INSTRUCTIONS FOR USE

ENT Treatment Chair

SIT 4
SIT 4 PLUS
SIT 4 PLUS E
SIT 4 PLUS ER

Please keep this manual always near the equipment.

CE

Rev. 11.04.2024

otoprontⓇ

Index

1 Preface

Dear customer

Congratulations on the purchase of your new ENT treatment chair **SIT 4 / SIT 4 PLUS / SIT 4 PLUS E / SIT 4 ER**.

You have acquired a product which was manufactured with great experience and care. The present INSTRUCTIONS FOR USE are intended to familiarize you with the functioning of the chair and to assist you in trouble-free handling. Please read the INSTRUCTIONS FOR USE in full detail before operating the chair. Pay special attention to the safety instructions which are emphasized graphically.

These INSTRUCTIONS FOR USE are applicable to all versions of the chair and describe the complete set of equipment, including special accessories. Therefore, it is possible that you will find descriptions of equipment which is not present in your chair.

As we always make efforts to improve our products, we reserve the right to change the design and specification without prior notice.

2 Intended Use

The ENT treatment chair SIT 4 is intended for the examination and treatment of sitting and lying patients in ENT medicine. The SIT 4 is intended for indoor use only and is operated by medical specialists and assistants. The ENT treatment chair is not intended as an operating chair or operating table or as a bed substitute. Patients must be conscious. The ENT treatment chair is not intended as a rotatory or pendular chair for vestibular testing. The electrical installation of the room must comply with the national requirements. We recommend to connect the chair to the potential equalisation conductor. The ENT treatment chair may not be operated in an explosive environment.

2.1 Contraindications

Contraindications relating to the use of the ENT treatment chair are currently not known. The decision to use the chair must be made from a medical point of view, taking into account the general condition of the patient. Use of the ENT treatment chair is considered contraindicated if, in the opinion of an experienced physician, such use would pose a risk to the patient.

3 Safety Instructions

3.1 Explanation for the safety instructions

The safety instructions in the present user manual aid in the protection and safety of patients, users and third parties. In addition, instructions are given to prevent possible damage to technical components of the chair.

The safety instructions are marked with the terms *“Attention”* and *“Note”* as well as the icon ⚠. The safety instructions have the following meaning:

⚠	**Attention**
	Disregarding of the safety instructions may result in injury to the patient, the user or other persons.

⚠	**Note**
	Disregarding of the notes may result in damage to the chair or other equipment.

3.2 General safety instructions

For a trouble-free and safe handling of the ENT treatment chair please observe the following safety instructions. Please pay also attention to the additional safety instructions stated in the chapters later in this manual.

⚠	**Attention**
	The ENT treatment chair must only be used by persons who have been trained in the correct use and who are familiar with all aspects of functioning and handling. The training must include all contents of these INSTRUCTIONS FOR USE.

⚠	**Attention**
	Otopront will not accept any liability with regard to safety, reliability and performance of the chair, if assembly, extensions or repairs have been carried out persons who are not authorized by us or if the equipment is not used in full compliance with the INSTRUCTIONS FOR USE.

Attention

Please be aware that the chair is not fixed to the floor. Therefore, the backrest must only be moved into the horizontal position if the rotatable top part of the chair is in the 0° position or rotated less than ± 45° (Fig. 3)! That means, the backrest must not be inclined into the horizontal position (lying patient), if the rotatable top part of the chair is outside the permissible rotation angle of ± 45° the maximum. If you wish to use the chair outside the ± 45° angle in connection with the inclined backrest, the anti-tilt support (Fig. 1 (13)) must be installed. Please inform the customer service and order the anti-tilt support for subsequent installation.

Attention

In order to maintain the tilting stability of the chair when the backrest is inclined (patient lying down), make sure that the patient's body weight is evenly distributed on the chair. As the chair is not fixed to the floor, a sudden weight shift may impair the stable stand of the chair. A lying patient must not shift the body weight towards the upper end of the backrest. The chair might tip and fall over!

Attention

Do not allow anyone to sit on the backrest, footrest or armrest! Risk of mechanical failure! The chair might tip and fall over!

Attention

The ENT treatment chair is a medical device with moving parts. When adjusting the backrest, make sure that the patient's hands and arms rest permanently on the armrests (Fig. 1 (2)). This is the safe position for the patient. Improper use may lead to entrapment and crushing hazards!

Attention

The footrest (Fig. 1 (6)) must not be used by the patient to get in or out of the chair! The footrest must not be loaded with the full body weight! Risk of mechanical failure and patient falling! The footrest is intended solely to support the patient's feet during examination and treatment.

Attention

When the seat of the chair is moved downwards, please take care that no objects are underneath the seat (Fig. 1 (3)) or the footrest (Fig. 1 (6)). Pay special attention to the patient's feet and also to your own feet! Risk of crushing injuries!

