



User Manual

Sonesta P2 & P3

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Important Information

Important information regarding this user manual and usage of the Sonesta P2 & P3

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Technical lifetime 7 years.

The contents of this manual are the property of SONESTA MEDICAL AB. Any reproduction in whole or in part is strictly prohibited.

At the time of printing, this manual correctly described the device and its functions. However, as modifications may have been carried out since the production of this manual, the system package may contain one or more amendments to the manual. This manual including any such amendments must be thoroughly read, before servicing/using the device.

Warranty

SONESTA MEDICAL AB is only responsible for the reliability and performance of the device if the following are strictly observed:

- Authorized personnel carry out all repairs and modifications, see the back of the manual for authorized service centers.
- Only Sonesta spare parts are being used. Service manual with spare part list can be ordered from a Sonesta authorized distributor or from Sonesta Customer Service.
- The device must be used in accordance with the intended use and standards put forth in the Safety Information section.

If the points above are not strictly observed, the warranty will be considered invalid.

Safety Information

This product is CE marked in conformity with the requirements of the Medical Device Regulation (EU) 2017/745. This product is UL certified and marked in conformity with the requirements of the IEC 60601-1-6:2010/AMD2:2020. Adhere to the following recommendations for safe operation of the device:

Intended Use

- The device is intended to support patients and to assist medical professionals during examinations and procedures such as urodynamics, vasectomy, coloscopy and gynecologic procedures.
- The device is not intended to be used during invasive surgical procedures.
- The device is not intended to be used to transport patients. This can cause overbalance and personal injuries, equipment damage or property damage.

Power Connection

- Do not attempt to open the control box or actuators.
- Do not immerse the control unit device in water or any other liquid (see the cleaning section for specific details).
- The power connector also serves as the main power switch i.e. remove the power connector to power off.
- Unplug the power connector from its power source before cleaning or servicing. Failure to do so could result in equipment damage.

- Ensure that the power cord does not become pinched between mechanisms during normal operation of the chair. Failure to do so can result in equipment damage.
- Ensure that the cables are undamaged before use.
- Do not connect the power connector or any control unit connector to anything other than the appropriate input on the device.
- The device is connected with a emergency battery back up, the battery is charged when the AC-power cord is connected to the the power source.
- Always keep the power cord connected to the power source when in use.
- Use only Sonesta spare parts.

Flammable

- The device is not intended for use with flammable anaesthetic gases. A possible explosion hazard exists and personal injury or equipment damage could occur.

Positioning

- Ensure that hands, feet and equipment are clear of the frame assemblies when changing positions of the chair.
- Always engage the brakes, except during transport, verify the stability after brakes are engaged.
- A patient should never enter the chair by using the footrests to stand on. This may cause tipping of the chair, and can cause patient injury.
- Ensure that the patient is correctly positioned on the seat before use. Forward displacement of the patient's body weight, sitting on the front edge of the seat, or placing significant body weight on the leg rests or footrests may cause instability or forward tipping, resulting in patient or user injury.

Limitations and Warnings



- 170 kg

The Sonesta P2 chair is tested for a patient weight of maximum 170 kg. The maximum patient weight applies when the patient is positioned on the intended seat surface and the chair is used according to this manual.



- 210 kg

The Sonesta P3 chair is tested for a patient weight of maximum 210 kg. The maximum patient weight applies when the patient is positioned on the intended seat surface and the chair is used according to this manual.



- 50 kg

Ensure that the patient does not attempt to stand on footrests or extensions cushions. The chair may become unstable and risk tilting, causing injury. The maximum weight the footrests can bare while standing is 50 kg each. The extension cushions are designed only for the patient's leg to rest on during an exam. The extension cushions should never be used to enter or exit the chair. The warning label should always be fixed to the end of the extension cushion.



NOTE:

Ensure that the patient is never left unattended due to the risk of the patient not using the chair according to the user manual.

Maintenance

On a weekly basis, test the device for proper function and inspect cables for cuts and other damage. If in doubt, replace the relevant parts. The device should be cleaned routinely, as described below. Additional preventive maintenance and cleaning is required according to the Service Manual.

Cleaning

All Sonesta's chairs and accessories must be cleaned regularly to maintain high quality and keep the items in a good condition. Please make sure that the following cleaning instructions are followed when cleaning the chair and its accessories.

