STILLE

Surgical perfection. For life.

imagiQ3™ Legacy

Operating table

User manual

2024-10-23

Patents: USA 9,125,782, Japan, 6154888, Sweden 1250370-2, Germany 602013021761.0, EU 2836130, EU 002025551, USA US D540,949, Italy 80906, UK 2096131, France 005422, Germany 40009025.2, Benelux 32806-01, 32806-02. (Expired USA 6681423, EU 1267723, Germany 60122299.7) Trademarks: True Free Float™, ISO ROLL™, Low-Dose Enabler™ and imagiQ3™ are patents and trademarks owned by STILLE AB.

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 using the device. This manual supersedes any prior information.

The following imagiQ3™ Legacy operating table models are covered by this manual: 550-1700, 550-1701, 550-1702, 550-1703 imagiQ3 with regional adaptations.

The original signed EU declaration of conformity can be obtained upon request.

Medical device risk class:	Class I
GMDN code:	40658
FDA Regulation Status:	Class I Exempt 878.4960 (GDC)
FDA List No.:	E130044

Warranty terms for imagiQ3™ Legacy operating table:
To be able to benefit the full warranty terms of the imagiQ3™, the installation report that comes enclosed with the documentation must be completed online (https://www.STILLE.se/register-product/) at the time of installation, or filled in and returned to installation@stille.se.

Information regarding STILLE warranty provisions can be found on STILLE´s website, http://www.STILLE.se.
If you do not find the installation report please do contact qa@stille.se for a copy.
It is recommended that all repairs are carried out by authorized personnel.

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Sweden

ETL CLASSIFIED

Intertek

This user manual was issued: 2024-10-09

TABLE OF CONTENTS

SAFETY INFORMATION

Always follow the manufacturer's instructions!
Read carefully and always follow the instructions for use (IFU) in this document (user manual) before first using the imagiQ3™ operating table. This manual has been written to ensure that you will handle the table in a safe and correct manner.

Precautions

- Always place a surgical drape between the patient and table. Direct contact between the patient and table is not intended.
- The manual must always be stored within reach of the operating table.
- The table, its use and maintenance does not require any special training outside the requirements defined in this manual.
- Keep the patient under constant observation.
- Use precaution as the table can be activated by another operator.
- Particular precaution must be taken for positioning with a foot control to avoid unintended activations and cause unwanted movements.
- The table shall be installed and put into service and be maintained according to information in the user and service manual.
- Do not use a malfunctioning device or accessory.
- Max safe work load is 661lb/300kg in normal position and 330lb/150kg in reverse position.
- Always use certified grounded power cords, for US market use only grounded hospital grade cords.
- Use only spare parts and accessories approved by STILLE AB.
- The table shall be centered before and during transport.
- When moving the table it is recommended to use two persons.
- It is recommended to remove any arm rests or armboard when transporting the table.
- All table movements cease immediately if the button in question is released.
- If another mattress is used than the original mattress, it must be of antistatic properties and a grounding connection must be established with the table chassis.
- Never place surgical cloths/ sheets so that the grounding points are totally covered. Surgical cloths/ sheets might prevent electric discharge to anti-static floors.
- Position the table to allow for easy connection and disconnection of the mains power cord.
- Centre the table before patient loading or unloading.
- Secure and keep the patient under observation when changing the position of the table (it is recommended to use a leg/body strap to secure the patient during procedures).
- Ensure that hands, feet and equipment are clear of the frame assemblies and moving parts when changing positions of the table. Risk of pinch injury.
- Remove any obstacles under or near the tabletop before lowering or tilting the operating table. It could tip over.
- Center the tabletop longitudinally over the column before lowering the free end of the tabletop.
- Only use the table for supported procedures, do not use the tables for other procedures.
- To isolate the imagiQ3 operating table from the power supply, disconnect the power cable from the medical equipment. (ME Equipment = MEDICAL ELECTRICAL EQUIPMENT)
- Any serious incident that occurs in relation to the table should be reported to STILLE AB and the competent authority of the Member State / country in which the user and / or patient is established.
- Always comply with local rules and regulations for decommissioning / disposal of the table and its components. The table contains batteries, electronics, batteries and hydraulic oil.
- All service and repairs shall be performed without any patient placed on the table.
- Replenishment of oil into the hydraulic system shall only be done by service personnel.
- Addition to the Service Manual: Never overfill the hydraulic system when refilling oil (version dependent).
- Skin contact with hydraulic fluid may cause skin irritation. Clean and wash with soap and water.
- Always have the table in parked position except for transport.
- Always wear protective gloves and eye wear when performing work such as service, repair or maintenance.
- Always follow local laws and regulations for personal protection.
- Always follow local laws and regulations for waste handling and decommissioning of products and substances.
- Always clean and disinfect parts before disposal.
- Preventive maintenance and repairs of the table shall always be performed according to the service manual and be performed by authorized personnel.
- Replacement of the batteries shall only be done by service personnel.
- Service and repair must follow the LOTO instruction in the service manual.
- It is not allowed to lift the table in the tabletop.
- If the table is being disturbed or is suspecting to disturb other equipment, it is recommended to connect the tables power cord and the PROTECTIVE EARTH CONDUCTOR.
- If the hand control is used inside the sterile field, it is recommended to cover the hand control with a sterile draping.
- UV-sterilization is not suitable for disinfecting the table or its accessories.
- Always use the cable lock nuts or rings to secure the cable of control and display units.
- The emergency trend controller must be charged annually during preventive maintenance.
- The built-in batteries are of type Lithium-ion, see local regulations for training, storage, handling, personal protection, recycling, transport and fire preventions. It is recommended to use AVD fire extinguisher.

Warnings

- The imagiQ3 table protection classification IP24, is equivalent to protection against contact with hazardous parts larger than 12.5 mm and a level of protection against harmful ingress of splashing water. If there is any ingresses of water, it will not have any harmful effect on the device.
- Always check that there is no liquid in the appliance inlet before connecting the power cord to the table.
- imagiQ3 should not be used adjacent to or stacked with other equipment because it could result in improper operation. If adjacent or stacked use is necessary, imagiQ3 should be observed to verify normal operation in the configuration in which it will be used.
- Use of accessories, transducers, cables, and spare parts other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of the imagiQ3 and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the imagiQ3 including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- The patient must not lie on conductive mattresses or on damp bedding when defibrillators, defibrillator monitoring screens or high frequency apparatus are being used and avoid any contact with metal components or accessories present on the operating table. This could result in patient burns, explosion hazard or electrical shock of the patient or the operator.
- To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.
- There is a risk of reciprocal interference with other devices normally used in the investigations or for the treatment given.
- Do not subject the operating table to electromagnetic fields that exceed the applicable standards for radio frequency equipment, such as diathermy apparatus, defibrillators and defibrillator monitors, or other devices that might cause potential electromagnetic or other interference. Only use the imagiQ3 with medical equipment complying with EN 60601-1, EN 60601-1-2.
- No modification of this equipment is allowed without authorization of the manufacturer.
- During operation, make sure to not touch the patient and at the same time, touch external ports, connectors of contacts, fuse holders, or accessible parts inside the imagiQ3.
- For moving safely over a threshold 15 mm or higher, it is required to be two persons.
- The INTERNAL ELECTRICAL POWER SOURCE (the battery) is to be used if the integrity of the PROTECTIVE EARTH CONDUCTOR or the protective earthing system in the installation is in doubt.
- If electrical disturbances are noticed, it is recommended to disconnect the AC power and only use the INTERNAL ELECTRICAL POWER SOURCE (batteries) as means of powering the table during the procedure.
- Always connect the table's potential equalization connection point to protective earth.
- Do not operate the device if the protective covers/guards are removed, risk for personal injury.
- The device is not intended for use with flammable anesthetic gases. A possible explosion hazard exists, and personal injury or equipment damage could occur
- Never use a broken or damaged product.
- Do not use the device if it is defective or shows fatal errors; if needed to complete an ongoing surgery it might be acceptable to use the device, but only under careful supervision of the responsible surgeon.
- Potential hazardous biological material could ingress under the protective covers. Wear protective gloves and eye wear, clean and disinfect before any work is performed.
- There is a risk of electrical shock when the protective covers are removed.
- NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to make mitigation measures, such as relocating or re-orienting the equipment.
- During HF surgery, the table should be in standby mode; no table movements or functions should be requested.
- The touch display (optional) should not be used during HF surgery; it is recommended route the HF surgery cables away from the touch display.
- As the device is an electrical equipment, always follow local laws and regulations regarding disposal, scrapping, decommission and waste handling of the device and its components.
- NOTE: Testing after modification, service, repair and maintenance before PUTTING INTO SERVICE must be performed according to the service manual.
- After any REPAIR and/or MODIFICATION of the ME EQUIPMENT conducted not in accordance with MANUFACTURER's instructions, the changes to the equipment shall be assessed with respect to the applicable design standards, and to the requirements of this standard prior to returning to service.
- Do not use in an oxygen rich environment.
- Do not activate lateral tilting or return to zero position during transport of the table. Make a habit of switching off the table before any transport is begun.

SAFETY INFORMATION

Symbols

ISO 7010-W001 General warning sign

Emergency back up hand control

Instruction for emergency Trendelenburg

CE marking of conformity

IEC 60417-5840 Type B, equipment providing a particular degree of protection against electric shock

IP24 IEC 60529 Degree of protection, (ingress of water and foreign objects)

Duty cycle icon, duty cycle 10%

IEC 60417-5021 Potential equalization connection point (Equipotentiality)

IEC 60417-5019 Protective earth ground

IEC 60417-5017 Functional earth (general ground point)

WEEE symbol: Do not dispose of electrical components in household or municipal waste

LI-ion IEC60417-5001B Battery info

Connection for hand control

Connection for pan handle

Direction of movement

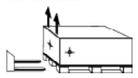
ISO7000-1321B Mass of mobile equipment

eIFU indicator, scan code to access service portal for support and downloadable material

Max safe work load (SWL) 661lb/300kg in normal position
and 330lb/150kg in reverse position.