Attention

If the chair is equipped with a brake (Fig. 1 (11)) for locking the seat, the brake must always be locked while the patient is entering and exiting the chair to prevent the seat from accidentally turning away. Risk of falling!

Attention

If the chair is equipped with a motor-supported seat rotation, ensure that the break (Fig. 1 (11)) is always locked during examination and treatment. Otherwise, the seat may turn away unintentionally if the switch for seat rotation is pressed accidentally (e.g. by the user, by the patient, by other persons or objects).

Attention

When adjusting the backrest, make sure that there are no persons or objects in the swivel range of the backrest (Fig. 1 (12)) as well as the footrest (Fig. 1 (6))! Always keep an eye on the area behind the chair! Please note that the simultaneous swivelling up of the footrest also requires a considerable amount of space towards the front. Risk of collision, trapping and fall hazards! Due to the strong lifting force of the motor-supported backrest, other equipment (e.g. ENT unit, instrument cabinet, video tower, microscope) could be damaged or knocked over in the event of a collision!

Attention

After the plug of the mains connection cord (Fig. 1 (15)) is connected to the power supply, the treatment chair can immediately be operated as the chair is not equipped with an additional mains switch. To disconnect the chair from the mains, pull the mains plug out of the power socket. When setting up the chair in the room, make sure that the power socket is easily accessible at all times.

Attention

The casing of the chair and the external foot switch (Fig. 1 (7)) are not protected against splashing water. So, please take care if you use liquids for cleaning and disinfection. The treatment chair must not be operated in areas subject to explosion hazards.

4 View of the Product

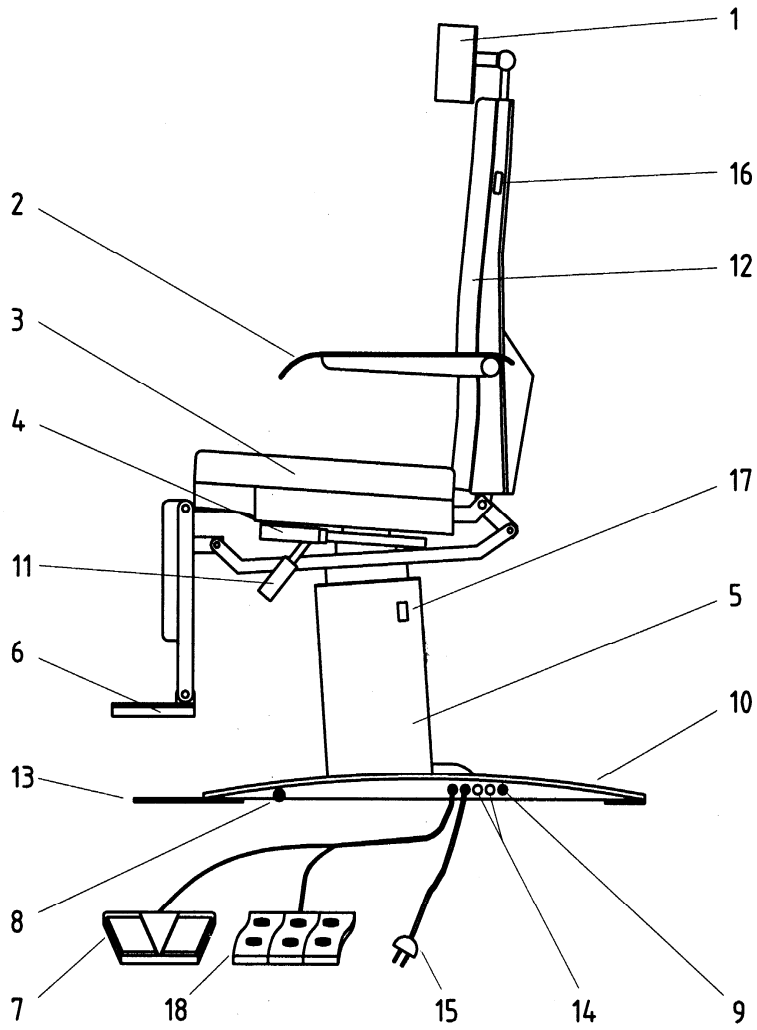


Fig. 1: View of the ENT treatment chair

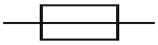
(1) Headrest
(2) Armrest
(3) Patient seat
(4) Lever for adjusting the backrest
(5) Lifting cylinder
(6) Footrest
(7) External foot switch (option)
(8) Integrated foot switch
(9) Potential equalization bolt
(10) Base plate
(11) Locking brake (option)
(12) Backrest
(13) Anti-tilt support (option)
(14) Mains fuse
(15) Mains connection cord
(16) Button for adjusting the backrest (option)
(17) Button for lifting the chair (movability option)
(18) Multifunctional foot switch (option)