- The unit needs to be unplugged from the wall power before any disinfection is made.
- Wipe all surfaces on the chair and the accessories thoroughly after each patient use.
- Wipe off urine, blood, and other body fluids from the device throughout the procedure and as soon as possible after, to prevent them from drying onto the surfaces.
- Please note that Sonesta recommends removing the seat cushion after each use and to wipe the surfaces below the seat cushion as well as the back of the seat cushion. Sonesta also recommends disassembling the leg rest holders and leg rests from the side rail to allow all angles of these items to be cleaned.
- **Sonesta recommends cleaning the chair and its accessories with a dampened cloth and ordinary disinfectants, soap suds or mild detergents. Use any of the below listed recommended disinfectants on all surfaces. If they are not available, use any disinfectant with a 1:10 dilution of bleach (5.25% sodium hypochlorite) or 45 % isopropyl alcohol.**



Suggestions on recommended disinfectants

- PDI Sani-Cloth SANI-CLOTH ® Bleach Wipe: Germicidal Disposable wipe.
- Clorox HealthCare Disinfecting Wipes ®
- Ytidesinfektion LIV Des +45 ®



WARNING: Improper, or lack of cleaning after each use of the chair will cause damage to the appearance and performance such as corrosion.



WARNING: Iodophor-type disinfectants (betadine, for example) may stain the cushions.



WARNING: Prolonged contact with bleach solutions with improper dilution ratios (for) in any cleaning agent may cause damage to both the appearance and performance.

Symbols

Explanations of the symbols found on the body of the device:



Attention, see accompanying documents



Type B, equipment providing a particular degree of protection against electric shock



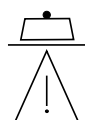
The device complies with the Medical Device Regulation (EU) 2017/745 on medical devices

IPX6

Degree of protection, EN 60529 (ingress of water and foreign objects)



Alternating current



Maximum safe workload icon
P2: Maximum safe workload 170 kg
P3: Maximum safe workload 210 kg



2 min per 18 min

Duty cycle icon, duty cycle 2 min per 18 min



Protective earth (ground)



The UL certification mark

Icons and Symbols

This manual contains different icons and typefaces designed to improve readability and increase understanding of its content. Adhere to the following recommendations and the ones in the user manual for safe operation of the device and service.



NOTE: Sets apart special information or important instruction clarification.



CAUTION: The symbol points out special procedures or precautions that personnel must follow to avoid equipment damage.



WARNING: The symbol identifies situations or actions that may affect patient or user safety. Disregarding a warning could result in patient or user injury.

Explanations of the symbols found in the user manual



Moves up



Moves down



Secure



Release



Adjustable in shown directions



Adjustable in shown directions



Push



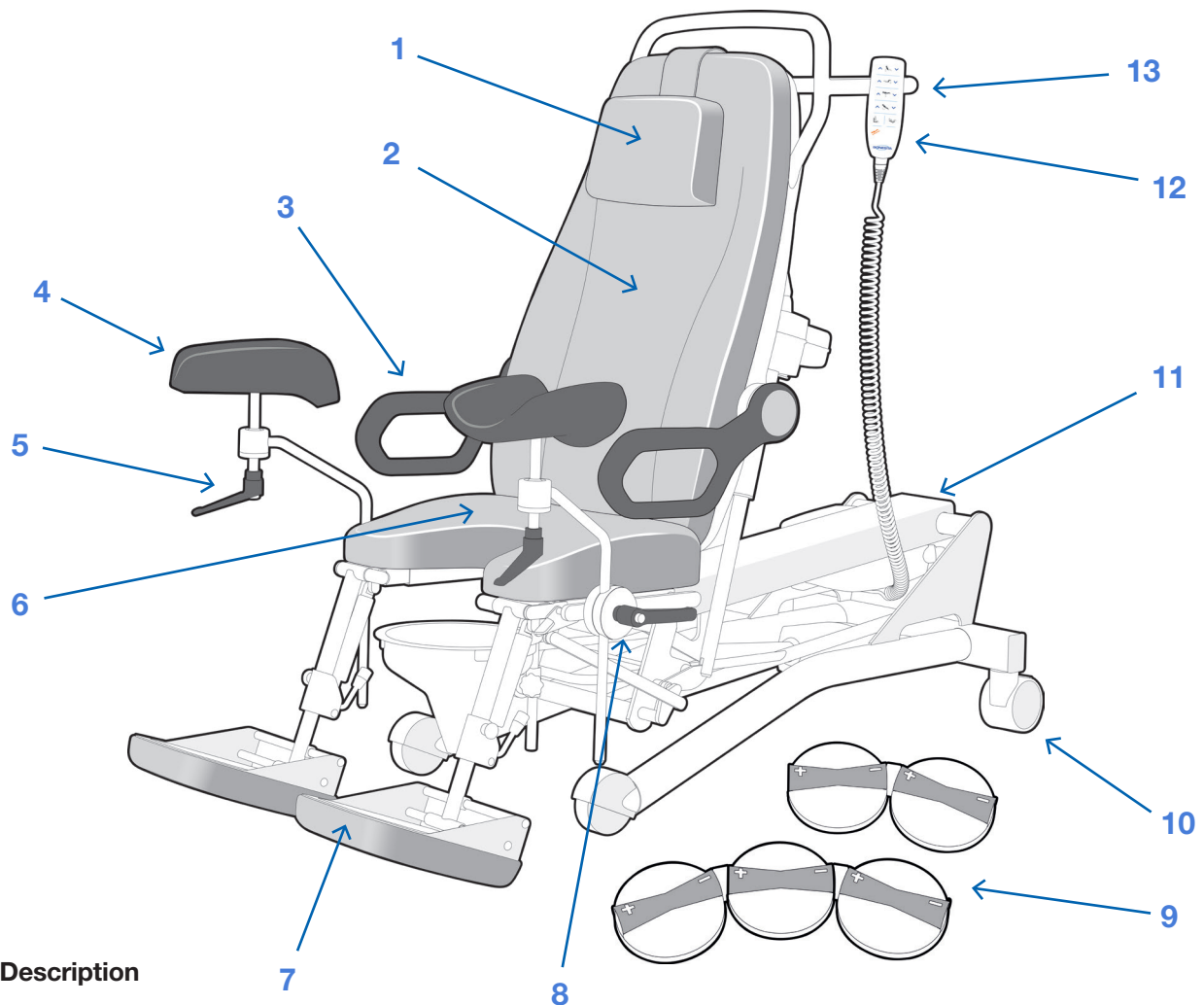
Insertion direction (part)