Emergency trend battery (for manual Trendelenburg)

Instructions for emergency Trendelenburg



Forklift -lift the crate on this side, if crossed over, do not lift

Do not sit

SAFETY INFORMATION

ISO 7010-M002 NOTE On ME EQUIPMENT “Follow instructions for use”

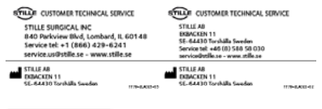
Product identifier, UDI, Type and Serial number label

IEC60417-5016 (Fuse), IEC 60417-5534 (AC plug) Input

IEC 60417-5021 (Equipotentiality), ISO7000-2567 (Fuse box access)

ISO7010-W024 Risk for pinch / squeeze injury

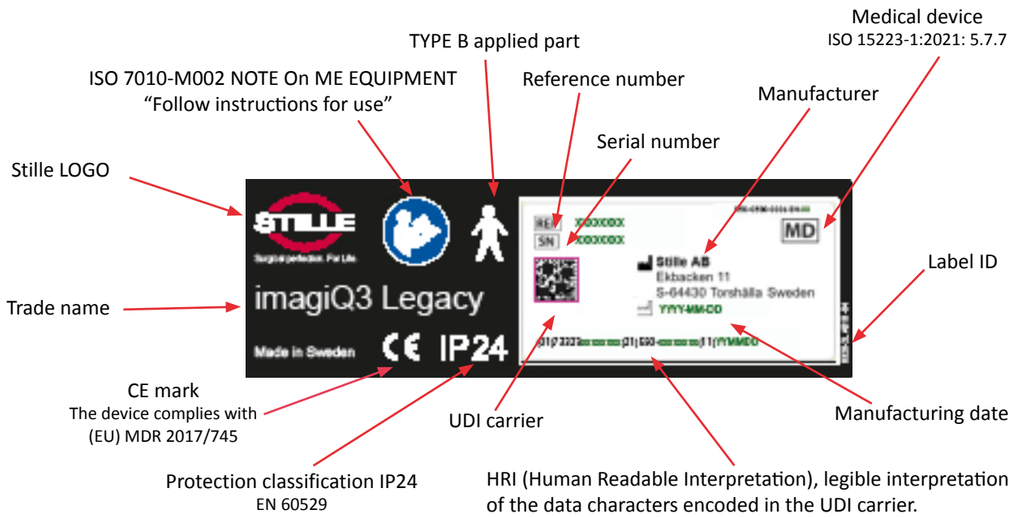
ISO 7010-W012 Risk of electrical shock



Technical service contact

Trademarks and patent

Accessory/ peripheral equipment label



INTRODUCTION

imagiQ3 is a mobile operating table powered by battery or by connection to mains.
imagiQ3 is especially suitable for image-guided endovascular and cardiovascular surgery. imagiQ3 also fulfils the requirements set out for a standard operating table making it also suitable for traditional open surgery.

The tabletop of imagiQ3 is made of radiolucent carbon fibre giving high degree of radiolucency of X-rays, which in turn gives a reduced radiation dose during C-arm radiation procedures. The slim design and low base make it an ideal complement for any size of C-arm enabling the receiver to get close to the patient. The tabletop has a unique free float movement (True Free Float), which is a special characteristic distinguishing imagiQ3 from other operating tables on the market.

All movements of the table are controlled and monitored by the user, normally the surgeon. With little effort, the user can move the tabletop freely in the x- or y-plane to get an image of the concerned area of study. The free float enables the possibility to get an image of the study area without moving the C-arm which can be very heavy and difficult to move, and take more time. The table gives the surgeon an unprecedented control and freedom of movement in any desired direction, including rolling the patient, while providing state-of-the-art smoothness, allowing for shorter procedure times and efficiency in the operating room. The shortened surgery time increases productivity as well as reduces radiation exposure for both personnel and patients.

imagiQ3 is operated in two basic modes: operating mode or transport mode.

The Safe Work Load (SWL) is 661lb/300kg (patient + equipment) in normal position and 330lb/150kg SWL (patient + equipment) in reverse position.

The imagiQ3 table can be equipped with a large number of accessories, both specific and general, that can be used on the table.

These accessories are described in the accessory section of this manual.

Intended purpose
imagiQ3 is intended for positioning and supporting of patients before, during and after human surgery in operating rooms.It is suitable for general open surgery, endovascular surgery and cardiovascular surgery.

Intended users
- The device is intended to be used by qualified healthcare professionals.

Indication
- Minimal invasive surgery.

Contraindication
- Brain surgery.
- Surgery on Infants.

Intended conditions of use
- To be used in operating theatres/rooms in a professional healthcare facility.
- To be used on an anti-static floor.
- Always clean, and disinfect before use.
- Use outside scope of intended use may cause a hazardous situation and harm to patient, user and device.
- STILLE AB provides accessories compatible with the imagiQ3's intended use (see the accessory manual).
- Always place a surgical drape between the patient and table. Direct contact between the patient and table is not intended.

Intended patient population
- Patients who need general open surgery, endovascular surgery or cardiovascular surgery.

Principles of operation
imagiQ3 mobile operating table is operated through AC power or through a high-endurance battery.

Transport mode (Not parked table)
- When the table is not parked, the table is on wheels and can be used for intra-clinic transportation.
- Transport mode requires the table to be in safe position.
- During unparking the table, the locked and unlocked LED will flash. To indicate a completed unparking, the unlocked LED will be constantly lit.

Operating mode (Parked table)
- The table shall be in parked mode when used for surgery. The table is lowered down onto the floor and when the LED next to the lock button is constantly lit up, the table is in parked position and resting on the floor.
- In this position all the table functions can be activated.

The table position adjustment:
- Motor-driven mode for Trendelenburg tilting, column up/down, lateral tilting (ISO-centric roll™) and un-parking table can be activated through the hand control.
- Manual tabletop floating function (True Free Float™) in X (longitudinal) and Y (lateral) position, is available through the activation of the pan handle and a manual adjustment of the tabletop position.

Position the patient
Position the patient on the table, either for imaging the torso or the legs. The head direction is defined/set via the hand control.

If a C-arm is to be used
Position the table to desired imaging area.

Floating the table
When the table is in horizontal position the table is ready for floating in the x- and y-axis.
By pushing the pan handle downwards, the floating function is released.
Floating can now easily be done empowering the surgeon to float the tabletop with total precision & freedom of movement in any desired direction.
As soon as the pan handle is released, the float function is immediately blocked.

Trendelenburg
In case of need, a Trendelenburg or anti- Trendelenburg function is available on the hand control. For emergency, a quick-action button allows for rapid Trendelenburg adjustment.

CPR
It is recommended to center the tabletop sideways and lengthwise over the column before performing any CPR or emergency treatment.

INTRODUCTION

Introduction

Controls
All movements are interrupted when the hand control button is released, or when the hand control is switched off (OFF).
All motor driven movements can be activated from the hand control. Only one movement at a time can be selected.
All movements except the parking function stop immediately when the buttons on the hand control or foot controls are released.

The imagiQ3 table has an integrated, fully automatic charging unit for charging the batteries in the operating theatre also with a patient on the table. Battery and charging indicator as well as sounds (beeps) alert the user for condition changes.

The imagiQ3 should be cleaned and disinfected after each use (follow hospital cleaning procedure). See recommendations in this manual regarding cleaning and disinfection of the table and the mattress.

Essential performance
The essential performance of the imagiQ3 table is defined as the ability to support a patient without unwanted movement as well as the ability to reach positions for emergency treatment, in this case Trendelenburg position and flat table position for CPR (Cardiopulmonary Resuscitation)
The function can be activated by the use of the hand control and can be achieved as an emergency function in cases of power failure.

Frequently used functions
The floating tabletop is the most frequently used function, followed by column up and down, and 0-position. Then support function parking / unparking.

Least favorable working condition
The least favorable working condition is when the table is in its highest position, with the tabletop all the way out and to the side with max safe work load (SWL) 661lb/300kg in normal position.

HF surgery
The imagiQ3 is suitable for high frequency surgery (HF-surgery) when in standby mode.

Table function priority detailed description
- All movements of the table cease immediately if the operating button or pedal of the control device has been released.
- All operations can be interrupted by pressing the main "OFF" button on the hand control.
- If several commands are given simultaneously from a control unit, all movements cease. (With the exception of fast lowering of the head end ("Quick-Trendelenburg") in combination with head end down).
- Certain tabletop movements can be activated by foot control.
- Trendelenburg and column up/down can always be maneuvered independent on the status of parking/ unparking.
- Emergency Trendelenburg - lowering of the head end is executed from the independent Emergency Trend Controller which is separated from the rest of the system.
- Should a parking/ unparking sequence be interrupted, the lock/unlock symbol LED´s on the hand control will flash, and some functions will be limited.
- The lateral tilt command or a return to 0-position command is only possible when the table is parked.
- An attempt to activate 0-position when the table is unparked will result in an automatic parking of the table.
- The return to 0-sequence is activated by pressing the 0-button and holding it pressed until all movement has stopped. If the 0-button is released, all movements cease immediately.
- Lateral and longitudinal tilt movements are provided with automatic stop functions at the 0-position.
- Lateral and longitudinal tilt movements cease automatically when the table has reached 0-position.
- Tilt movement that stops at 0-position can be reactivated by releasing and depressing the button/pedal.
- There is no automatic stop at 0-position function while fast lowering of the head end when using the quick Trendelenburg function.
- The system goes to OFF after 10 minutes, to turn the system ON, press the On button on the hand control.
- The Pan handle activation knob also works as an ON button.

Patient transportation
imagiQ3 is approved for patient transportation. The table requires the user to position the table in the safe position to allow transportation.

Unparking limitations
imagiQ3 can only be unparked when the table is in safe position. If trying to unpark outside the safe position, the table will beep and the hand control will indicate how to maneuver the table to reach the safe position.

Auto parking
If the 0-function is requested, the table will initiate parking and beep while parking. Once the table is parked it will continue to position the table in 0-position.

Safe position
imagiQ3 might need to be adjusted to achieve safe position to allow unparking.
The safe position is achieved when the tabletop is centered side to side in lateral direction, and centered between the blue arrows on the side in longitudinal direction.

Electronic instruction for use - eIFU
This manual can be obtained as an electrical copy, eIFU.
imagiQ3 is equipped with an eIFU indicator that allows the user access to all user and product related information.
Currently an Adobe reader (PDF) is required to open the files.
The manual can also be accessed through the support page on www.stille.se. Currently this requires an account and a login which can be obtained throught the web page.

