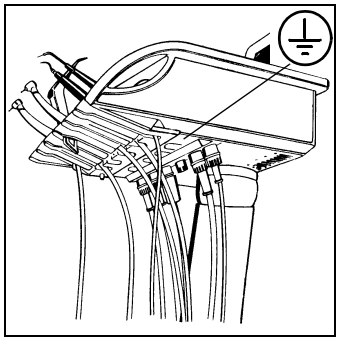


Fig. 3-5 Dentist element

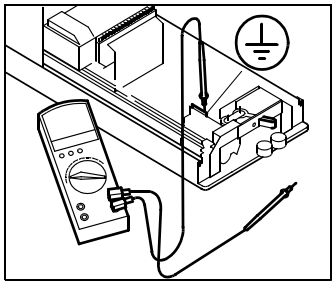


Fig. 3-6 Location of mains terminal

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

- Seat frame of the dental chair
- Screw on the bottom of the dentist element
- Chassis of the water unit
- Protective ground wire connection of the monitor (if available)
- Protective ground wire connection of the external PC on treatment centers with video system (PC power plug pulled)
- Cold plug socket for additional devices (if available)

Document the measuring results obtained during initial start-up 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

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 10 mA 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 mains voltage. If you are not using an automatic tester, see the example on page 12.

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

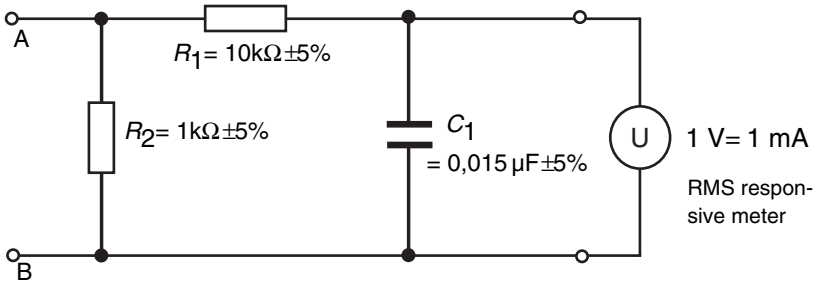


Fig. 3-7 Measuring set-up (MD = measuring device)

R_1, R_2, C_1: Non-reactive components

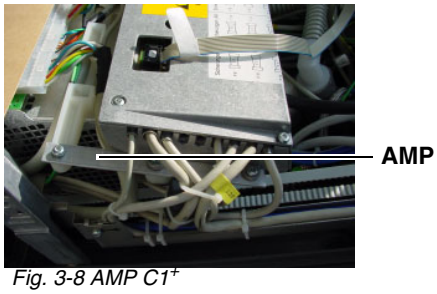


Fig. 3-8 AMP C1+

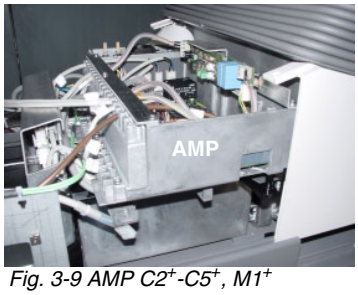


Fig. 3-9 AMP C2+-C5+, M1+

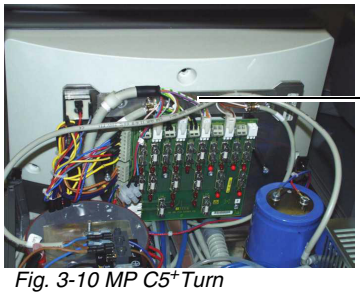


Fig. 3-10 MP C5+Turn

NOTE

The equivalent leakage current measurements also include the applied parts (dental instruments).
Since the treatment center is in non-operating state, e.g. the motors of the dental instruments and their supply cables as well as the lamps are disconnected by relays and hence not connected to potential of the patient circuit. Faults in the applied parts might not be detected therefore.
For that reason, measurements to an auxiliary measuring point (AMP) in the connection box of the chair are performed as well in the following tests. The AMP is connected to potential of the patient circuit. It is treated like an applied part.

The MP is located in the connection box of the chair (see Fig. 3-8 and Fig. 3-10).