Sonesta P2 & P3

Intended Use

The Sonesta P2 and P3 chair is designed to position the patient in a desired position during the following procedures:

Urodynamics, Pelvic Muscle Rehabilitation, Anorectal Manometry, Pelvic Exam, Cystoscopy, Ultrasound, Vasectomy, Colposcopy, Biopsy, Colonoscopy, Gynecologic Procedures.

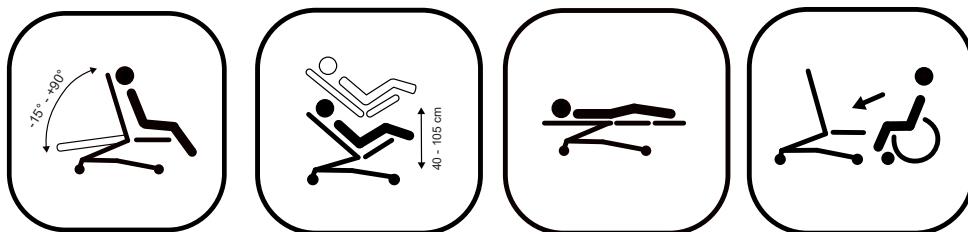


Description

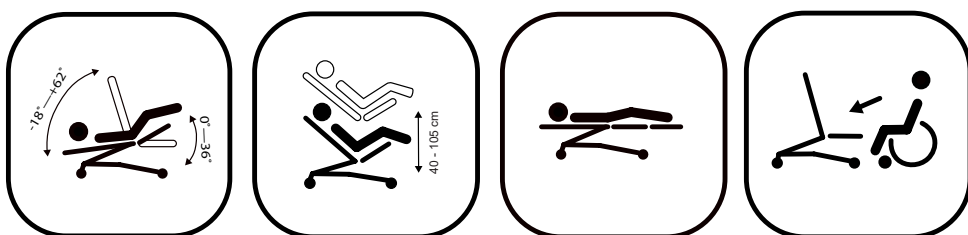
1. Neck pillow
2. Back cushion
3. Arm rest
4. Leg rest
5. Leg rest handle, release the screw to adjust the angle of the leg rest and then secure
6. Seat cushion
7. Fold up footrests
8. Leg rest holder, release the screw to adjust the height of the leg rest or the leg rest holder
9. Foot control
10. Wheels with locking mechanism
11. Back-up battery
12. Hand control
13. Paper roll holder

Operation Specifications

Operation Range Sonesta P2



Operation Range Sonesta P3



General Operation

The table is operated with the hand control or optional foot control.

Maximum Duty Cycle

2 minutes per 18 minutes.

Battery Back-Up System (optional)

The back-up battery charges every time the power cord is connected. The battery turns on automatically when the power is cut. The estimated back-up capacity is 12 minutes.

Please be aware that the lifetime of the battery, patient loading and position of the chair may reduce the back-up capacity of the table's battery. The battery is equipped with a led light and buzzer function which indicates different operations:

- Solid yellow light = Charging (battery is not ready for use)
- Flashing yellow light = Error occurred during charging
- No LED light: Fully charged (battery ready for use).

Buzzer sound = the buzzer will make a warning when a button on the hand control is pressed and the battery capacity is low.

Control box

The control box is equipped with a green LED light for indication of mains power connection. When the chair is connected to mains power the LED is green, if the chair is disconnected to main power the LED is off.

