



User Manual

Video Fluoroscopy Table F3

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Important Information

Important information regarding this user manual and usage of the Sonesta F3

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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.

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: See below and in the user manual.

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 video urodynamics, imaging examinations, fluoroscopy procedures, ultrasound, vasectomy, colonoscopy 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 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).
- 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.

- 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 equipped with a emergency battery back-up, the battery is charged when the AC-power cord is connected to the power source.
- Always keep the power cord connected to the power source when in use.

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.
- Remove drainage reolder/funnel or other option fitted beneath the seat cushion before setting the chair in standing position.
- Make sure the table is in the highest position before setting the table in standing position.
- A patient should never enter the chair by using the foot rests to stand on. This may cause tipping of the chair, and can cause patient injury.

Limitations and Warnings



- 250 kg The product is tested for a patient weight of maximum 250 kg/ 551 lbs.



- 50 kg Ensure that the patient does not sit on the foot rests, when folded up. The table may become unstable, causing injury if maximum weight of 50 kg / 110 lbs is exceeded.



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



A patient should never enter the chair by using the foot rests to stand on while the F3 is in a chair position or in a vertical position, unless the foot rests are flushed with the floor.

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 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 surgical 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 damped 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 ®
- Ytdesinfektion 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.

Mattress Cleaning Instructions

The following cleaning and decontamination materials are known to be compatible with medical devices made of coated-flexible-foam and UltraFoam materials and rigid formed plastics, including rigid parts reinforced with carbon fiber or glass fiber:

- Rubbing alcohol (45 % isopropyl alcohol).
- Bleach solution (10 % household-type bleach in cold, cool or warm water).
- General-purpose soap- or detergent-type cleaners ("409", etc.) at their normal manufacturer-recommended strength.

Avoid the following types of materials for cleaning:

- Detergent cleaners/disinfectants that also contain hydrocarbon solvents such as butyl acetate, acetone, etc., which can dissolve plastic materials. Such cleaners are sometimes described as being intended for removal of graffiti, or heavy degreasing.
- Ammonia solutions, which can cause some plastics to turn greenish.
- Detergent-type cleaners at abnormally high concentrations (i.e. concentrated cleaners, intended to be used in diluted form, that instead are used in undiluted, concentrated form).
- Steam.
- Water or other cleaning materials at temperatures higher than 150°F/66°C.
- Certain grades of "Vespene" and similar sterilants/cleaners.
- Acids of any kind.
- Rough brushes, aggressive scrubbers, sharp objects, and abrasive materials.
- Iodine solutions, such as "Betadine".

The most common clinical contaminants, i.e. skin oils, blood, urine, vomit, feces, contrast medium, etc., are cleanable from patient contact surfaces of CFI coated- flexible-foam, UltraFoam and rigid formed plastic products using general-purpose soap- or detergent-type cleaners ("409", etc.) at their normal manufacturer-recommended strength. If needed, rinse with clear water (temperature no higher than 150°F/66°C) to remove gross contamination before applying the cleaner. Dried contamination may need to be kept moist for an extended period to re-hydrate the contaminant material before cleaning.

Avoid vigorous scrubbing, stiff brushes, sharp objects such as knives and scrapers, abrasive cleansers, abrasive pads, steel wool, and similar cleaning methods that are capable of causing mechanical damage. Whenever possible, vomit and other aggressive contaminants should be wiped or washed off surfaces promptly so as to minimize the likelihood of permanent chemical-attack effects.

Symbols

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

	Attention, see accompanying documents		Duty cycle icon, duty cycle 2 min per 18 min
	Type B, equipment providing a particular degree of protection against electric shock		Protective earth (ground)
	The device complies with the Medical Device Regulation (EU) 2017/745 on medical devices		Battery back-up capacity: approximate 5 minutes with maximum weight
	UL Classification Mark		Maximum safe workload icon, maximum safe workload 250 kg / 551lbs
	Degree of protection, EN 60529 (ingress of water and foreign objects)		Alternating current
	CAUGHT WARNING: The symbol highlights a risk of physical danger to the user or operator (ensure that hands and equipment are clear of the steel beam on the foot rest when changing its positions.)		CAUGHT WARNING: The symbol highlights a risk of physical danger to the user or operator (ensure that hands, feet and equipment are clear of the steel beam when lowering the table).