5 Explanation of the Symbols

Warning symbol – observe accompanying documents

Observe the instruction manual

Alternating current



Mains fuse

Potential equalization bolt

Type B equipment

Production year

Manufacturer

The device is subject to the requirements of WEEE Directive 2012/19/EU

Motor-supported backrest adjustment - Lifting the backrest

Motor-supported backrest adjustment - Lowering the backrest

CE marking accord. to Medical Device Regulation (EU) 2017/745

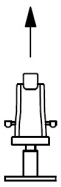
MD Medical device

UDI Unique device identifier

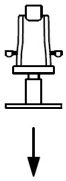
REF Reference number

SN Serial number

Symbols on the remote-control unit *(option)*



Seat height adjustment - Lifting the patient



Seat height adjustment - Lowering the patient

Motor-supported backrest adjustment - Lifting the backrest

Motor-supported backrest adjustment - Lowering the backrest

6 Installation

A mains socket 220-240 V~, 50/60 Hz is required to operate the ENT treatment chair. Please make sure that the mains socket is provided with a protective earth terminal.

If the mains voltage in your area is 110-127 V please make sure that the nominal voltage stated on the type label corresponds with the mains voltage available in your area. The type label of the chair must bear “110-127 V~, 50/60 Hz” to operate the chair.

The ENT treatment chair is equipped with a bolt for potential equalization *(Fig. 1 (9))*. We recommend to connect the chair to the potential equalization system.

	Attention
⚠	*Please observe that the backrest must only be moved into the horizontal position if the rotatable top part of the chair is in the 0° position or rotated less than ± 45° (Fig. 2)! That means, the backrest must not be inclined into the horizontal position (lying patient), if the rotatable top part of the chair is outside the permissible rotation angle of ± 45° the maximum. If you wish to use the chair outside the ± 45° angle in connection with the inclined backrest, the anti-tilt support (Fig. 1 (13)) must be installed. Please inform the customer service and order the anti-tilt support for subsequent installation.*

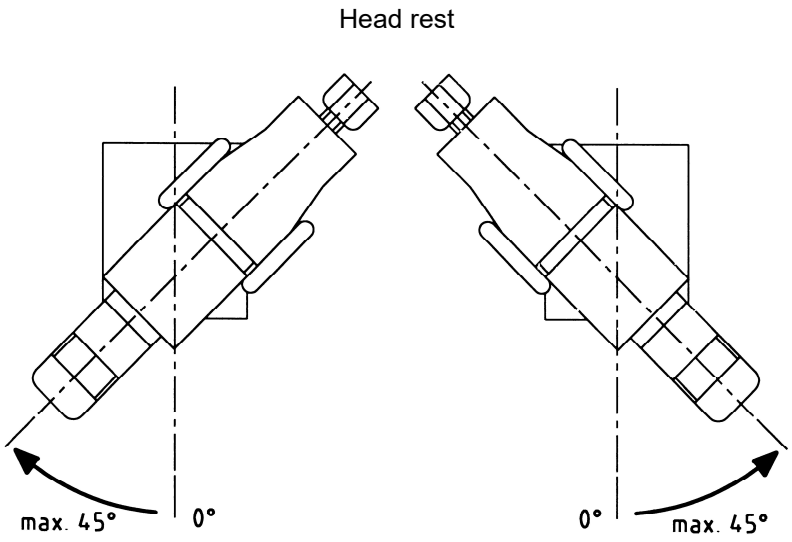


Fig. 2: Permissible rotation angle if the back rest is in horizontal position (rotation ±45° the maximum!) (view from above)

7 Explanation of Individual Functions

7.1 Adjusting the backrest *(Fig. 1 (12))*

	Attention
	The ENT treatment chair is a medical device with movable parts. Please ensure that the patient's hands and arms rest on the armrests (Fig. 1 (2)) while adjusting the backrest. This represents the safe position for the patient. Improper use may lead to entrapment and crushing hazards!

	Attention
	Please be aware that the chair is not fixed to the floor. Therefore, the backrest must only be moved into the horizontal position if the rotatable top part of the chair is in the 0° position or rotated less than ± 45° (Fig. 3)! That means, the backrest must not be inclined into the horizontal position (lying patient), if the rotatable top part of the chair is outside the permissible rotation angle of ± 45° the maximum. If you wish to use the chair outside the ± 45° angle in connection with the inclined backrest, the anti-tilt support (Fig. 1 (13)) must be installed. Please inform the customer service and order the anti-tilt support for subsequent installation.