Controls

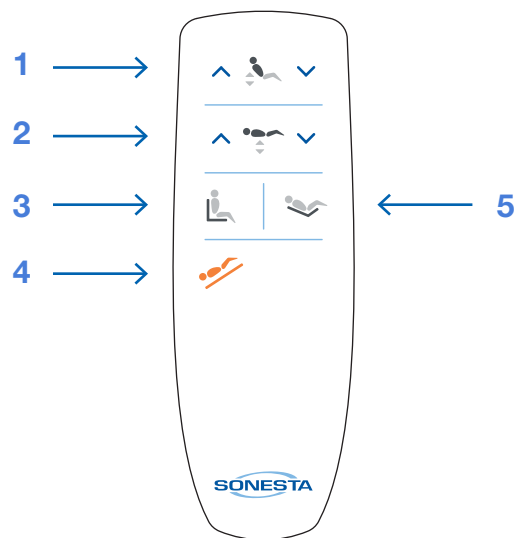
Sonesta P2

The Sonesta P2 has two motors which are operated with the foot control or hand control.

Hand Control

Press one button at a time and hold until the desired position is reached.

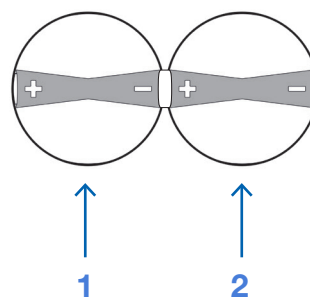
1. Back rest, up / down adjustments
2. Height of table, up / down adjustments
3. Sitting position (pre-set position)
4. Trendelenburg (pre-set position)
5. Uro-position (pre-set position)



Foot Control (optional)

Press one button at a time and hold until the desired position is reached.

1. Back rest, up / down adjustments
2. Height of table, up / down adjustments



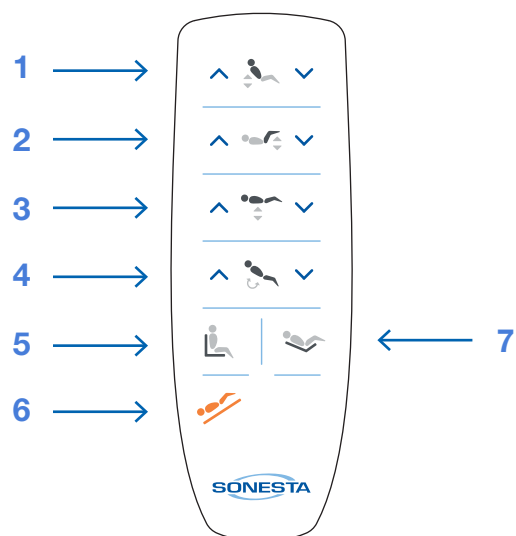
Sonesta P3

The Sonesta P3 has three motors which are operated with the foot control or hand control.

Hand Control

Press one button at a time and hold until the desired position is reached.

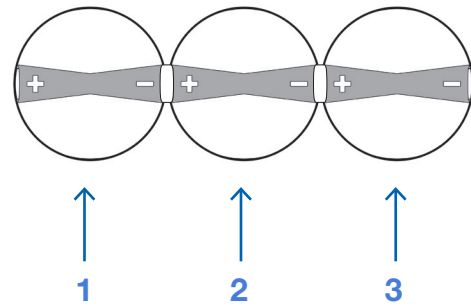
1. Back rest, up / down adjustments
2. Seat up / down adjustments
3. Height of table, up / down adjustments
4. Tilting position up / down adjustments
5. Sitting position (pre-set position)
6. Trendelenburg (pre-set position)
7. Uro-position (pre-set position)



Foot Control (optional)

Press one button at a time and hold until the desired position is reached.

1. Back rest, up / down adjustments
2. Height of table, up / down adjustments
3. Height of seat, up / down adjustments



How to pair the foot control with the P2/P3

1. Open the battery cover on the back of the foot control. Insert the two batteries and move the foot control within two meters of the chair.
2. Activate direct pairing by pressing the circled button under the battery cover for three seconds, this will activate the buzzer sound.
3. Move the foot control within 10 cm of the control box of the chair until the buzzer frequency changes from slow to fast.
4. Confirm the pairing by pressing the circled button again under the battery cover. A double beep from the foot control indicates that the pairing is OK.
5. Mount back the battery cover.

Low battery indication

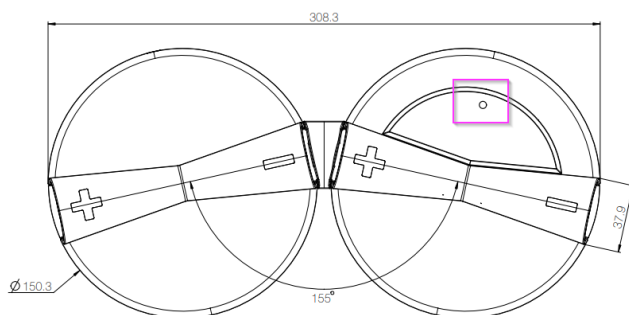
The chair comes with two AAA batteries inserted in the foot control.

Depending on usage, the lifetime is expected to 3-4 years.