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.



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



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



CAUGHT WARNING: The symbol highlights a risk of physical danger to the user or operator (ensure that hands and equipment are clear of the steel beam on the footrest when changing its positions.)



CAUGHT WARNING: The symbol highlights a risk of physical danger to the user or operator (ensure that hands, feet and equipment are clear of the steel beam when lowering the table).

Explanations of the symbols found in the user manual



Moves up



Moves down



Secure



Release



Adjustable in shown directions



Adjustable in shown directions



Push

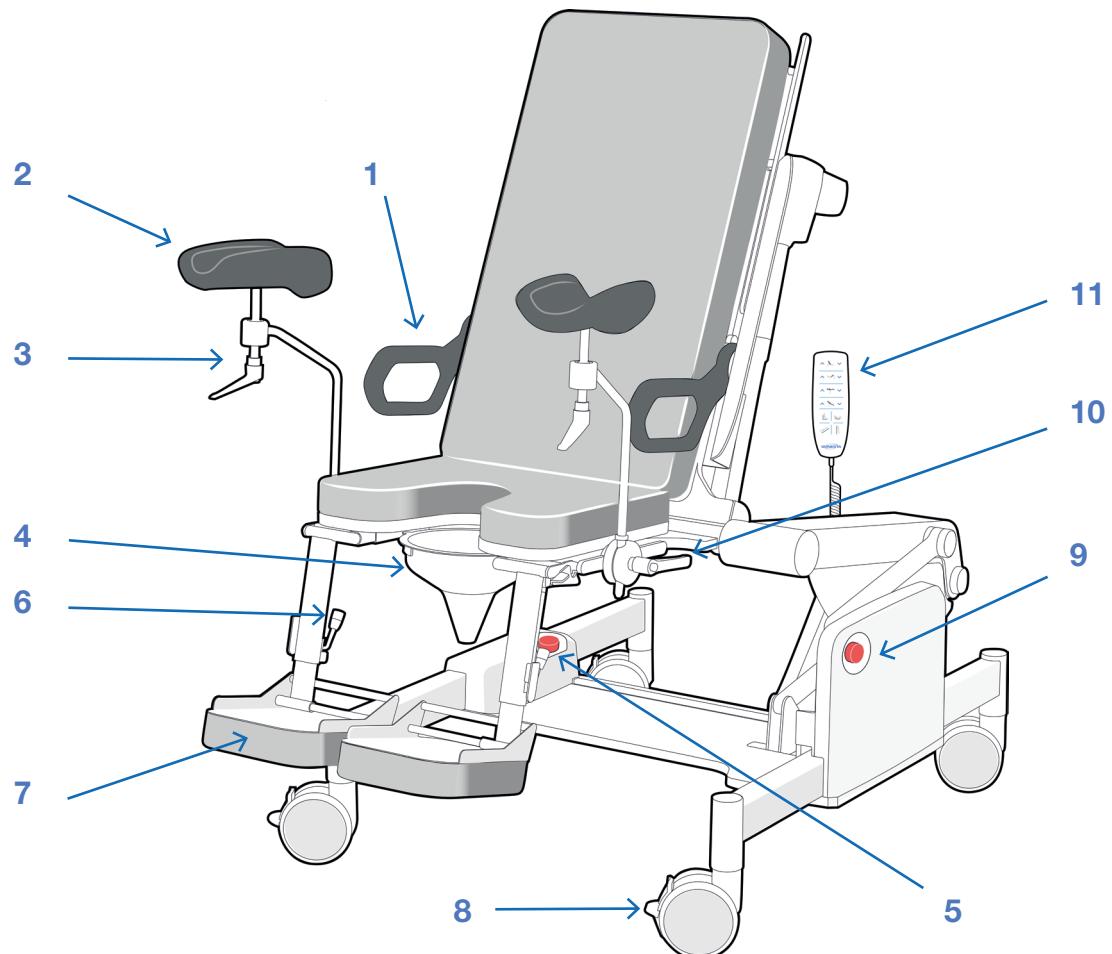


Insertion direction (part)

Video Fluoroscopy F3

Intended Use

The F3 is intended to position the patient in a desired position during urodynamics or video fluoroscopy examinations and procedures.