C1+	–	Cast-metal housing which accommodates board SA
C2+-C5+, M1+	–	Cast-metal housing which accommodates board CJ
C5+ Turn	–	Metal strip above fuse board CF

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

Extrapolating the leakage current for the nominal line voltage

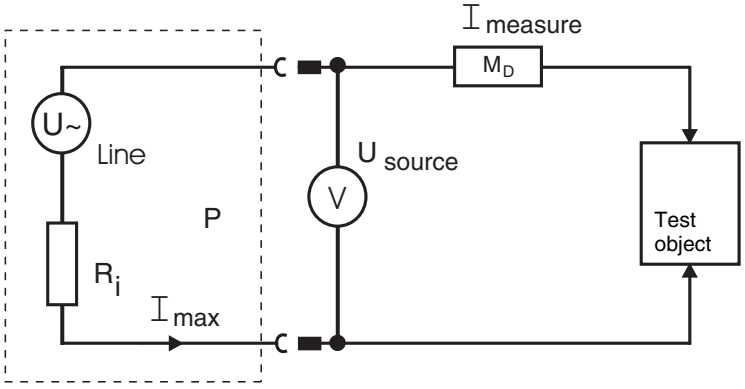


Fig. 3-11 Measuring voltage source

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 ⇨ O. K.

Case 2: Measured:

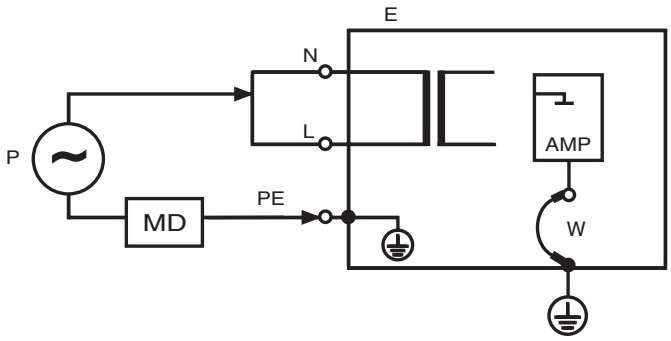
U_{source} = 26V, $I_{measure}$ = 3mA

Leakage current:

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

3.3.1 Equivalent device leakage current

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



→ - Connections of measuring device
L, N - Phase, neutral conductor at mains terminal
PE - Protective ground wire at mains terminal
P - Power-frequency measuring voltage source
E - Accessible conductive parts (housing) at protective ground potential
AMP - Auxiliary measuring point (potential of the patient circuit)
W - Measuring wire

Fig. 3-12 Measuring circuit for equivalent device leakage current

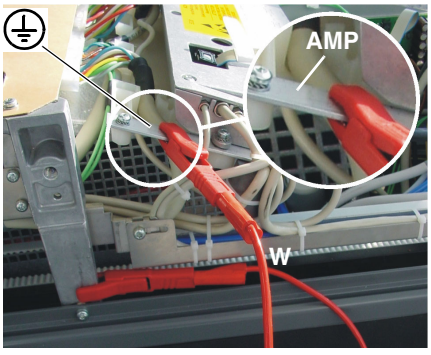


Fig. 3-13 Measure wireC1⁺

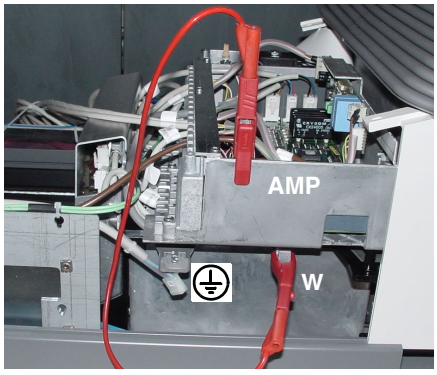


Fig. 3-14 Measure wire C2⁺-C5⁺,M1⁺

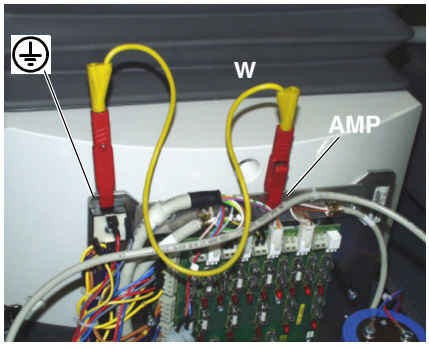


Fig. 3-15 Measure wire C5⁺ Turn

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 auxiliary measuring point AMP (Potential of the patient circuit) with a measuring wire (W) to the protectective ground wire (PE) (see Fig. 3-13 – Fig. 3-15).