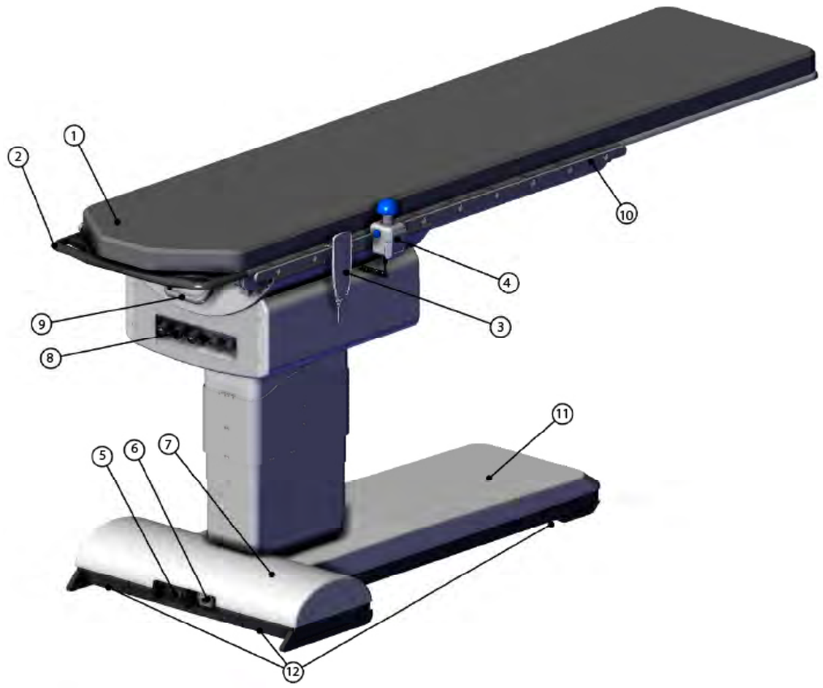
Accessories
The imagiQ3 table can be equipped with a large number of accessories, both specific and general, that can be used on the table, these accessories are described in the accessory section of this manual.

Preventive maintenance and repairs
The imagiQ3 requires periodical preventive maintenance to maintain BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to the ELECTROMAGNETIC DISTURBANCES, and for the safe usage during its intended service life, the instruction for preventive maintenance, service and repairs are described in the separate service manual.

INTRODUCTION

Device description

1. The mattress is made of ”Slow Recovery” material to minimize pressure sores on patients during long procedures. The mattress is attached to the tabletop using Velcro® making it easy to remove.
2. The tabletop is made of radiolucent carbon fiber composite laminate. The rear-end of the tabletop is equipped with handle grips which are not radiolucent.
3. The hand control manages the movements of the table. Usually, it is suspended on the tabletop accessory rail.
4. The pan handle is a maneuvering function allowing the True Free Float™ function - the panning of the table-top. The pan handle normally remains in a locked position on the accessory rail. Two pan handles can be used simultaneously to maneuver the True Free Float™.
5. IEC 60417-5021 Potential equalization connection point (Equipotentiality).
6. Appliance inlet and main fuses (AC-Mains connection).
7. Emergency cover holds the emergency Trendelenburg connection which allows the Emergency Trend Controller to connect to the Trendelenburg circuit, and the back up hand control.
8. Connection panel with 5 inlets for connection of the pan handle, hand control and accessories like the Integrated Control Module.
9. Emergency Trend Controller, a detachable unit that can connect to the Trendelenburg circuit to allow position the tabletop in position for emergency treatment, normally flat for CPR or in Trendelenburg.
10. Fixed accessory rails run along part of the tabletop. EU and US style versions available.
11. Protective covers, stainless steel covers that protect the inside of the table.
12. Transport wheels, for transport and to park the operating table the wheels can be retracted or extracted.



A QR-code label is located at the rear of imagiQ3 table. This QR-code label is unique for each table. Scan it with a smartphone to access to:

- imagiQ3 Support Page information - It includes details such as:
  - your table serial number and part number
  - quick guide, user manual, brochures, training videos, ...
- imagiQ3 Support Page actions:
  - click on “Report Installation“ to get the warranty extension.
  - click on “Report Issue“ to send us your requests and claims.

Operating instructions

Start-Up procedure

Follow the procedure described below before the imagiQ3 operating table is used for the first time:

- Read the user manual carefully before starting to operate the table.
- Charge the built-in batteries in the table until they are fully charged, see charging instruction in this manual, (depending on model and current charge this can take up to 10 hours, see page 23).
- Remove the Emergency Trend Controller and charge the batteries, reinstall when fully charged, depending on current charge, this can take up to 4 hours, see page 23).
- Follow and fill out the installation report. See doc 0320-6PF001-01 Installation report imagiQ3 https://www.STILLE.se/register-product/
- Follow and fill out the test protocol ISO -EN 62353 (see page 77) in the service manual.
- Clean and disinfect the table and its accessories according to the instruction in this manual (see page 22).

1. Test run all functions on the hand control as described below:
2. Column, Run column from lowest position to highest position and down again.
3. ISO ROLL™/Lateral tilt right, run tabletop from zero position to maximum right inclination, and then zero the table.
4. ISO ROLL™/Lateral tilt left, run tabletop from zero position to maximum left inclination, and then zero the table.
5. Longitudinal tilt (Trendelenburg), run tabletop from zero position to maximum head down, and then zero the table.
6. Reversed longitudinal tilt (anti-Trendelenburg), run tabletop from zero position to maximum head up and then zero the table.
7. Quick-Trendelenburg (or “Quick-Trend“), run tabletop from zero position to maximum head down and then zero the table.
8. Zero position. Lateral tilt, run tabletop from maximum left inclination to maximum right inclination and back. Make sure that the table stops both times it passes zero position.
9. Longitudinal tilt (Trendelenburg), run tabletop from maximum head down to maximum head up and back. Make sure that the table stops both times it passes zero position.
10. True Free Float™ / Panning. Pan functions, place table in 0-position and test run both axis. Check that motion works effortlessly and smooth (maneuver with one hand only).
11. Run the parking lock/unlock function all the way in and out, verify that the LED´s on the hand control indicates when the function is in it´s position with beep and a fixed light.
12. All above mentioned steps shall be inspected on the back up hand control as well.
13. Table is now ready to be used.

Daily inspections before procedures

14. Make sure the table is properly cleaned and disinfected.
15. The operator should have knowledge how to operate the device, should be aware of warnings and signals described in the user manual. The user manual should always be available.
16. The operator should perform a function according to point 2-12 (from the instructions “before the table is used for the first time”).
17. Test the functions of the device and inspect cables for cuts and other damage. If any doubt, replace the relevant parts.

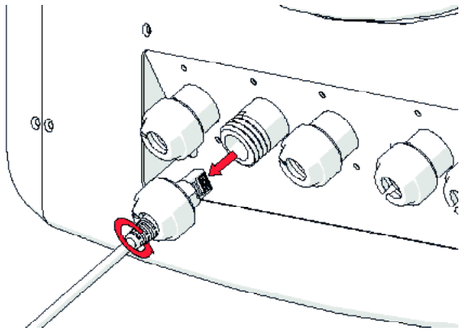
Introduction

Back up hand control

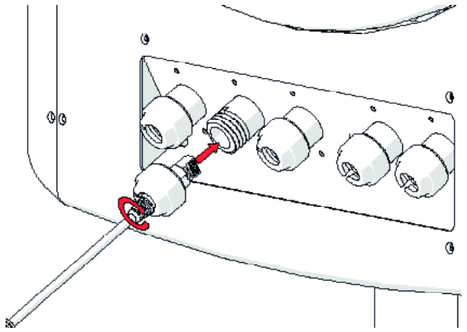
In case of a broken hand control, the table is equipped with a backup hand control located under the emergency cover.
Always unplug a damaged hand control before connecting a new unit.
If the emergency hand control has been used, make sure to replace it with a new one.
Always discard a broken hand control.

Lift up the rear cover to get access to the hand control.

Lift up the hand control



Unscrew the cable restrain and unplug the cable.

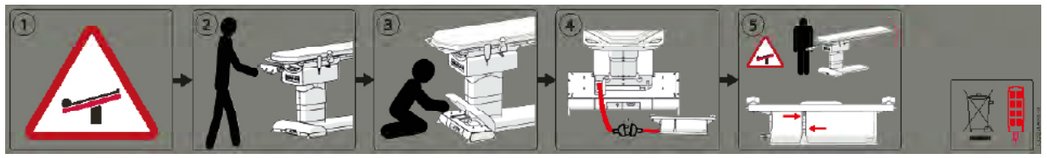


Plug in the cable and tighten the cable restrain.

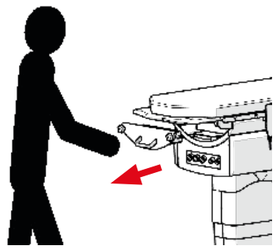
Position for Emergency treatment Trendelenburg or CPR position

In case of a non functional table, if the patient needs to be placed in a position for emergency treatment, the table is equipped with an independent emergency power supply / control system for the Trendelenburg motion.
Follow the procedure below for connecting the emergency power supply / control system.

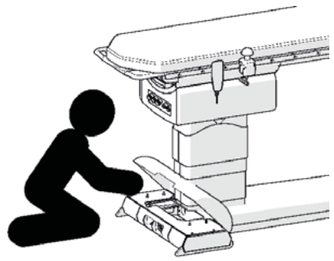
NOTE! it is required to charge the Emergency Trend Controller annually (max time in between charging 18 months).



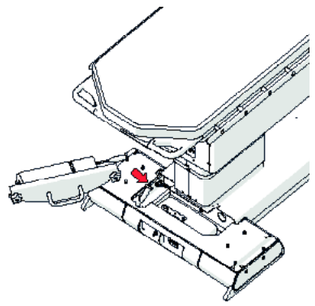
Instruction label located on the emergency cover on the device.



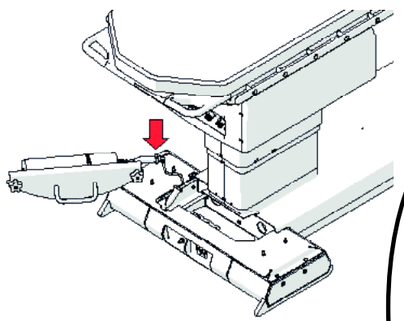
Unscrew the 2 screws and pull out the rear cover to get access to the Emergency Trend Controller.