Description

1. Arm rest
2. Leg rest
3. Leg rest handle, release the screw to adjust the angle of the leg rest and then secure
4. Funnel, holder and bracket
5. Stop switch
6. Adjustment handle for foot rest, use handle to set position
7. Fold up foot rest
8. Wheels with locking mechanism
9. Stop switch
10. Leg rest holder, release the screw to adjust the height of the leg rest or the leg rest holder
11. Hand control

Operation Specification

Operation Range



General Operation

The table is operated with the hand control.

Maximum Duty Cycle

2 minutes per 18 minutes

Stop Switches

Use one of the stop switches if you want to terminate all movements of the table.

Activate the stop switches by pushing the stop knob.

Deactivate by pulling the knob out and turning it to the right.

Battery Back-Up System

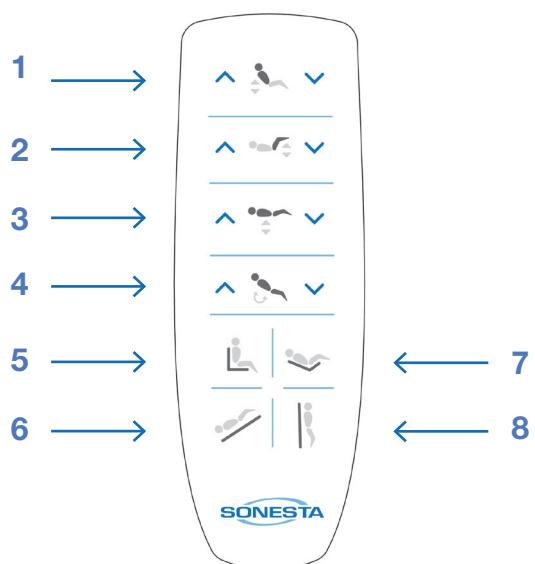
The back-up battery charges every time the power cord is connected. The battery turns on automatically when the power is cut. The estimated back-up capacity is 5 minutes.

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

Hand Control

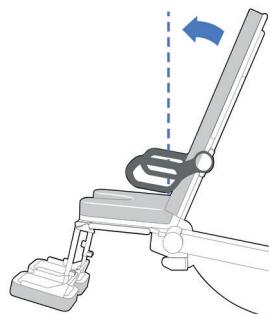
1. Back rest, up / down adjustments
2. Seat, up / down adjustments
3. Height of table, up / down adjustments
4. Pelvic rotation, up / down adjustments
5. Sitting position (pre-set position)
6. Trendelenburg (pre-set position)
7. Uro-position (pre-set position)
8. Standing position (pre-set position)



Maneuvering Instructions

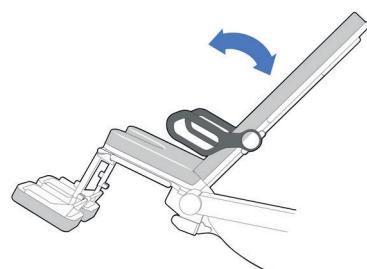
Sitting position

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.



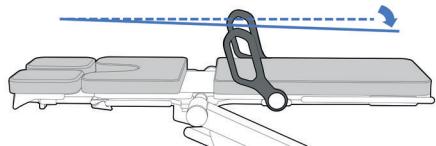
URO-position

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

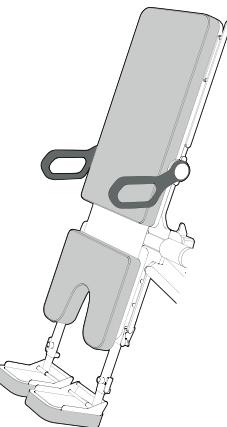
1. Hold down the Trendelenburg position button until the unit stops moving.
2. For adjustments, use the four adjustments buttons until you reach the desired position.