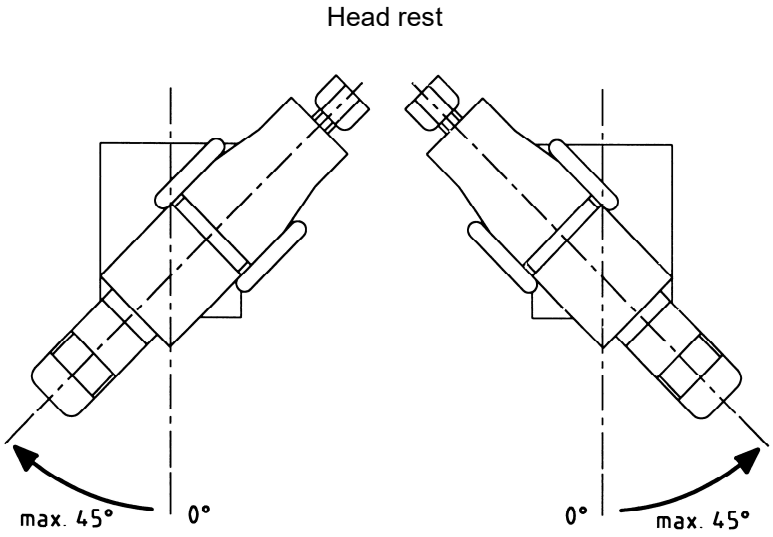


Fig. 3: Permissible rotation angle if the back rest is in horizontal position (rotation ±45° the maximum!) (view from above)

	Attention
⚠	*The backrest must only be moved into horizontal position if the patient sits properly on the chair. As the chair is not fixed to the floor, a lying patient must not shift the body weight towards the upper end of the backrest. This might lead to a critical situation as the center of gravity changes considerably. The chair might tilt and fall over!*

7.1.1 Backrest adjustment - Manual version

By pressing down the adjustment lever *(Fig. 1 (4)),* the backrest is released from its locking position and can now be swivelled backwards. Once the desired position has been reached, the backrest has to be locked again by releasing the adjustment lever.

If the backrest is to be raised, first ask the patient to take the weight off the backrest. Then press down the adjustment lever *(Fig. 1 (4))* to release the backrest from its locking position.

	Attention
⚠	*Never press down the adjustment lever (Fig. 1 (4)) of the backrest (Fig. 1 (12)) under full body load! Always ask the patient to take the weight off the backrest (i.e. shift body weight forward). Otherwise, the backrest might come down all of a sudden! Risk of tipping and falling!*

7.1.2 Backrest adjustment – Motor-supported version *(option)*

The ENT treatment chair is optionally equipped with a motor-supported backrest. The adjustment of the backrest *(Fig. 1 (12))* is controlled by operating the adjustment buttons *(Fig. 1 (16))* integrated on the left and right of the backrest. When the backrest is adjusted, the footrest follows the movement of the backrest synchronously. That means, when the backrest is lowered, the footrest swivels upwards. If the chair is equipped with remote control, the backrest can be adjusted by operating the remote-control unit *(see Chapter 7.10)*.

Please note that when raising the backrest with a heavy weight patient, the patient should relieve the backrest. Otherwise, the motor may not be able to bear the load.

	**Attention** *When operating the motor-supported backrest, make sure that there are no persons or objects in the swivel range of the backrest (Fig. 1 (12)) as well as the footrest (Fig. 1 (6))! When lowering the backrest, always keep an eye on the area behind the chair! Please note that the simultaneous swivelling up of the footrest also requires a considerable amount of space to the front. Failure to observe this can lead to collision, trapping and fall hazards! Furthermore, due to the strong lifting force, other equipment such as an ENT unit, instrument cabinet, video tower, microscope etc. could be damaged or knocked over in the event of collision!*

7.2 Adjusting the seat height

The height of the chair can be adjusted by operating the foot switches *(Fig. 1 (8)* which are integrated left and right at the base plate of the chair. The switches are designed in a two-step mechanism. Pushing the foot switch half the way in will lift the seat up. If the switch is pushed completely in, the seat will move down. The switches can either be operated from the left or the right side of the chair.

As an option the chair can be equipped with an external foot switch *(Fig. 1 (7))*. The symbols on the foot switch indicate the direction of the movement (up/down).

The normal operating time of the electric lifting motor is 2 minutes operation and 5 minutes pause (40% operating time). To protect the lifting motor from thermal overcharge, the chair switches off automatically after approx. 4 complete lifting cycles. The chair can be used again after a cooling phase of about 20 minutes depending on the room temperature.