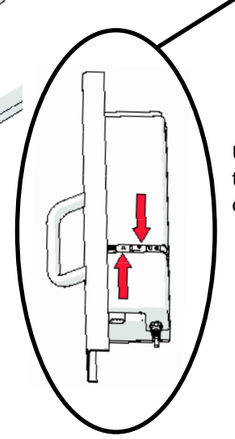
Lift up the rear cover to get access to the connection point.

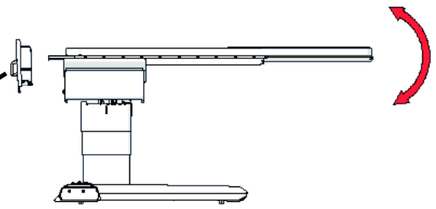


Disconnect the plug.



Connect the Emergency Trend Controller cable.





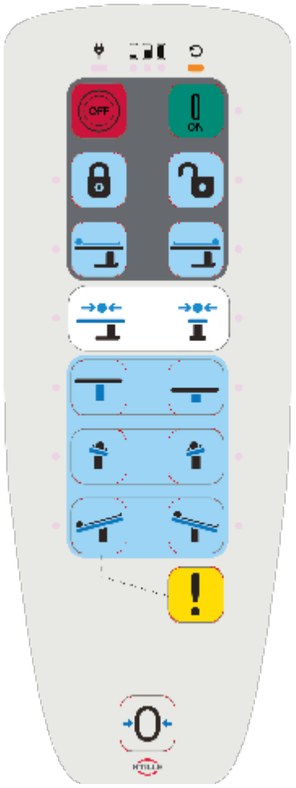
Use the buttons on the Emergency Trend Controller to position the table in desired position for emergency treatment.

Note, when re-installing theEmergency Trend Controller, make sure all cables are correctly located and that the lip of the cover is under the roof cover, not above it.

Hand control and Integrated Control Module

Hand Control

The hand control is the main interface for interacting with the table.
Before any patient loading or unloading, the table should be parked using the lock function.
The OFF button only deactivates the buttons on the hand control; the system cannot be turned OFF. The system has an auto power off function that will deactivate and power down the system automatically. To activate the system press the ON button.



Important information

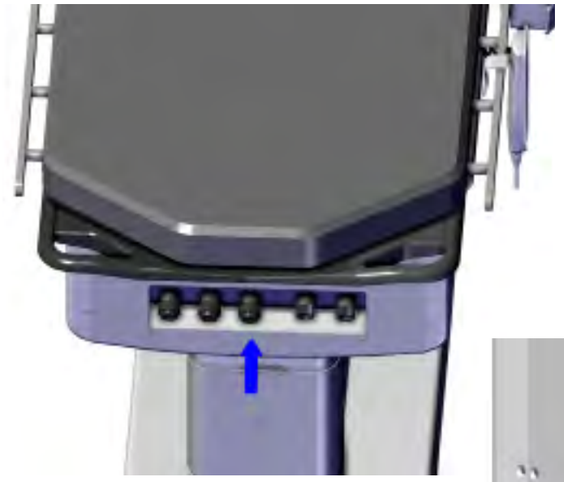
- The hand control must be switched on (ON) for any movements to function.
- All motor-driven movements can be activated from the hand control.
- Only one movement at a time can be activated, 2 different inputs will stop the table.
- All movements stop immediately when the buttons on the hand control are released.
- The parking function must be kept manually activated until the wheels have reached the final locked/unlocked position.
- For unparking the table is required to be in safe position, the white tabletop direction section indicates with LEDs which axel(s) that are out of position.Use the pan handle to move the True Free Float™ in Longitudinal or lateral direction. Once the axels(s) are in the correct position the LED(s) will be lit up.
- Do not pull the hand control cord when disconnecting hand control from table. This can result in damage to the hand control.
- The hand control cable shall be connected to the connector closest to the area of use, to ensure secure attachment to the accessory rails.
- Clean the hand control regularly with recommended cleaning agents or use a transparent protective cover during use.
- If the hand control is used inside the sterile field, it is recommended to cover the hand control with a sterile draping.

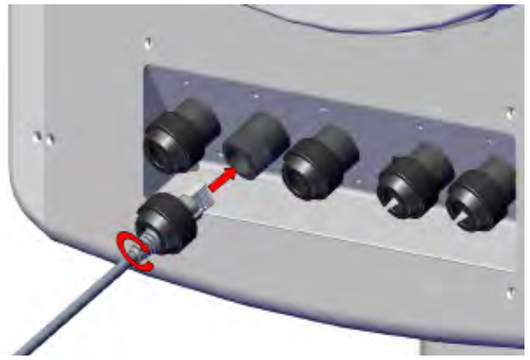
Hand control (included in the standard configuration)

- Hang the hand control on the side rail when not in use.
- Connect the hand control connector in the connection port in the rear of the table.
- Hand control functionality, see page 14-16, Handling.

Preventive maintenance:
Annually, as part of the imagiQ3 table preventive maintenance program.

Cleaning and disinfection of the hand control:
Clean and disinfect before use.
Follow the general guidelines for cleaning and disinfection in the Care and Maintenance section of this manual.





Plug in the cable and tighten the cable restrain. All 5 connectors can be used for hand control, pan handle or ICM.

Battery indicator

INDICATOR	ICON	FUNCTION	FUNCTION
Power supply		Indicates low level of battery with a red light.	White light when input from power supply is detected.
Battery level		Indicates a low level of battery with a red light.	Light corresponding to current charge level is lit. If very close to battery depletion, indicator flashes. Indicators 'indicate increase' when charging.
		Indicates a medium level of battery with a yellow light.	
		Indicates the full level of battery with a green light.	
Fatal error Reset		Indicates that table must be reset.	Orange light flashing when reset is needed. Run the table column to the top position, lock and unlock the wheels, level the table, then run all table movements to full IN and then to full OUT position and then back to flat, finalize with running the table column to fully retracted.

Operating Modes

imagiQ3 is operated in two basic modes:

Transport mode (Unlocked wheels)

- The wheels are unlocked, and the table can be transported intra-clinic.
- To indicate wheels unlocked, the corresponding LED are constantly lit.

Operating mode (Locked wheels)

- The wheels are locked, and the table can used for patient loading and surgery.
- To indicate wheels locked, the corresponding LED are constantly lit.

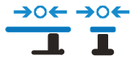
Locking/unlocking wheels

- To lock/unlock the wheels, the lock/unlock button is held for about 15 seconds.
- Movement of table sections shall not be activated during locking/unlocking. A warning beep will be heard if this is done.
- To indicate wheels in between the locked/unlocked position, the two LEDS are FLASHING.

Error codes and sounds explanation

Description	Error	Action
Functions missing and fatal error indicator flashes	Fatal error	Enter manual mode and try to run the indicated function to its end positions.
Table turns OFF or does not turn ON	Battery low	Connect the table to mains and charge the batteries.
When pan handle is depressed a Beep will sound (no led indication) no float function	Inclinometer	Calibration of inclinometer
Fast flash led (both) and beep (100ms on 100 ms off) on trend buttons when tend or level button is depressed	Inclinometer	Calibration of inclinometer
If a movement is stopped or not initiated, and the LED´s corresponding is fast flashing	Overcurrent	Lower the load on the table
LED fast flashing	LED intermittently turned on and off, being on for 200 ms and off for 200 ms.	
LED slow flashing	LED intermittently turned on and off, being on for 400 ms and off for 400 ms.	
Beep 3 three repetitions (parking and un-parking)	Beep intermittently turned on and off, being on for 100 ms and off for 50 ms.	
Beep warning/manual mode (warning for not allowed function, sync of LA23.	Beep intermittently turned on and off, being on for 100 ms and off for 100 ms.	
One Beep (for system ON)	Beep 50 ms ON one repetition	

User Interface Hand Control and ICM control function overview

BUTTON	ICON	FUNCTION		LIGHT/SOUND
System OFF		Deactivate all buttons. System cannot be turned OFF, it will go into a power sleep mode.		No lights when controller is deactivated.
System ON		Activate all buttons. Auto power off function will deactivate and power down the system automatically.		Light stays on as long as buttons are activated, once the light is off the hand control is in sleep mode, press ON to activate the buttons again.
Table - Up/Down		Table Up Raise tabletop.	Table Down Lower tabletop.	Light on while the button is pressed. Blink when limit has been reached.
Patient orientation - Normal		Set patient orientation to Normal.		Light on when set. To change the setting it is required to keep the button pressed for 1 second.
Patient orientation - Reverse		Set patient orientation to Reverse.		Light on when set. To change the setting it is required to keep the button pressed for 1 second.
Trendelenburg		Move tabletop to Trendelenburg position. The movement automatically stops at 0-position.		Light on while button is pressed. Fast blinking and a beep confirms that position has been reached. If actuated from other controller, trend/reverse trend will flash.
Reverse Trendelenburg		Move tabletop to reverse Trendelenburg position. The movement automatically stops at 0-position.		Light on while button is pressed. Fast blinking and a beep confirm that position has been reached. If actuated from other controller, trend/reverse trend will flash.
Lateral tilt (ISO-ROLL™)		Tilt Right Tilt table clockwise as seen from the direction of the patient's head using the active setting for patient orientation. The movement automatically stops at 0-position.		Light on when active. Light on while button is pressed. Fast blinking and a beep confirm that position has been reached.
Lateral tilt (ISO-ROLL™)		Tilt Left Tilt table counterclockwise as seen from the direction of the patient's head using the active setting for patient orientation. The movement automatically stops at 0-position.		Light on when active. Light on while button is pressed. Fast blinking and a beep confirm that position has been reached.
0-position (level tabletop)		Move tabletop to flat position. The movement automatically stops at 0-position.		No light Beeps to confirms that position has been reached.
Parking		Lock table by retracting the wheels.		Blinking if table is neither parked nor un-parked status. Beeping confirms that position has been reached and led light showing parked or un-parked status.
Unparking		Unlock table by extracting the wheels.		Blinking if table is neither parked or un-parked status. Beeping confirms that position has been reached and led light showing parked or un-parked status. Unparking is blocked if table not in the safe position The table will Beep, and button depressed and the LED corresponding to the axis not in safe pos will flash as button depressed.
Quick trendelenburg		Moves the tabletop in Trendelenburg. The movement does not stop at 0-position.		No light. Connected to Patient orientation.
Safe position indicator (no button)		If unlock (unparking) is requested and the table is not is safe position the LED for the axel(s) outside of position will indicate.		Light indicating when tabletop is in safe position in X and Y. Flashing as unparking button depressed. Lights indicate when the axel(s) are in safe position.
Position of ICM on the table		Inverts coordinate system. Choose which side the ICM is located on the table for correct Trendelenburg and ISO-ROLL™ function.		Light indicates the position on the table. Press the button to change position.