Standing position

The table can be placed in a standing position, this is described in the following section. If you intend to use the table in a standing position daily we suggest that you use the restraint straps for increased patient safety.

1. Remove the funnel and the funnel holder, drainage receptacle or other accessory fitted beneath the seat before setting the table in standing position.
2. Make sure the table is in it's highest position before setting the table in standing position.
3. Make sure that the patient weight is evenly distributed in between the two foot rests.
4. If a patient weighs more than 100 kg /220 lbs, never put the table in a standing position unless the foot rests are flushed with the floor. The two foot rest can together bear a weight of maximum 100 kg/220 lbs.
5. Hold down the standing position button until the unit stops to move.
6. For adjustments, use the four adjustments button 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

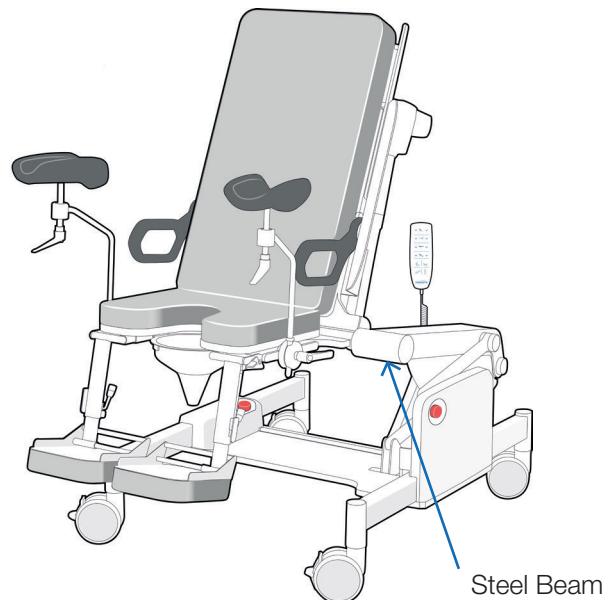
To reset any adjustments that have been made to the pre-set positionings, press the buttons for standing position and URO position at the same time for minimum 5 seconds. The default will be confirmed by a short beep from the control unit.



CAUTION: Both the sitting position and the URO position will be re-setted 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.



When operating the table make sure that there are no objects or limbs near or under the steel beam while lowering the table. Improper usage can result in patient or user injury.

Recommended Patient Entering/Exiting

Entering the Table

To ensure the safety of the patient, the table should always be in a lowered seated position, with the foot rests folded up to allow the patient to sit down. Once the patient is positioned the foot rests can be lowered, and the table raised for use.

Exiting the Table

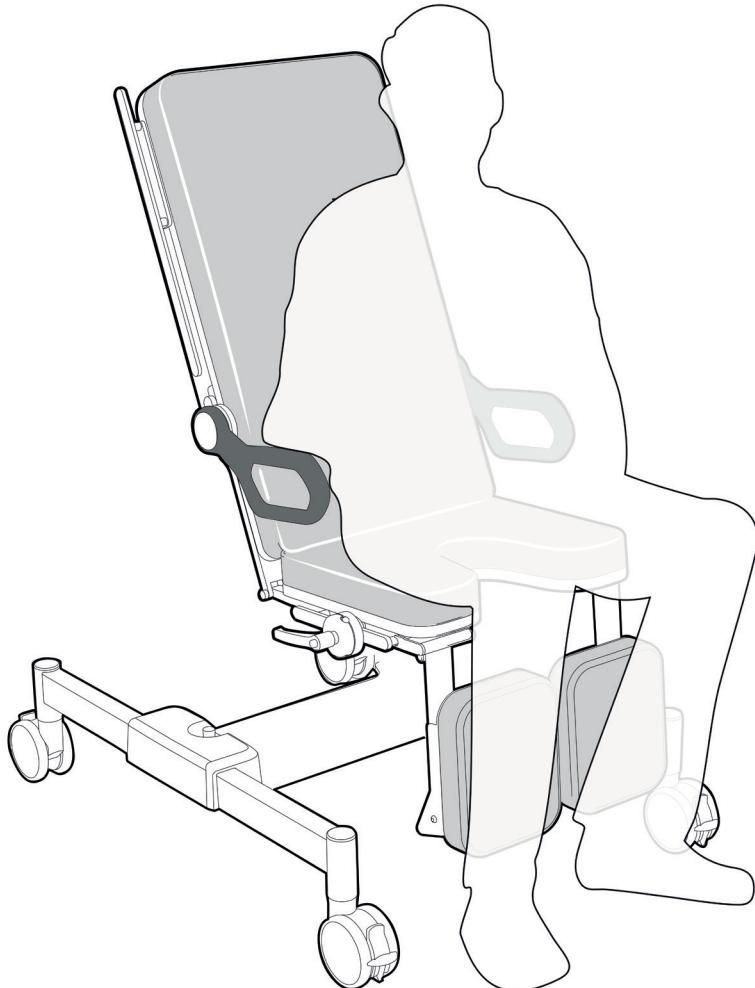
To ensure the safety of the patient when exiting the table, set the table to a lowered seated position and fold up the foot rests. The patient can then stand up from the table.