	**Attention** *When the chair is moved downwards please take care that no objects are underneath the seat (Fig. 1 (3)) or the footrest (Fig. 1 (6)). Please pay special attention to the patients' feet and also to your own feet.*

7.3 Locking the brake *(Fig. 1 (11))*

The brake is intended to lock the rotatable top of the treatment chair. With the lever *(Fig. 1 (11))* being pushed downwards, the chair is locked in the current position. If the lever is pulled upwards, the brake is released.

	**Attention** *To avoid sudden unintended movements of the chair, the break (Fig. 1 (11)) must always be locked while the patient is climbing or leaving the chair.*

	**Attention** *If the chair is equipped with a motor-supported seat rotation, ensure that the break (Fig. 1 (11)) is always locked during examination and treatment. Otherwise, the seat may turn away unintentionally if the switch for seat rotation is pressed accidentally (e.g. by the user, by the patient, by other persons or objects).*

7.4 Operating the rotating seat *(Fig. 1 (3))*

The seat can be separately rotated 90° to the left and 90° to the right (optional equipment). On the seat, handles are located on the left and right to move the patients into the desired direction. Please take care of your fingers when moving the seat to avoid crushing!

7.5 Folding back the armrests *(Fig. 1 (2))*

The armrests can easily be folded back to allow access for heavyweight or wheelchair patients.

7.6 Height-adjustment of the basic headrest *(Fig. 1 (1))*

The basic headrest is connected to the backrest via a latching double guide. By moving the headrest in the vertical direction, the headrest can be adjusted to the desired height. If the head rest does not engage directly in the reached position, the rest position must be found by a slight readjustment in vertical direction. Proper locking is important to keep the headrest at the desired height.

If necessary, the headrest can be completely removed from the chair. For this purpose, the headrest can be pulled vertically out of the guidance. The headrest can be removed without the use of tools.

	Attention
⚠	*The height adjustment of the headrest (Fig. 1 (1)) should always be carried out by using both hands! Please be careful to avoid unintentional removal from the guide.*

	Attention
⚠	*After each adjustment of the headrest (Fig. 1 (1)), it must be checked that the headrest is locked properly in the reached position! If necessary, readjust the height of the headrest slightly to ensure locking.*

7.7 Height-adjustment of the operation headrest *(option)*

The operation headrest provides more adjustment possibilities compared to the basic headrest and can be adjusted in the height, the inclination as well as in the horizontal position. The operation headrest is fixed in its respective position via two locking handles *(Fig. 4), (Fig. 5).*

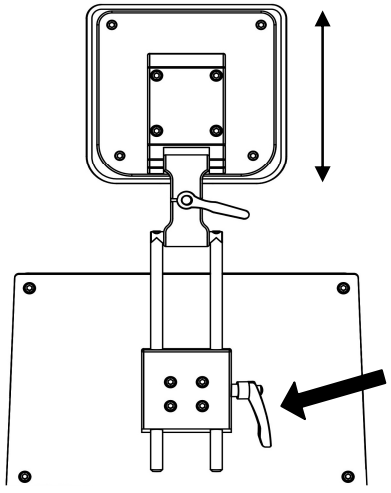


Fig. 4: Lower handle for adjusting height

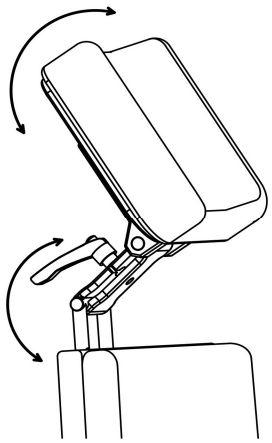


Fig. 5: Upper handle for adjusting position

	**Attention** *The operation headrest must always be adjusted with both hands! When adjusting the operation headrest, make sure that there are no hands or fingers in the movement area of the operation headrest. Crushing hazard! Please also pay attention to other persons. Special care must be taken when loosening the locking handle for height adjustment. Risk of crushing between headrest and backrest!*

	**Attention** *After each adjustment of the operation headrest, check that both locking handles are firmly tightened. A non-tightened locking handle can lead to a sudden and unintentional adjustment or sagging of the headrest during the examination or treatment!*

7.8 Movability of the chair *(option)*

By pressing the switch *(Fig. 1 (17))* the chair is brought into the “movability position”. Castors are driven out electrically which lifts the whole chair. Please observe that the activity radius of the movable chair is limited by the length of the mains connection cord *(Fig. 1 (15))*! Therefore, the mains plug must always be pulled out of the electrical socket before the chair is moved inside the room.