OPERATION INSTRUCTIONS
Pan handle connection and use

Pan handle (standard + option) 555-1760, 555-1761

Product description

An aluminum construction that enables the True Free Float function.

1 pan handle is included in the standard configuration. The table can be equipped with 1 additional pan handle.

Intended purpose
To allow to position the tabletop in horizonatal direction, therby position the patient.

Intended users
The device is intended to be used by qualified healthcare professionals.

Indication
N/A

Contraindication
N/A

Intended user profile
The device is intended to be used by qualified healthcare professionals.

Intended patient population
Patients who need general open surgery, endovascular surgery or cardiovascular surgery

Intended conditions of use
To be used in operating theatres/rooms in a professional healthcare facility.
Always clean, and disinfect before use.
Use a clear sterile plastic cover or similar to drape the pan handle.
Use outside scope of intended use may cause a hazardous situation and harm to patient, user and device.

Operating principle

Press down the large blue knob to release the True Free Float and maneuver the tabletop to its desired position, then release the blue knob.

The Green enable button must be visible to access the function. When the True Free Float function is not in use, it is recommended to block the function by pressing in the green button, the red button will be visible.

System ON function: by pressing down the large blue knob, the system will be activated in the same way as when the hand control ON button is pressed.

- Mount the pan handle on the side rail.
- Connect the connector in one of the connection ports in the table, secure the cable with the included locknut.
- It is possible to connect several pan handles on the imagiQ3.

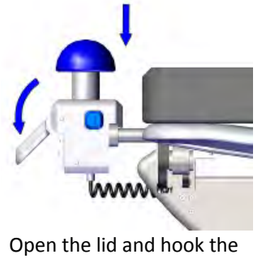
Maintenance
Periodical preventive maintenance (PM) is required annually 1 time every year. Check that the connection between the rail and the control unit is tight with the clamp connected, the clamp should withstand a minimum force of 50N and not move, adjust the tension if needed. Check functions 1 to 16 of the control unit, inspect the cable and connectors for damages.

Measures

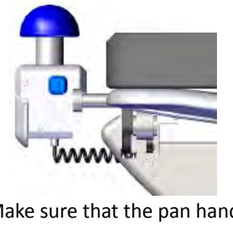
Length 9,1 cm	3.58 in
Width 7,7 cm	3.03 in
Height 15,5 cm	6.1 in
1,3kg	2,86 lb

True Free Float enabled when the green button is visible.

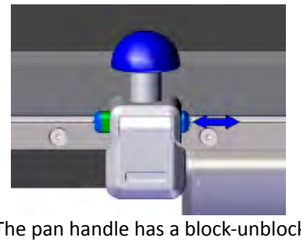
True Free Float disabled when the red button is visible.



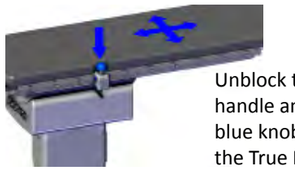
Open the lid and hook the pan handle onto the side rail and close the lid, pushing the lid with the palm of the hand.



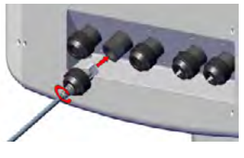
Make sure that the pan handle grips tightly on the rail.
The grip force can be adjusted if needed. See service manual.



The pan handle has a block-unblock function.
It is recommended that the pan handle always is blocked when it is not being used.



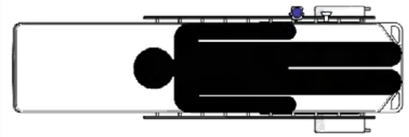
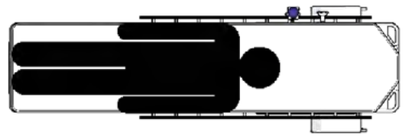
Unblock the pan handle and press the blue knob to release the True Free Float.



Plug in the cable and tighten the cable restrain. All 5 connectors can be used for hand control, pan handle or ICM.

PATIENT POSITIONING

Safe Working Load

Patient placement settings	300 kg / 661 lbs max. safe work load	150 kg / 330 lbs max. safe work load
Normal setting 		
Reverse setting 		

1. Verify patient weight, accessories used and intended position is within the SWL limit.
2. Select head-end by pressing the head-end selection button (1 second). Current setting is indicated through the patient orientation setting LED.
3. Check that attached accessories do not collide with the table or surrounding equipment.
4. Pan the tabletop lengthways as far out from the column as possible.
5. Position the flat panel detector / image intensifier and check the imaging area by panning the patient maximally length- and sideways.

Note 1: A greater longitudinal angle than ±2° will lock the lengthways panning function.
Note 2: Centre the tabletop longitudinally over the column as far as possible before lowering the free end of the tabletop.
Note 3: To make lengthways panning of heavy patients easier, adjust the head-end of the tabletop marginally (±2° around the zero position) by pressing the ”head-end up” button on the hand control briefly.

Patient transfer

- Always follow local procedures for patient transfer and patient loading and unloading.
- For patient loading and unloading, make sure the table is parked and that the tabletop is centered, and adjusted in height.
- Use a patient lift, draw sheet or other suitable device for transferring the patient to and from the imagiQ3.
- The patient should never be seated upright at either end of the table as the load should be distributed over a larger area.
- Sitting upright is only allowed over the column area.

ACCESSORIES

STILLE original accessories

- Only use accessories approved by STILLE AB.
- Always check accessories before use. Damaged or worn accessories shall never be used as they can cause harm or personal injury.
- Always check that the accessories are securely attached to the table before use.
- Always check that mounted accessories do not collide with the operating table or surrounding equipment when movement is activated.
- A clicking sound shall be heard when attaching the fixed headrest and catheter trays to be sure that they attach safely.
- All accessories are sold as a single unit unless explicitly stated that it contains a pair.

Part number	Part name	Standard	Option	Market	Measure	Weight	Country of origin
555-1760	Pan handle EU	x		EU model	75 x 77 x 155mm	2.86lb/ 1.3kg	SE
555-1761	Pan handle US	x		US model	75 x 77 x 155mm	2.86lb/ 1.3kg	SE
535-1720	Detachable side rails US		x	Worldwide	805 x 100 x 65mm	5.7lb/ 2.6Kg	SE
535-1721	Detachable side rail DIN		x	Worldwide	805mm / 31,6 inch	5.7lb/ 2.6Kg	SE
535-1723	Side rail US		x	Worldwide	700 x 100 x 65mm	5.5lb/ 2.5kg	SE
535-1724	Side rail short US		x	Worldwide	285 x 100 x 65mm	2.2lb/ 1kg	SE
535-1725	Side rail short DIN		x	Worldwide	285 x 100 x 65mm	2.2lb/ 1kg	SE
535-1729	Side rail EU		x	Worldwide	700mm / 27,5 inch	5.5lb/ 2.5kg	SE
535-1730	Fistula armboard		x	Worldwide	350/709 x 879 x 128mm	15.87lb/ 7.2kg	SE
535-1741	Headrest fixed (does only fit on the top side of the table, requires 2 pcs of Detachable side rails to be attached)		x	Worldwide	650 x 360 x 110mm	5.07lb/ 2.3kg	SE
535-1742	Headrest adjustable, (does only fit on the top side of the table)		x	Worldwide	650 x 360 x 110mm	6.6lb/ 3kg	SE
535-1745	3D Headrest (does only fit on the head-end of the table)		x	Worldwide	550 x 542 x 65mm	2.2lb/ 1kg	SE
555-1750*	Catheter tray 1000mm		x	Worldwide	1150 x 615 x 95mm	19.84lb/ 9kg	SE
555-1751*	Catheter tray 500mm		x	Worldwide	650 x 615 x 95mm	13.66lb/ 6.2kg	SE
555-1765	Integrated Control Module EU		x	Worldwide	244 x 77 x 155mm	5.07lb/ 2.3kg	SE
555-1766	Integrated Control Module US		x	Worldwide	244 x 77 x 155mm	5.07lb/ 2.3kg	SE
535-1770	Radiation shield kit grey		x	Worldwide	4pcs 160x 730mm 2pcs 190x730mm	12.12lb/ 5.5kg	FI
535-1771	Radiation shield kit blue		x	Worldwide	4pcs 160x 730mm 2pcs 190x730mm	12.12lb/ 5.5kg	FI
535-1772	Radiation shield loop grey		x	Worldwide	650 x 730mm	8.04lb/ 3.65kg	FI
535-1773	Radiation shield loop blue		x	Worldwide	650 x 730mm	8.04lb/ 3.65kg	FI

* Requires side rails 535-1720, 535-1721, 535-1723 or 535-1729 for mounting on the free end of the tabletop.

The weight and size is only indicational and may vary between individual units.

ACCESSORIES

External accessories distributed by STILLLE and approved for use on the imagiQ3™

- Always follow the manufacturers instruction for use.
- The configuration between the third-party accessories and imagiQ3 table is not type tested by a third party.
- The part numbers below show the STILLE sales configurations of third-party accessories and manufacturer's part numbers.
- All accessories are sold as a single unit unless explicitly stated that it contains a pair.