WARNING

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

WARNING

 Overloading the table's maximum weight can cause the table to bend downwards on the patient's right side, which can result in discomfort for the patient.



Accessories

The F3 has several accessories, either standard or optional.

Before usage: Always check that the accessories are mounted correctly to the table.

Standard accessories

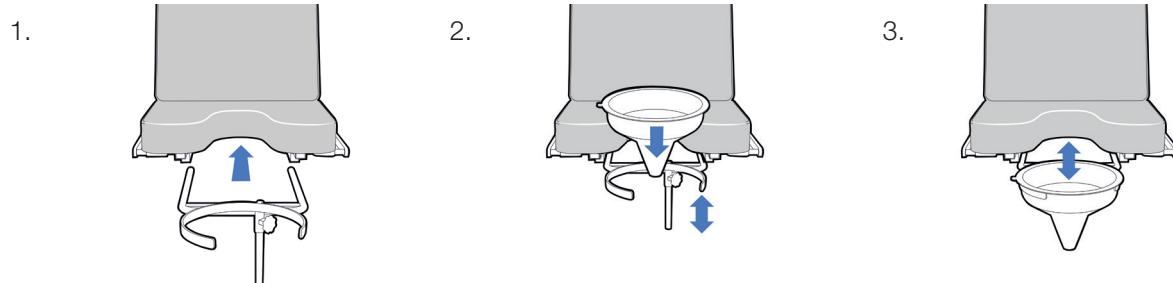
- 1 Hand control
- 1 Plastic funnel w/drainage and holder
- 2 Side rails
- 2 Arm rests
- 2 Leg rest holders
- 2 Leg rest
- 2 Fold up foot rests
- 1 Mattress with cutout
- 1 Back-up battery