When the wireless foot control is activated and the battery voltage is between 2.4 V and 2.2 V, the LED will flash with 250 m/s ON/OFF 4 times and then turn off.

When the battery voltage is lower than 2.2 V, the LED does not flash anymore and the battery must be replaced.

The LED is located in the top right corner of the wireless foot control, underneath the cover.



How to mount batteries correctly

Underneath the wireless foot control, remove Phillips screws and remove battery cover. Place batteries correctly to ensure polarity and place battery cover again.

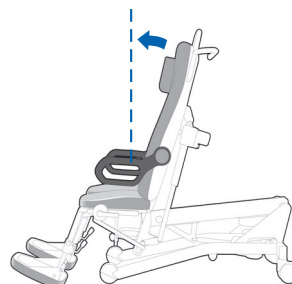
Maneuvering Instructions



WARNING: Before raising, tilting or repositioning the chair, verify that the patient is stable and correctly positioned on the seat. During procedures and chair movement, the patient should remain supported by the backrest whenever possible. Do not operate the chair if the patient is sitting too far forward, unstable, or placing significant body weight on the leg rests or footrests.

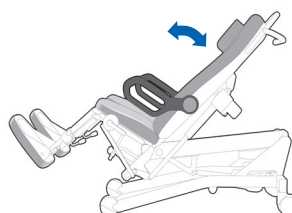
Sitting position

1. Hold down the sitting position button until the unit stops moving.
2. For adjustments, use the four adjustments buttons until you reach the desired position.



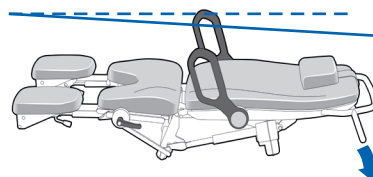
URO-position

1. Hold down the URO-position button until the unit stops moving.
2. For adjustments, use the four adjustments buttons until you reach the desired position.



Trendelenburg position

1. Hold down the Trendelenburg position button until the unit stops moving.
2. For adjustments, use the four adjustments buttons until you reach the desired position.



How to Change the Pre-set Positions

Sitting position:

To adjust the pre-set positioning named sitting position put the table in the desired position. Then press the buttons for back up and sitting position at the same time for minimum 5 seconds. The new and changed position will be confirmed by a short beep from the control unit.



URO-position:

To adjust the pre-set positioning named the URO position put the table in the desired position. Then press the buttons for back up and URO position at the same time for minimum 5 seconds. The new and changed position will be confirmed by a short beep from the control unit.



How to reset the pre-set positions to factory default

To reset any adjustments that have been made to the pre-set positionings, press the buttons for sitting position and URO position at the same time for minimum 5 seconds. The default will be confirmed by a short beep from the control unit.



CAUTION: Both the sitting position and the URO position will be re-set to factory default by doing this.

How to reset a fatal error

To reset a fatal error, press the buttons for lift up and lift down at the same time for minimum 5 seconds or until the control unit stops to beep.



Recommended Patient Entering/Exiting

Entering the table

To ensure the safety of the patient, the chair should always be in a lowered seated position with the back rest in an up-right position with footrests folded up to allow the patient to sit down. Once the patient is positioned the footrests can be lowered, and the table raised for use.

Exiting the table

To ensure the safety of the patient when exiting the chair, set the chair to a lowered seated position and fold up the footrests. The patient can then stand up from the table.



WARNING

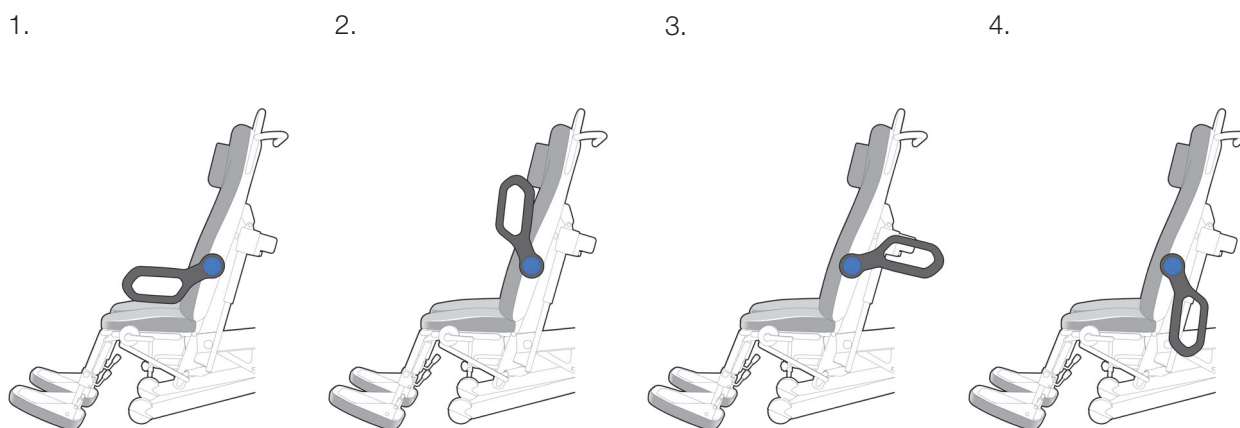
The patient should never stand on the footrests to enter and exit the table. The footrests are capable of a weight load of 50 kg / 110 lbs each.