	**Attention** *Please observe that the patient must leave the chair before the button (Fig. 1 (17)) is pressed for driving out the castors. The chair must not be loaded if the castors are driven out to avoid negative influence on the vertical stability.*

	**Attention** *Before a patient takes seat for an examination or treatment, the castors must always be driven in again (normal working position of the chair) to ensure the full stability of the chair. We recommend placing the chair into the normal working position immediately after the chair stands at its new position.*

7.9 Remote-control unit *(option)*

The ENT treatment chair SIT 4 is optionally equipped with a remote-control unit *(Fig. 6)* for the electric adjustment of seat height and backrest. Depending on the equipment, further adjustment devices like the electric rotation of the chair can be controlled.

Independent from the remote-control unit, all adjusting motors can be operated via the built-in buttons of the ENT treatment chair. The full range of functions will therefore remain available if the remote-control unit is not available. A description of the graphical symbols used on the remote-control unit can be found in chapter 5.

⚠	**Attention** *When the remote-control unit is operated, visual contact must always be held to the chair. At any time, it must be ensured that there will be no collision of the chair with persons or objects. Do not leave the remote-control unit unattended in the room.*

⚠	**Attention** *Please observe that due to the range of the remote control, operation from a greater distance or from neighbouring rooms might be possible. Unintended operation must strictly be prevented. Do not place the remote-control unit in the pocket to avoid accidental actuation. When leaving the room, the remote-control unit must always be left at the chair and be kept safe from unauthorized access.*

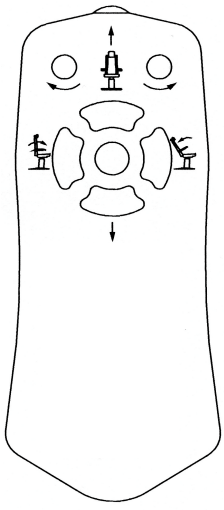


Fig. 6: Remote-control unit

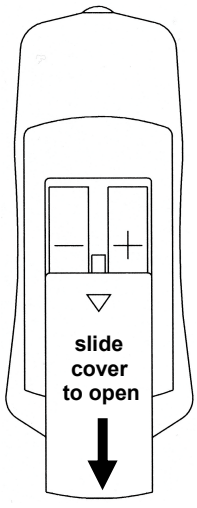


Fig. 7: Battery compartment at the back

7.10 Automatic position setting via remote control *(option)*

The ENT treatment chair SIT 4 is optionally equipped with an automatic position setting for the seat height and the backrest. To move the chair to the desired position, press the corresponding key on the remote-control unit continuously until the end position is reached.

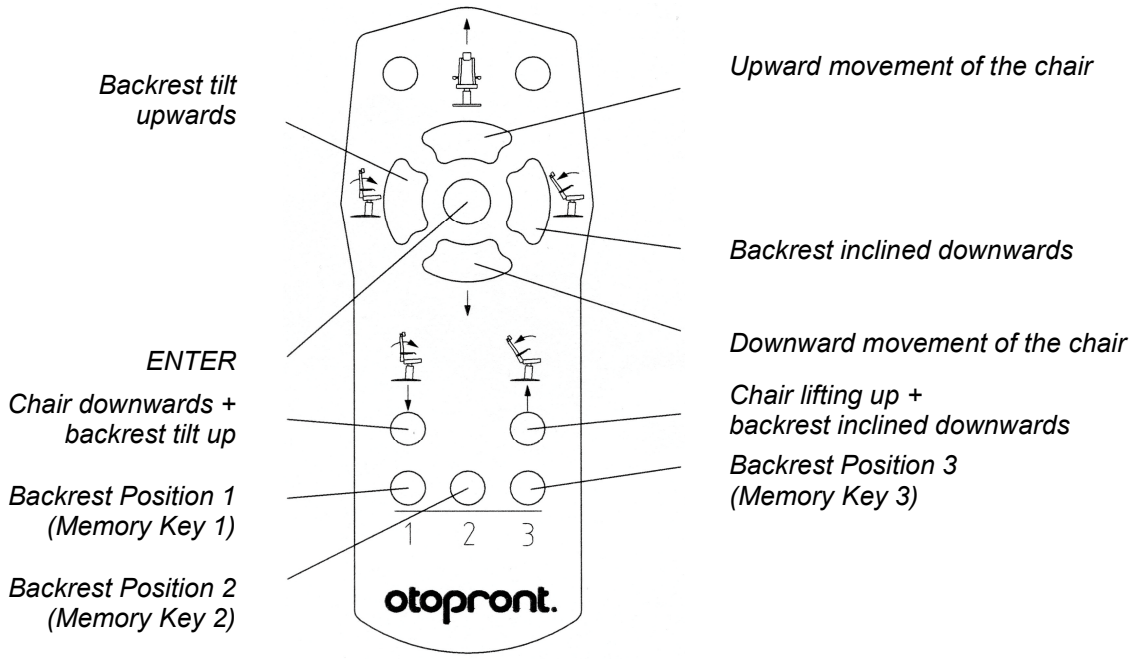


Fig. 8: Remote-control unit for automatic position setting

The memory keys < 1 > < 2 > < 3 > can be individually assigned for a preferred backrest position. To assign the keys individually, please carry out the following steps in the order given:

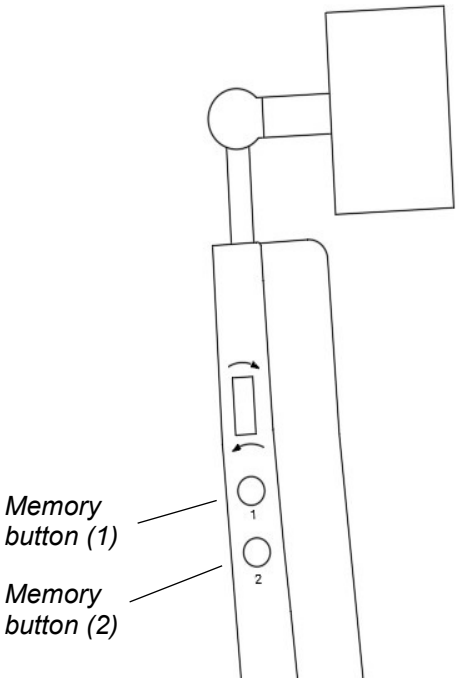
1. Adjust the backrest to your preferred position
2. Press ENTER for about 1 second
3. Press the corresponding memory key to which you want to assign the position

The ENT treatment chair SIT 4 is delivered with the initial factory settings:

Memory Key 1 = Backrest in upright position
Memory Key 2 = Backrest in 30° position
Memory Key 3 = Backrest in horizontal position (Trendelenburg position)

7.11 Memory buttons for positioning of back rest and seat hight *(option)*

The chair is optionally equipped with memory buttons *(Fig. 9 (1) (2))* for presetting a preferred working position. To assign the buttons, carry out the following steps in the specified order:



1. Adjust the chair to your preferred working position
2. Press the memory button *Fig. 9 (1)* or *(2)* for approx. 3 seconds until an acoustic beep signal is heard
3. Confirm the setting by pressing the buttons (1) and (2) simultaneously within 2 seconds until an acoustic beep signal is heard
4. The position is now permanently stored on the assigned memory button
5. To use the memory function during the examination, press the corresponding button twice in quick succession. The chair will then move automatically to the preselected position

Fig. 9: Backrest with memory buttons (1) and (2)

7.12 Electric rotation of the chair *(option)*

The electric rotation of the chair is operated by the external foot switch. The chair rotates 180° to the left and 180° to the right. Please make sure that the swivel range of the chair is free before operating the foot switch to avoid collisions.

	Attention
⚠	*Please ensure that the break (Fig. 1 (11)) is always locked during examination and treatment. Otherwise, the seat may turn away unintentionally if the foot switch is pressed accidentally (e.g. by the patient, other persons, objects etc.).*

8 Cleaning and Disinfection

Attention

Before starting to clean or disinfect, the ENT treatment chair must be disconnected from power supply! Pull out the mains plug (Fig. 1 (15)).

Attention

Cleaning agents and disinfectants should always be applied with a slightly moistened cloth. Never pour or spray liquids directly onto the surface of the chair, the upholstery or the external foot switch (Fig. 1 (7), (18)). Don't let any liquids get into the chair or the external foot switch! Take extra care if you use flammable liquids like alcohol!

Note

The upholstery and lacquered surface should be cleaned periodically with a soft cloth. Mild disinfectants incl. alcohol can also be used. Never use strong solvents such as thinner or cleaning fluids containing ammonia (e.g. Sidolin) as this will damage the surface! We recommend Care-Wipes by Otopront (Art. No. 466200) for cleaning and disinfection of the ENT treatment chair.

Note

The use of lukewarm water with the addition of a neutral cleaner is recommended for routine cleaning of the upholstery. Staining of the upholstery can usually be removed by damp wiping. The upholstery should then be wiped dry. Dirt and stains should always be removed immediately after they are discovered. Please note that clothing that is not colourfast (e.g. jeans) can impair the appearance of the upholstery in the long term. This applies in particular to light upholstery colours. Cleaning agents should first be tested on an inconspicuous area. Please do not use abrasives or products containing solvents. A punctiform rubbing on one spot should be avoided. We recommend Care-Wipes from Otopront (Art. No. 466200).

9 Maintenance

If the treatment chair is operated in compliance with the INSTRUCTIONS FOR USE, no preventive maintenance is required. However, we recommend lubricating the movable parts underneath the seat with acid-free grease in a 12 months interval.

10 Regular Safety Controls

Attention

Safety controls have to be carried out every 12 months. The qualification, personal experience and instrumentation of the personnel must be in accordance with the national regulations.