Optional accessories

- Optional arm rest
- Mattress without cutout
- Bolster

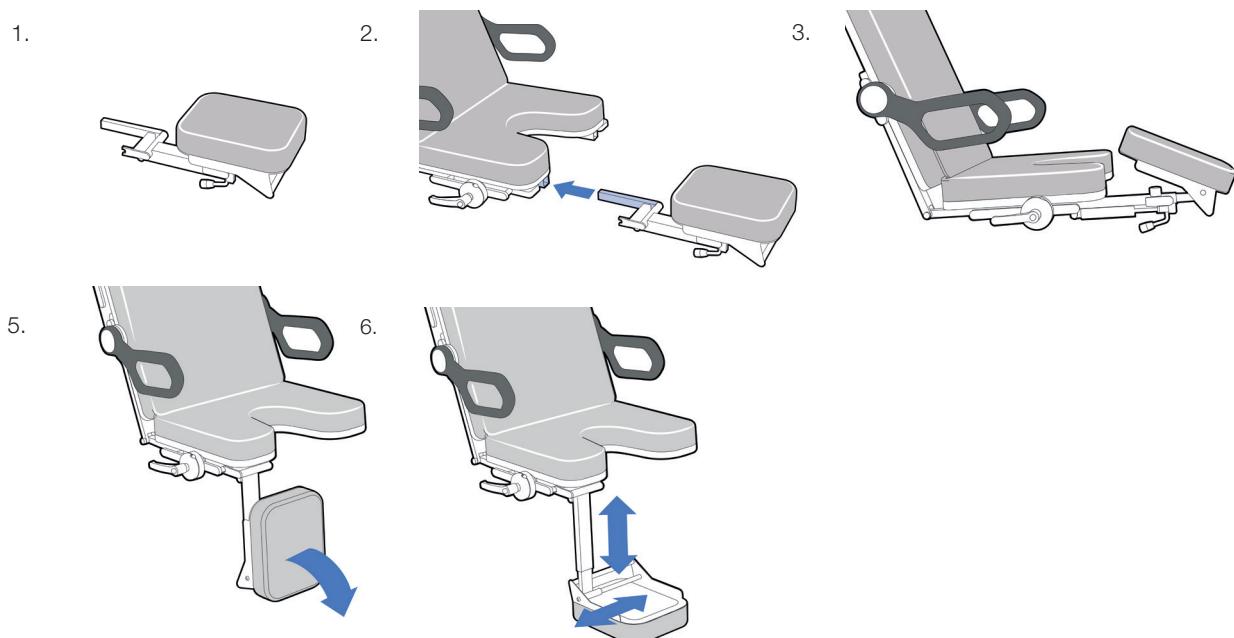
Plastic funnel with drainage – adjustable height

Installation:



Foot rests

Installation:



When lowering the foot rests, make sure to not stand directly below the placement of the foot rests as they are being lowered to the ground. Improper usage can result in patient or user injury.

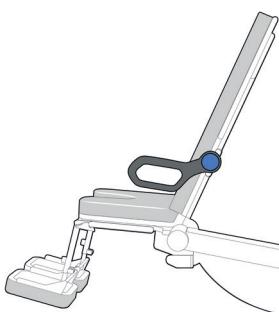


Be cautious when adjusting the foot rest with the handle, do not place any fingers or hands on the steel beam while adjusting the foot rests. Improper usage can result in patient or user injury.

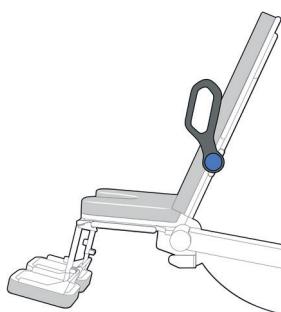
Arm rest

To move the arm rests, press the blue button and swivel the arm rest into the desired position.

1.



2.



Optional configuration: You can choose to remove the arm rest on the patient's right side and add an optional arm rest.

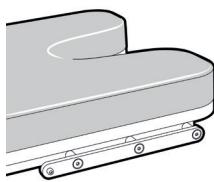


WARNING: The arm rests are not intended for patient weight support.

Leg rest holder

Installation (5 mm Allen wrench required):

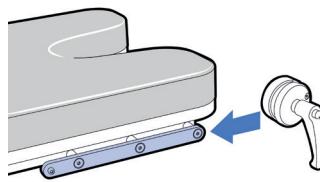
1.



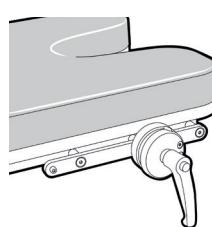
2.



3.



4.



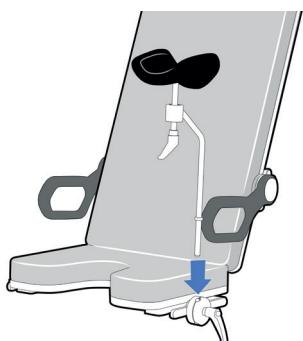
Leg rest

Installation:

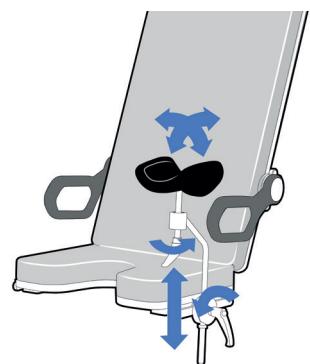
1.