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 wires (L and N) and the protective ground wire (PE) 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.

ATTENTION

*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).

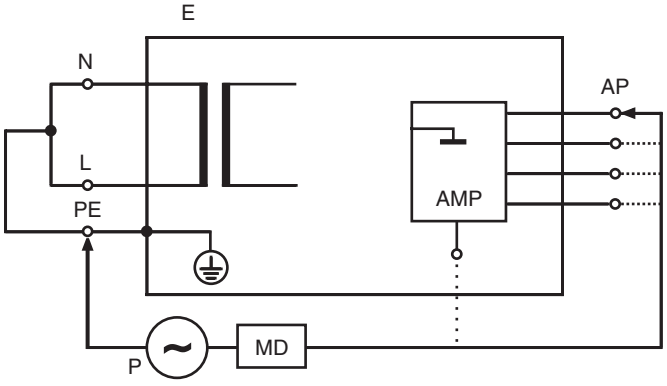
Document the measuring results obtained during initial start-up in section 3.4.
Document the measuring results obtained during re-tests in section 3.5.

ATTENTION

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 set-up according to VDE 0751-1:2001 is used:



→ - Connections of measuring device

L, N - Phase, neutral conductor at mains terminal

PE - Protective ground wire at mains terminal

P - Power-frequency measuring voltage source

E - Accessible conductive parts (housing) at protective ground potential

AMP - Auxiliary measuring point (potential of patient circuit)

AP - Applied parts (type BF)

Fig. 3-16 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) and the protective ground wire (PE).
2. Successively connect the measuring device between PE and the different applied metal parts. Applied metal parts include:
   - Metal nozzle of Sprayvit on dentist and assistant side
   - Micromotor housing
   - Turbine housing
   - Tip of the US handpiece
   - Tip of the HF surgery handpiece
   - Housing of the Sirocam 3
   - Other applied parts
   - Auxiliary measuring point (AMP) in the connection box (see section 3.3)
3. Measure the current flowing across the insulation and MD (1 V = 1 mA).

ATTENTION

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

Document the measuring results obtained during initial start-up in section 3.4.
Document the measuring results obtained during re-tests in section 3.5.

ATTENTION

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.

Model	☐ C ____$^{+}$, ☐ M1^{+}	Serial No. of Chair	

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

The values measured during initial start-up are documented in order to be able to compare them to the values measured during the re-tests.

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

3.5 Safety test (Re-tests)

On these forms, the results of the re-tests are documented.

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

Model	☐ C ____+ , ☐ M1+	Serial No. of Chair	

3 Safety tests

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

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

3 Safety tests

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

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

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

Model	☐ C ____+ , ☐ M1+	Serial No. of Chair	

3 Safety tests

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

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

Model	☐ C ____$^{+}$, ☐ M1^{+}	Serial No. of Chair	

3 Safety tests

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

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

4 Treatment centers with HF surgery equipment

4.1 General information

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

According to Section 6, safety tests are required for devices with HF surgery 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 devices with HF surgery 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 obligated to maintain 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 treatment centers with HF surgery 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 device 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 device 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)

Model	☐ C ____$^{+}$, ☐ M1^{+}	Serial No. of Chair	

4 Treatment centers with HF surgery equipment

4.2 List of trained personnel

The treatment center with HF surgery equipment must be operated only by personnel who have been trained on its use by the manufacturer or supplier. Such trained personnel are allowed to train other persons.

The relevant trainings are documented in the table below.

Date	Name, trainer	Depot	Signature	Name, person trained	Signature

4 Treatment centers with HF surgery equipment

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	

4 Treatment centers with HF surgery equipment

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	

Model	☐ C ____+, ☐ M1+	Serial No. of Chair	

4 Treatment centers with HF surgery equipment

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

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

NOTE

Please observe also 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**

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**

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**

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

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

6 Remarks / particularities regarding the treatment center

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

D 3264.102.02.04.02 04.2005
Sprache: englisch
Ä.-Nr.: 106 122
Printed in Germany

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