Accessories

The Sonesta chairs have several accessories, which are standard or optional. All of our accessories are designed with a user-friendly perspective and are easy to mount and adjust. Before usage: always check that the accessories are mounted correctly.

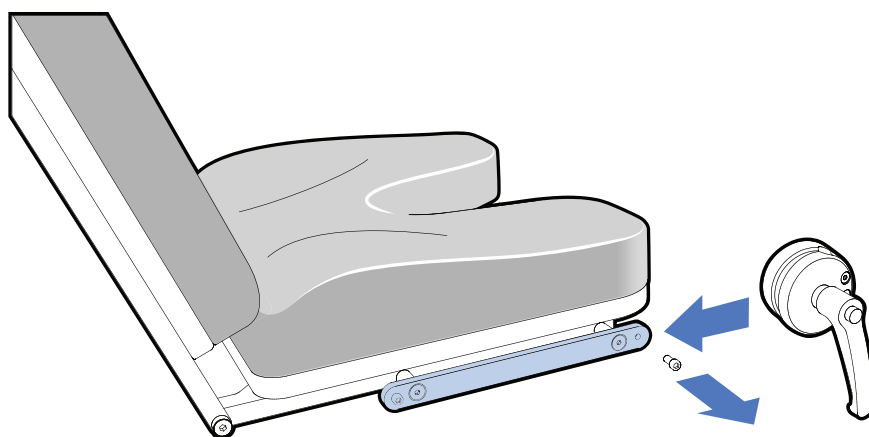
Arm rest

To move the armrests, press the blue button and swivel the armrest into the desired position.

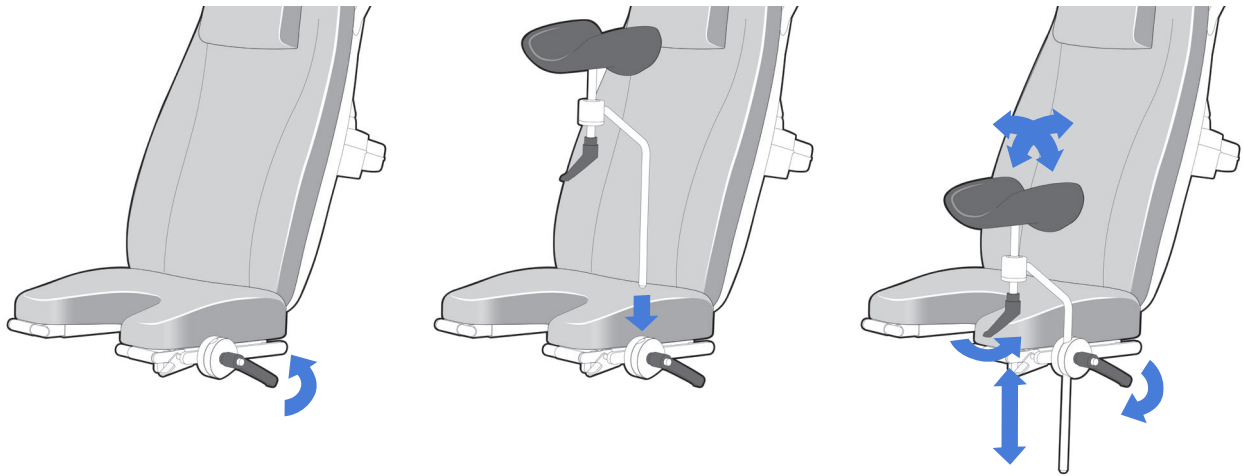


Leg rest holder

Remove the 5m screw in order to mount the leg rest holder, see blue arrows, put the screw back to prevent the leg rest holder to slip out. Repeat the steps on the other side of the chair.