Sales configuration number	Part name	Manufacturer part number	Option	Market	Measure	Weight	Country of origin
512-5000	Basic armboard	CFI-250/CFI-258	x	Only USA			US
O-RSX2	Deluxe maximum restraint	O-RSX2	x	Only USA			US
514-100301	Accessory clamp basic EU	10-301	x	Only EU	90x60x40mm	0,.66lb/ 0.3kg	SE
514-100301-US	Accessory clamp basic US	10-301-US	x	Only EU	90x60x40mm	0.66lb/ 0.3kg	SE
514-100305	Accessory clamp	10-305	x	Only EU	60x45x115mm	1.76lb/ 0.8kg	SE
514-100305-US	Accessory clamp US	10-305-US	x	Only EU	60x45x115mm	1.76lb/ 0.8kg	SE
514-100307	Radial accessory clamp	10-307	x	Only EU	125x160x65mm	2.2lb/ 1.1kg	SE
514-100307-US	Radial accessory clamp US	10-307-US	x	Only EU	125x160x65mm	2.2lb/ 1.1kg	SE
514-100311	Anesthesia frame	10-311	x	Only EU	180cm	8.48lb/ 3.85kg	SE
514-100311-US	Anesthesia frame US	10-311-US	x	Only USA	180cm	8.48lb/ 3.85kg	SE
514-100365	Lateral support, wide without clamp	10-365	x	Only EU	Curved cushion 200x200 mm. Length of post: 350 mm.	4.85lb/ 2.2kg	SE
514-100367-K	Tibia support (excluding clamp)	10-367-K	x	Only EU	Cushion Diameter 135 mm Length 270 mm Post Total length 400 mm	5.95lb/ 2.7kg	SE
514-100401	I.V. pole	10-401	x	Only EU	1050-1550x240mm	4.4lb/ 2kg	SE
514-100401-US	I.V. pole US	10-401-US	x	Only USA	1050-1550x240mm	4.4lb/ 2kg	SE
514-100422	Widening sections 455mm pair EU	10-422	x	Only EU	455x85x125mm	20.72lb/ 9.4kg/pair	SE
514-100465	Leg/Body strap	10-465	x	Only EU	2100×85mm	0.44lb/ 0.2kg	SE
514-100530	Side gates, foldable/ pair EU	10-530	x	Only EU	630x40x370mm	12.3lb/ 5.6kg/pair	SE
514-100530-US	Side gates, foldable/ pair US	10-530-US	x	Only USA	630x40x370mm	12.3lb/ 5.6kg/pair	SE
514-100530-H	Side gates cover single unit	10-530-H	x	Only EU		0.66lb/ 0.3kg/ pcs	SE
514-100552	Arm and leg holder curved	10-552	x	Only EU	565x227x170mm	3.08lb/ 1.4kg	SE
514-100553	Cover arm and leg holder curved	10-553	x	Only EU	575x200x12mm	0.39lb/ 0.18kg	SE
514-100554	Arm and leg holder straight	10-554	x	Only EU	400x200x210mm	2.75lb/ 1.25kg	SE
514-100555	Cover arm and leg holder straight	10-555	x	Only EU	410x200x12mm	0.33lb/ 0.15kg	SE
514-100560	Side support adjustable excluding clamp	10-560	x	Only EU	"Length of post = 350 mm Plate = 175x70 mm"	4.85lb/ 2.2kg/ pcs	SE
514-50-3SR025	Adjustable armboard compl. DIN	10-382/10-388	x	Only EU	L 605 mm, W 160mm, H 230mm	11.24lb/ 5.1kg	SE
514-50-3SR027	Adjustable armboard compl. USA	10-382/10-388-US	x	Only USA	L 605 mm, W 160mm, H 230mm	11.24lb/ 5.1kg	SE
514-50-3SR028	Lateral support complete w clamp EU	10-365/10-301	x	Only EU	Curved cushion 200x200 mm. Length of post: 350 mm.	6.28lb/ 2.85kg	SE
514-50-3SR030	Lateral support complete w clamp US	10-365/10-301-US	x	Only USA	Curved cushion 200x200 mm. Length of post: 350 mm.	6.28lb/ 2.85kg	SE
514-50-3SR032	Leg rest with clamp EU (pair)	10-450/10-305	x	Only EU	350x760x195mm 20 mm rod diameter	21.16lb/ 9.6kg	SE
514-50-3SR033	Leg rest with clamp US (pair)	10-450/10-305-US	x	Only USA	350x760x195mm 20 mm rod diameter	21.16lb/ 9.6kg	SE
514-50-3SR036	Adjustable tray with clamp	10-065/10-305	x	Only EU	495 x 260 x 35mm folded	7.7lb/ 3.5kg excl clamp	SE
514-50-3SR037	Adjustable tray with clamp US	10-065/10-305-US	x	Only USA	495 x 260 x 35mm folded	7.7lb/ 3.5kg excl clamp	SE

The weight and size is only indicational and may vary between individual units.

Accessories

WARNING - INFECTION HAZARD

(OSHA standards for blood borne pathogens (BBP, 29 CFR 1910.1030))

- To protect against aerosols being reflected from contaminated surfaces, wear rubber or plastic gloves, masks and eye protection and follow OSHA blood-borne pathogens standards when cleaning.
- When cleaning/disinfecting table, note that alcohol-based cleaning agents might not have sufficient cleaning/disinfection properties.

Maintenance

Periodical preventive maintenance (PM)

The imagiQ3 requires a maintenance period of 1 time every year, with the first preventive maintenance performed maximum 12 months from date of installation.
If the Periodical preventive maintenance (PM) is not correctly documented in technical documentation 953-G550-0002-EN imagiQ3 Service manual, the warranty is void.
STILLE AB cannot guarantee the product's safety if Periodical preventive maintenance (PM) has been neglected.
During maintenance, service and repairs, personal protection eye wear and gloves should always be worn, also consider local work regulations.
For service and repairs see the technical documentation 953-G550-0002-EN imagiQ3 service manual.

The device should be cleaned routinely, as described below. Additional preventive maintenance is required, see the technical documentation 953-G550-0002-EN imagiQ3 service manual. During cleaning use personal protections like gloves, also consider local work regulations. Third-party accessories might have their own instruction for cleaning and Periodical preventive maintenance. Do not immerse the control unit device in water or any other liquid.

Cleaning & Disinfection

The table should be thoroughly cleaned, after each procedure (follow hospital cleaning procedure, and the manufacturer´s instruction for use). Cleaning procedures requiring articulation of the table should be performed only by persons familiar with table operation. Clean the device as follows, see special recommendations regarding cleaning and disinfection of the mattress.

- The imagiQ3 table should only be cleaned and disinfected by hand.
- Do not use steam cleaning.
- Not intended to be sterilized.
- Inspection of contamination on the device shall be done before each use.
- The mattress shall be inspected on the regular service interval.
- Scratches or holes in mattresses or pads are not acceptable.
- Unplug the power connector from its power source before moving and/or cleaning. Do not spray cleaning fluid into electric receptacles
- When cleaning the imagiQ3 table and its accessories, use a lightly alkaline universal cleaning agent (soap water).
- The cleaning agent should contain phosphates and tensides as active ingredients.
- Cleaning agents containing hydrogen peroxide can cause discoloration on the mattresses and on painted surfaces.
- When surfaces are heavily soiled, concentrated cleaners can be used. In this case the table should be wiped off with clean water afterwards.
- Disinfect the metal surfaces of the operating table with disinfectants that do not contain chlorine or compounds that give off chlorine on decomposition, this can cause discoloration on the surfaces.

Cleaning and care of the polyurethane coated mattress

General Guidance

- Attention must be paid to the properties of any other materials, (e.g. washing agents and washing instructions).
- Some surface wrinkling may result from cleaning procedures. This has no adverse effect on the fabric's properties.
- Do not use washing machines
- Abrasive cleaning agents should not be used.

Washing and Disinfection

- Superficial dirt on the coating may be removed by wiping with a soft cloth moistened with water containing a neutral detergent. More persistent contamination may be treated by wiping with alcohols or turpentine substitute, followed by hot water and detergent.
- Routine cleaning and disinfection in situ may be carried out on the coating with hand hot water and a neutral detergent or with a sodium hypochlorite solution (0.1% or 1000 parts per million available chlorine).
- The material is compatible with the 10,000ppm available chlorine in solution required for the decontamination of blood spills. After the 2 minute required dwell, excess solution must be removed and the surface thoroughly rinsed and dried prior to reuse or storage.
- Proprietary disinfectants may be used provided manufacturer's instructions are followed.
- All cleaning agents, and disinfectants, must be thoroughly rinsed off and the item dried before storage. Failure to do this may result in the accumulation of reagent that could damage the polyurethane coating, react with the bed frame, or negate the biocompatibility results of the fabric.

Drying

- It is essential that articles be thoroughly dried after all cleaning procedures and before storage.
- Drying may be affected at temperatures up to 130 °C (266°F).

Storage

- Store in a cool, dry area. Avoid excessive pressure and contact with non colourfast materials

Recommended cleaning agents (Chlorine dioxide)
KBM Disinfection free, effective on spores, viruses, multi resistant bacteria, fungus and mold (Manufacturer Life Clean)

- Remove superficial dirt and previously applied chemicals

- Use a rag with a generous amount of KBM Disinfection free and wipe down the surface
- Let the solution work for at least 2 minutes for proper disinfection

- After disinfection, wipe the surface clean
- Since some metals can react at low pH, we recommend rinsing or drying the surface after the disinfection.

Follow the manufacturer´s recommendation for cleaning, disinfection, protection, storage and recycling. These instructions might have changed since this manual was written

Recommended cleaning agents (Alcohol)
DAX Surface Disinfection Plus, effective against bacteria, fungus and viruses according to EN13727, EN13624, EN14476 and EN13697 (Manufacturer Kiilto)

- Remove superficial dirt and previously applied chemicals
- Apply a generous amount of the cleaning agent, either directly onto the surface or on a dry cloth
- Work the surface over several times with the solution
- The surface must remain damp at least 30 seconds to have effect
- After disinfection, wipe the surface clean

Follow the manufacturer´s recommendation for cleaning, disinfection, protection, storage and recycling. These instructions might have changed since this manual was written

NOTE! Alcohol based disinfections might not be effective against spores

Battery charging

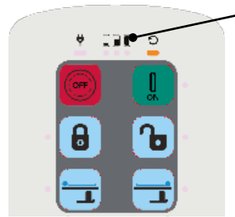
The imagiQ3 table has an integrated, fully automatic charging unit. Regular charging gives high operational reliability and a long life for the batteries.

- The mains voltage is 100-240 V AC, 50/60 Hz.
- The imagiQ3 table is approved for charging in the operating room with a patient on the table.

Charging instructions

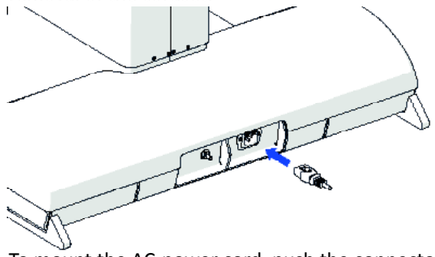
1. Lock the wheels.
2. Connect main power cord and check that the indicator for the battery charging on the hand control lights up.
3. Battery charging is shown by the indicator on the hand control when the battery symbols are giving a pulsing light.
   Charging time is approximately 8 hours.