2.



3.



The leg rests include a block ring that prevents the leg rests from being lowered too far. The block ring must always be mounted onto the leg rest, if this is not used accordingly usage of the leg rests can result in patient or user injury.

Technical Data

Model

Video Fluoroscopy Table, Sonesta F3, three motors (lift, seat, back).

Power Supply

100 V 430 VA 50/60 Hz.

120V 430 VA 50 Hz.

230V 430 VA 50 Hz.

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 -5°C to +40° (23°F to 104°).

Humidity 10% – 80%rh.

Including Condensation.

Atmospheric Pressure 700hPa – 1060hPa.

Disposal

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

Measures and Weights

Video Fluoroscopy Table F3

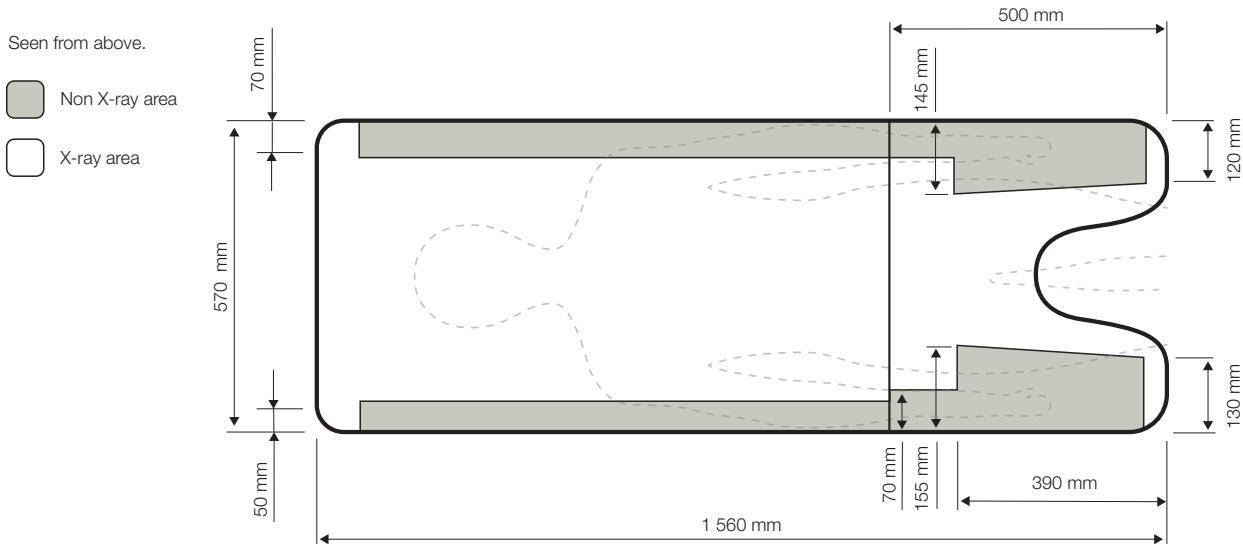
Unit	Width (max.)	Length (max.)	Height (min.-max.)	Chair weight (max.)
Metric (cm)	115	156 W/O extension 194-205 W/ extension	49-137	250 kg
US (Inches)	45	61 W/O extension 76-81 W/ extension	19-53	551 lbs.

Seat tilt: 0° to vertical 90°

Back tilt: vertical 90° to -17° Trendelenburg

Maximum patient weight: 250 kg/551 lbs

Imaging Area



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

This product has a technical lifetime, which by Sonesta Medical AB is considered to be 10 years. At the time of delivery the product fulfils the existing regulations and standards, but as all other electro-mechanical products, the Sonesta Video Fluoroscopy table is subjected to age and wear, and even though the product undergoes regular and prescribed service, Sonesta Medical AB can not guarantee the product's safety after the expiry of the technical lifetime. Sonesta Medical AB recommends that the product is taken out of service after latest 10 years. By Sonesta Medical AB provided spare parts and service after the expiry of the specified technical lifetime does not mean an extension of Sonesta Medical AB's liabilities.



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