Contents

- **Electrical measurements according to IEC 62353 or IEC 60601-1**
  - impedance of protective earthing system
  - leakage current (enclosure, earth, patient)

- **Function and performance**
  - moving parts
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  - locking mechanism of backrest and headrest
  - brakes

- **Visual control**
  - enclosure
  - mechanics of footrest, armrest, backrest, headrest
  - mains connection cord
  - cord of the external foot switch (optional equipment)
  - markings
  - mains fuses
  - accompanying documents

11 Technical Data

Power supply	220 - 240 V~, 50/60 Hz
	110 - 127 V~, 50/60 Hz *(only if stated on the type label)*
Power consumption	550 VA
Mains fuses	T6.3AH250V (6.3 x 32 mm)
Height adjustment	Motor-supported
Lifting range	200 mm (300 mm optional)
Lifting power	2200 N
Lifting speed	15 mm/s (200 mm lifting column)
	18 mm/s (300 mm lifting column)
Seat height	550 mm to 750 mm (550 mm to 850 mm optional)
Inclination of the backrest	-10° up to 100° from the vertical position
Rotation of the chair	360° (±180° if motor-supported backrest)
Dimensions	660 x 900 x 1400 mm (W x D x H)
Weight	105 kg to 120 kg
Ambient conditions for operation	Temperature +10°C to +40°C Humidity without condensing 20 % to 80 % Air pressure 700 hPa to 1060 hPa
Ambient conditions for transport/storage	Temperature +1°C to +55°C Humidity without condensing 20 % to 80 % Air pressure 700 hPa to 1060 hPa

Classification

Electrical protection class	Class I equipment
IP classification	IP X0
Applied part	Type B
Mode of operation	Non-continuous, e.g. 1 min. operation / 5 min. pause
UMDNS code	10-794
GMDN code	10794
Basic UDI-DI	426015454SITTC202111101FR
Medical device classification	Class I
CE mark	In accordance with MDR (EU) 2017/745

Cleaning / Disinfection

Upholstery / paintwork	Care-Wipes humid wipes, Art. No. 466200 Care-Wipes humid wipes (Refill bag), Art. No. 466201

12 Address of the Manufacturer

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13 Disposal

	*According to the provisions of the European directive 2012/19/EU on used electrical and electronic equipment (WEEE), this symbol signifies that the product must not be disposed of as unsorted municipal waste, but must be collected separately. Contact your dealer regarding the return and / or the collection systems available in your country.*

Appendix

Information on Electromagnetic Compatibility

The device is designed for use in professional healthcare facility environment. The device needs special precautions regarding EMC and needs to be installed and put into service according to the following EMC information.

Warnings!

- Portable and mobile RF communications equipment (including peripherals such as antenna cables and external antennas) can affect the device and should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- The device may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements.

The following charts give you information, how the device is classified and tested regarding the EMC standard EN 60601-1-2 and how it is to use in its electromagnetic environment.

Guidance and manufacturer's declaration – electromagnetic emissions		
The device is intended for use in electromagnetic environment specific below. The customer or the user of the device should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low - voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity

The device is intended for use in electromagnetic environment specific below. The customer or the user of the device should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	+/- 2 kV for power supply lines +/- 1 kV for input / output lines	+/- 2 kV for power supply lines +/- 1 kV for input / output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1 kV differential mode +/- 2 kV common mode	+/- 1 kV differential mode +/- 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % UT (> 95 % dip in UT) for ½ cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (> 95 % dip in UT) for 5 s	passed passed passed passed criteria B	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power main interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level			

Guidance and manufacturer's declaration – electromagnetic immunity

The device is intended for use in electromagnetic environment specific below. The customer or the user of the device should assure that it is used in such an environment.

Immunity test	IEC 60601- test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF IEC 61000-4-6	3 Veff	3 Veff	d = 1,17 $\times \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 1,0 GHz	3 V/m	d = 1,17 $\times \sqrt{P}$ 80 to 800 MHz d = 2,33 $\times \sqrt{P}$ 800 MHz to 2,5 GHz
			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a, should be less than the compliance level in each frequency range b. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency ranges apply.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between Portable and mobile RF communications equipment and the device

The device is intended to use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter meters		
	150 kHz bis 80 MHz d = 1,17 $\times \sqrt{P}$	80 MHz bis 800 MHz d = 1,17 $\times \sqrt{P}$	800 MHz bis 2,5 GHz d = 2,33 $\times \sqrt{P}$
0,01	0,12	0,12	0,233
0,1	0,37	0,37	0,74
1	1,17	1,17	2,33
10	3,7	3,7	7,40
100	11,7	11,7	23,3

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Appendix

Electrical Diagram