Note 1: A damaged main power cord must be replaced immediately. Always use imagiQ3 table original cord.
Note 2: Unplug the main power cord before unlocking the wheels.

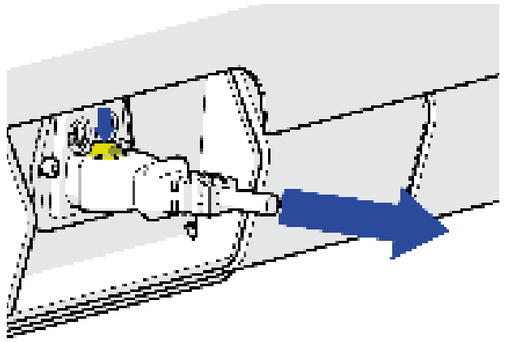


Hand control
Left indicator - Red = Low battery
Middle indicator - Yellow = Medium battery
Right indicator - Green = Full battery
Pulsing light = Charging

The imagiQ3 uses an grounded AC power cord equipped with a V-Lock system.
The connector is equipped with a notch intended for use with the latching cordset.
The cord latching system prevents against accidental removal of the cordset.

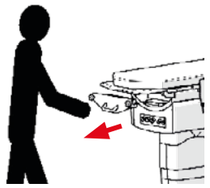


To mount the AC-power cord, push the connector into the appliance inlet until the lock latch hook up.



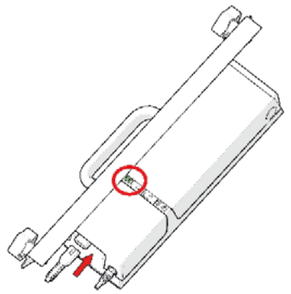
To remove the AC-power cord, push the yellow release button on the connector and pull the plug.

The imagiQ3 Emergency Trend Controller needs to be charged at regular intervals, reccomend interval is 12 months, maximum every 18 months. To charge the battery, remove the Emergency Trend Controller and plug in the power cord.
The charging power cord can be found under the emergency cover.



Remove the Emergency Trend Controller by unscrewing the knobs and pulling out the unit.

The charging cable is normally stored under the emergency cover.



Plug in the power cord and charge until the LED indicators show green light, this can take up to 4 hours.

Technical specifications

Dimensions

Outside dimensions

Length	240 cm / 94.4 in
Width	77.2 cm / 30.3 in
Height	71-109 cm / 28-43 in (center of the tabletop)

Tabletop

Length	240 cm / 94.4 in
Width	55 cm / 21.6 in (excluding accessory rails)

Aluminum equivalence
0.4 mm (0.0157 in) according to IEC 60601-1-3:1994 / 0.65 mm according to IEC 60601-2-54:2022 Ed. 2.0

Panning lengthways	90 cm / 35.4 in
Panning sideways	25 cm / 9.9 in
Trendelenburg	+25 °
Reverse Trendelenburg	-21 °
ISO ROLL™/Lateral tilt	±15 °
Maximum weight capacity	300 kg / 661 lb (normal) 150 kg / 330 lb (reverse)
Weight of imagiQ3	approx. 286-287 kg
Mass of Equipment	approx. 585 kg
	Device + SWL (Table + max. load)
Ground clearance	15 mm

Speed of movement (under full load)

Hi/low	35 sec
Trend (max trend to 0-pos)	45 sec
ISO ROLL™(max to 0-pos)	15 sec
Parking	15 sec / 0.59 in

All movement and measurements have the following tolerances:

Length measures:	±0.5 in (±1.25 cm)
All angles:	±2.0°
All height adjustments:	±0.5 in (±1.25 cm)
Approx. table weight:	±10% (w/o accessories)
Speed	±5 sec

Electrical system

Mains voltage	100 - 240 VAC, 50 / 60 Hz
Rated power	Max 390 VA
Fuse rating	T6.3 A
Input current	Max. 4.5 A
Output power	350W
Enclosure	IP 24
Classification	type B
Electric safety	Class I
Internal fuses	1pcs 30A 250 VAC Slow

Leakage current: The imagiQ3 complies with the leakage current requirements according to IEC 60601-2-46, when powered through the internal power source (batteries) or connected to mains.

Duty cycle > 200 kg	10% 2 min ON 18 min off
Duty cycle > 300 kg	5% 1 min ON 19 min off
Battery type	Lithium-Ion technology: Nickel Manganese Cobalt Oxide (NMC)
Battery capacity	2.9 Ah/73.25 Wh/unit, max 3 units allowed + 1 extra for the Emergency Trend Controller
Output voltage	27,5 VDC
Battery recycling	follow the local environmental regulations

Electrical & Electronic Waste:
follow the local environmental regulations

Hydraulic system

Max system pressure	160 bar
Oil volume approx.	1.0 L
Max. flow of pump	0.9 L/min
Oil grade	Castrol Hyspin/AWH-M32 Shell Tellus 32 grade or equivalent

Hydraulic oil recycling: follow the local environmental regulations, remove all fluid from the system prior to recycling.

Operating conditions

Temperature: +5°C to +40°C (41°F to 104°F) when powered by the batteries.
Temperature: +5°C to +30°C (41°F to 86°F) when connected to mains and charging.
Humidity: 30% -75% RH - non condensing.
Atmospheric pressure 800 hPa - 1060 hPa.

Storage conditions / Transportation requirements

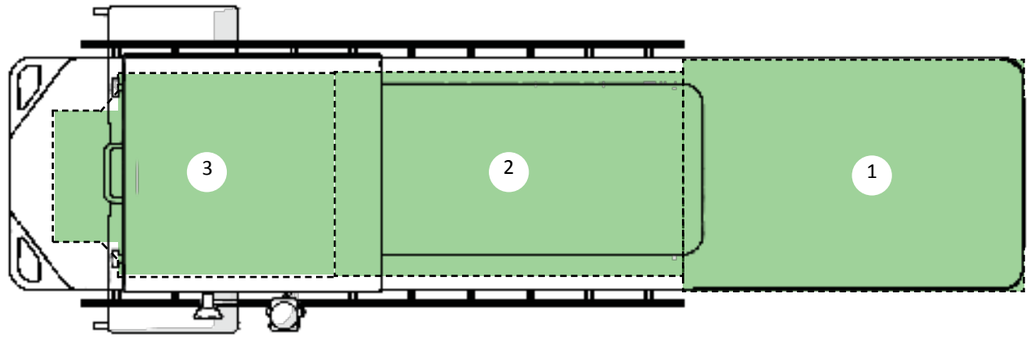
Temperature: -20°C to +50°C (-4 °F to 122°F).

Storage maintenance

The batteries must be charged at regular intervals in order to maintain their capacity. Make sure the batteries are fully charged when table is put into storage, check battery status annually, recharge if below 60%.

Imaging area

The area suitable for imaging illustrated in “green” below.
Aluminum equivalence for radiolucency reference:
0.4 mm Al. Eq. according to IEC 60601-1-3:1994
0.65 mm Al. Eq. according to IEC 60601-2-54:2022 Ed. 2.0.
Picture shows table with the standard tabletop, positioned in full float forward, with area 3 located over the column.
During float operating, area 2 and 3 will change in size as the tabletop moves over the column, area 1 will remain unchanged and will never pass over the column.



ID	AREA	Note
1	550 x 804 mm	360 ° free imaging
2	483 x 888 mm	AP imaging area
3	280/483 x 608 mm	AP imaging area
Mattress	N/A	0.44 mm Aluminum equivalence

Technical information

Error messages and system failures

Indication	Description
Flashing position lost indicator	The motor position has been lost and calibration is needed.
All lights flashing	A fatal error has occurred. Can be caused by for example a loose cable between a motor and the control box. Reset by holding table up/down button simultaneously for five seconds. Note! The usage of the imagiQ3 during a fatal error is to be avoided but can be possible under careful supervision, if needed to finalize an ongoing procedure.

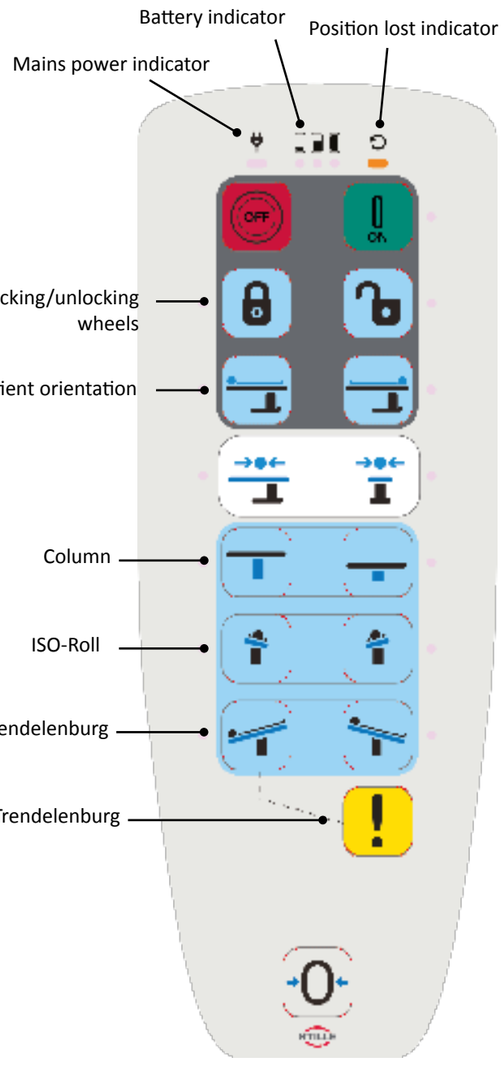
Calibration of motors

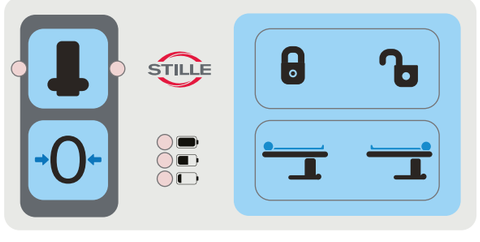
If the control box has lost the motor position, a calibration is needed. This is indicated by a flashing position lost LED on the hand control.