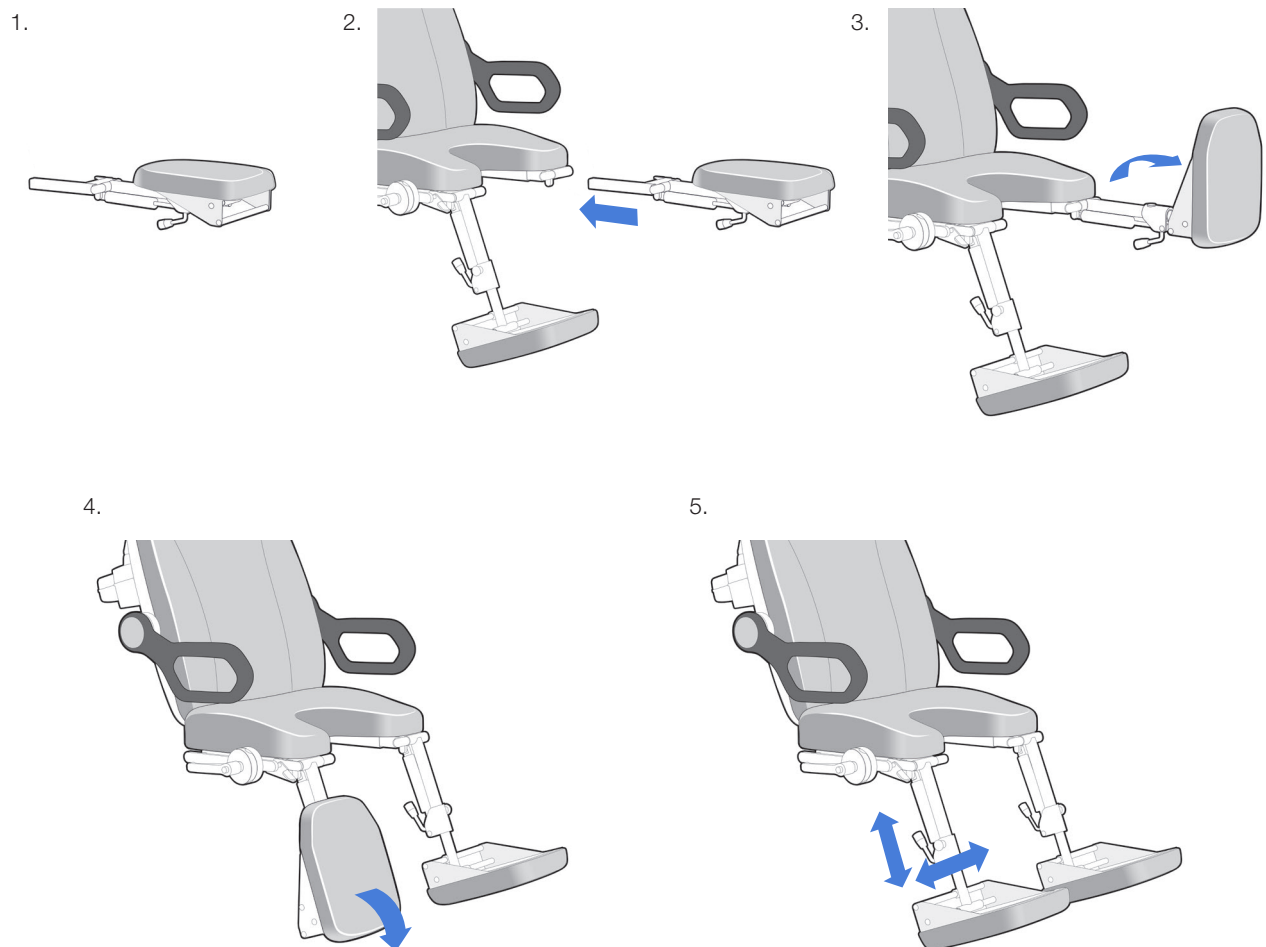


Leg rest This leg rest has a ball and socket construction, setting the leg rest in any direction. Secure or release the grip as to angle it into the desired position.



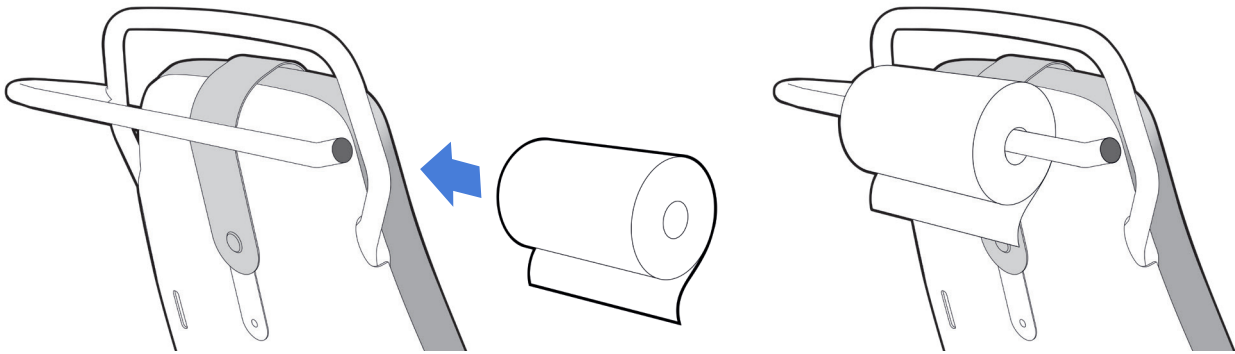
Foot rest

Easily attached and removed with a click-off system. Adjustable in length as well as width, can slide outwards. Push lever to fold up.



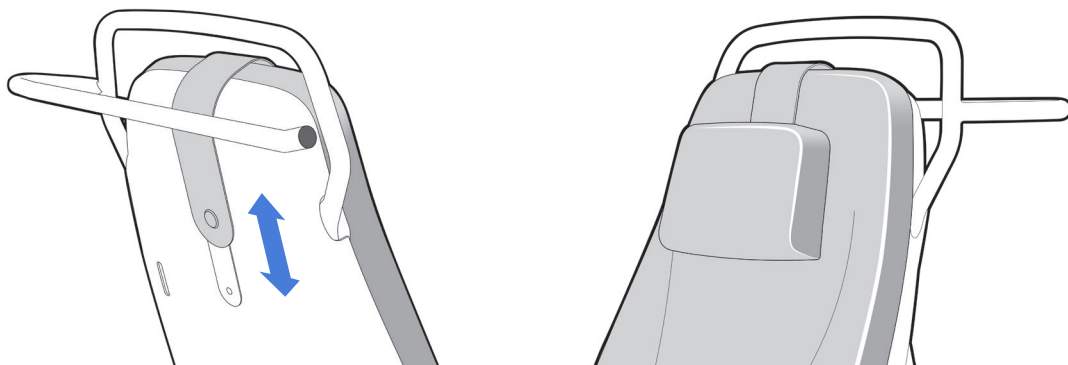
Paper roll holder

Simply slip the paper roll onto the paper roll holder.



Neck pillow

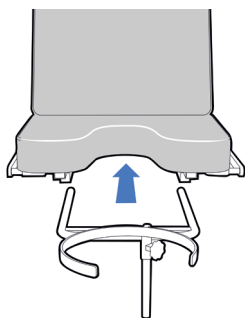
Put the neck pillow band on the magnetic plate on the back and adjust the length into desired position.



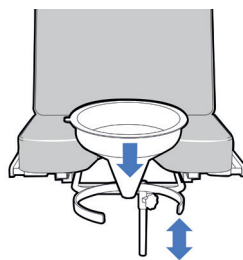
Plastic funnel drainage — adjustable height

Installation:

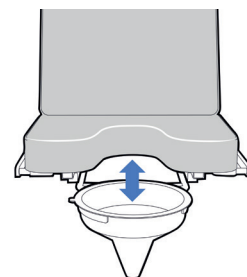
1.



2.



3.



Classification

Degree of Protection Against Electric Shock:

Type B (Body): equipment providing particular degree of protection against electric shock, particularly regarding allowable leakage current.

Degree of Protection Against Harmful Ingress of Foreign Objects and Water:

IPX6

Degree of Safety in Presence of Inflammable Anesthetics:

The device is not intended for use with flammable anesthetic gases.

Mode of Operation:

Intermittent operation.

Duty Cycle:

2 minutes per 18 minutes.

Technical Lifetime

These products have a technical lifetime which, by Sonesta Medical AB, is considered to be 7 years. At the time of delivery the products fulfil the existing regulations and standards, but as all other electro-mechanical products, the Sonesta P2 and P3 chairs are subjected to age and wear, and even though the products undergo regular and prescribed service, Sonesta Medical AB can not guarantee the products' safety after the expiry of the technical lifetime.

Technical Data

Model

Sonesta P2, two motors (lift, back)

Sonesta P3, three motors (lift, seat, back)

Power Supply

Power consumption P2 / P3:

- 100V 430VA 50/60Hz
- 120V 430VA 50/60Hz
- 230V 430VA 50/60Hz

Type of Protection: Class 1, Type B.

Operating Conditions

Temperature +10°C to +40°C (50°F to 104°F)

Humidity 30% – 75%.

Atmospheric pressure 700hPa – 1060hPa

Storage Conditions / Transportation Requirements

Temperature -10°C to +50°C (14°F to 122°F)

Humidity 10% – 80%rh @ 30°C not condensing

Atmospheric pressure 700hPa – 1060hPa

Disposal

The chair should be disposed or recycled according to local laws and regulations.

Measures and Weights

Sonesta P2 chair:

Unit	Width (max.)	Length (max.)	Height (min.-max.)	Chair weight (Net)
Metric (cm)	69	134 W/O extension cushions 179 W/ foot rest 182 W/ extension cushions	40-105	80,5 kg
US (Inches)	27	53 W/O extension cushions 71 W/ foot rest 72 W/ extension cushions	15-41	177 lbs.

Sonesta P3 chair:

Unit	Width (max.)	Length (max.)	Height (min.-max.)	Chair weight (Net)
Metric (cm)	69	134 W/O extension cushions 179 W/ foot rest 182 W/ extension cushions	40-105	83 kg
US (Inches)	27	53 W/O extension cushions 71 W/ foot rest 72 W/ extension cushions	15-41	183 lbs.

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