For buttons with LED's on the hand control, they light up to mark the position lost.

To calibrate motor(s) do the following:

- Run the column to the top position.
- Run the ISO-Roll™ all the way to the left side, then all the way to the right side.
- Lock the wheels.
- Run the Trendelenburg fully head up (free end of the table), then all the way down.
- The motors are now calibrated!





Cables maximum lengths and EMC information

■ List of cables and maximum lengths for cables of imagiQ3

Maximum cable lengths for the imagiQ3					
Cable		Maximum length	Type	Dimensions	
Mains power cord	AC-cable EC	5 meters / 16.4 feet	16 AWG / < 1.291 mm²	3* 1.291 mm²	3 x 0.0508 in²
	AC-cable UK	5 meters / 16.4 feet	16 AWG / < 1.291 mm²	3* 1.291 mm²	3 x 0.0508 in²
	AC-cable US (Hospital grade)	5 meters / 16.4 feet	16 AWG / < 1.291 mm²	3* 1.291 mm²	3 x 0.0508 in²
	AC-cable JP	5 meters / 16.4 feet	16 AWG / < 1.291 mm²	3* 1.291 mm²	3 x 0.0508 in²
Hand control including extension cord, shielded		>3 meters/< 9,84 feet allowed	26AWG/0,14mm2	6x0,14mm2	0.0000015069 ft2
Pan handle including extension cord, shielded		>3 meters/< 9,84 feet allowed	26AWG/0,14mm2	6x0,14mm2	0.0000015069 ft2
Foot control including extension cord		>3 meters/< 9,84 feet allowed	min 24AWG/0,25mm	9x0,25mm2	0.0000026909 ft2

■ Electromagnetic Emissions

ImagiQ3 is intended for use in a Professional healthcare environment. The customer or the user of imagiQ3 should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment-guidance
RF-emission CISPR 11	Group 1	imagiQ3 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-emission CISPR 11	Class A	imagiQ3 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 purpose.
Harmonic emissions IEC 61000-3-2	Approved	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Approved	

Not: Figure 1 of the EN 60601-1-2 standard used for creation of this table (Table 1 in the standard).

■ Recommended separation distance between portable and mobile RF communications equipment and imagiQ3

imagiQ3 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of imagiQ3 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and imagiQ3 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 m		
	150KHz to 80MHz d= [0,58]VP	80MHz to 800MHz d= [0,35]VP	800MHz to 2,5GHz d= [0,7]VP
0,01	0,058	0,035	0,07
0,1	0,18	0,11	0,22
1	0,58	0,35	0,7
10	1,8	1,1	2,2
100	5,8	3,5	7,0

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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 to 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.
Note: Figure 5 of the IEC 60601-1-2 standard used for creation of this table (Table 6 in the standard).
Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
Not: Figure 5 of the EN 60601-1-2 standard used for creation of this table (Table 6 in the standard).

■ Guidance and manufacturer's declaration – electromagnetic immunity

The imagiQ3 is intended for use in a Professional healthcare environment. The customer or the user of the imagiQ3 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	+/- 8 kV contact +/- 2, +/-4, +/-8 +/-15 kV air	+/- 8 kV contact +/- 2, +/-4, +/-8 +/-15 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 %.
61000-4-3 Immunity to radiated RF, 80 – 2700 MHz + Table 9	3 V/m 80MHz – 2,7GHz 80%AM at 1 kHz	3 V/m 80MHz – 2,7GHz 80%AM at 1 kHz	Mains power quality should be that of a typical commercial or hospital environment.
Electrical fast transient / Burst IEC 61000-4-4	+/- 2 kV for power supply lines 100 kHz repetition frequency	+/- 2 kV for power supply lines 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
61000-4-5 Surge Line-to-line	+/- 0,5, +/-1 kV	+/- 0,5, +/-1 kV	Mains power quality should be that of a typical commercial or hospital environment.
61000-4-5 Surge Line-to-ground	+/- 0,5, +/-1, +/-2 kV	+/- 0,5, +/-1, +/-2 kV	Mains power quality should be that of a typical commercial or hospital environment.
61000-4-6 Immunity to conducted RF	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80% AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80% AM at 1 kHz	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 60 Hz	30 A/m 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles h) Single phase: at 0° 0 % UT; 250/300 cycle	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles h) Single phase: at 0° 0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the [Equipment or System] requires continued operation during power mains interruptions, it is recommended that the [Equipment or System] be powered from an interruptible power supply or battery.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

■ Electromagnetic Immunity

imagiQ3 is intended for use in the electromagnetic environment specified below.
The customer or the user of the imagiQ3 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 imagiQ3, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
61000-4-3 Immunity to radiated RF, 80 – 2700 MHz + Table 9	3 V/m 80MHz – 2,7GHz 80%AM at 1 kHz	3V/m	d= [0,35]√P 80 MHz to 800 MHz d= [0,7]√P 800 MHz to 2,7 GHz
61000-4-6 Immunity to conducted RF	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80% AM at 1 kHz	6 V	d= [0,58]√P
			Where P is the maximum output rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strength 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 80MHz and 800 MHz, the higher frequency range applies.
Note 2 These guidelines may not apply in all situations. Electromagnetic propagations are affected by absorption and reflection from structures, objects and people.

a Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, armature 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 imagiQ3 is used exceeds the applicable RF compliance level above, imagiQ3 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating imagiQ3.
b Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 10 V/m.

■ WARNING: Using other cables and accessories than the specified, can possibly increase the emission and decrease the immunity in regards of EMC requirement.

Not: Figure 5 of the EN 60601-1-2 standard used for creation of this table (Table 4 in the standard).

■ Test specifications for Enclosure port Immunity to RF wireless communication equipment

Test frequency (MHz)	Band a) (MHz)	Service a)	Modulation b)	Maximum power (W)	Distance (M)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation b)18 Hz	1,8	0,3	27
450	430-470	GMRS 460, FRS 460	FM c) +/-5 kHz deviation 1 kHz sine	2	0,3	28
710 745 780	704-787	LTE band 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9
810 870 930	800-960	GSM 800/900 TETRA 800 iDEN820 CDMA 850 LTE band 5	Pulse modulation b) 18 Hz	2	0,3	28
1720 1845 1970	1700-1990	GSM 1800 CDMA 1900 GSM 1900 DECT LTE band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	2	0,3	28
2450	2400-2570	Blue tooth WLAN 802.11 b/g/n RFID 2450 LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Compliance criteria.
Under the test conditions specified in IEC 60601-1-2-2014. 8.9 IMMUNITY TEST LEVELS, the equipment shall be able to provide the essential performance and remain safe. The following degradations associated with essential performance and basic safety shall not be allowed:

- Component failure	Not allowed
- Change in programmable parameters (zero-position)	Not allowed
- Initiation of any unintended operation, including unintended or uncontrolled motion, even if accompanied by an ALARM SIGNAL	Not allowed
The equipment may exhibit degradation of performance that does not affect essential performance or safety.	

TECHNICAL INFORMATION

The imagiQ3 is intended for use in the electromagnetic environment specified below. The customer or the user of the imagiQ3 should assure that it is used in such an environment.			
TEST	Voltage	Mode of operation / Cable	Test level
Radiated emission, 30 - 1000 MHz	230 V, 50 Hz, Hand control 100 V, 60 Hz, Hand control	On / Enclosure	Class A
Conducted emission, 0.15 - 30 MHz	240 V, 50 Hz, Hand control 100 V, 60 Hz, Hand control	O / AC Mains	Class A
Harmonics	230 V, 50 Hz	Standby / AC Mains	A
Flicker	230 V, 50 Hz	Standby / AC Mains	-
ESD	230 V, 50 Hz	Standby / Enclosure	C: ± 8 kV A: ± 2, ±4, ±8, ±15 kV
Immunity to radiated RF, 80 - 2700 MHz	230 V, 50 Hz	Standby / Enclosure	3 V/m
Immunity to radiated RF spot frequencies, 80 - 6000 MHz	230 V, 50 Hz	Standby / Enclosure	See test levels in table 9, IEC60601-1-2:2014
ISO 18000-3 Mode 3	13.56 MHz, 12 A/m	13.56 MHz, 12 A/m	
ISO/IEC 18000-7	433 MHz 3 V/m	433 MHz 3 V/m	
ISO/IEC 18000-63 Type C	860-960 MHz 54 V/m	860-960 MHz 54 V/m	
ISO/IEC 18000-4 Mode 1	2.45 GHz 54 V/m	2.45 GHz 54 V/m	
Burst	230 V, 50 Hz	Standby / AC Mains, 1 signal cable (hand control HB190)	± 2 kV ± 1 kV
Surge	230 V, 50 Hz	Standby / AC Mains	± 0,5 kV ± 1 kV ± 2 kV
Immunity to conducted RF	230 V, 50 Hz	Standby / AC Mains, 1 signal cable (hand control HB190)	10 V
Immunity to magnetic fields	230 V, 50 Hz	Standby / Enclosure	30 A/m
HF-surgery	230 V, 50 Hz	Standby / Enclosure	
Immunity to radiated RFID frequencies	134.2 kHz 65 A/m 13.56 MHz 12 A/m	Standby / Enclosure	
Voltage dips and interruptions	100 V, 50 Hz; 240 V, 50 Hz	Standby / AV mains	
NOTE! UT is the a.c. mains voltage prior to application of the test level. NOTE! The pass/fail criteria shall be based on the essential performance and basic safety for the product. Other criteria which do not affect the essential performance and basic safety are not included in EN/IEC 60 601-1-2, Ed. 4. If that should be supervised as well, please specify those pass/fail criteria as additional criteria. NOTE! If the product or system is tested with radio-module, specify allowed degradation of performance regarding radio communication during immunity testing (see relevant EN301489 – X standard(s)).			

Essential performance. The essential performance of the table is defined as the ability to support a patient without unwanted movement as well as the ability to reach positions for emergency treatment, in this case Trendelenburg position and flat table position for CPR (Cardiopulmonary Resuscitation). Note: For EMC testing, the only relevant essential performance is the ability to support a patient without unwanted movement. The function can be activated by the use of the hand control and can manually be achieved as an emergency function in cases of power failure.

1. Description of the Essential Performance and basic safety of the EUT: For EM disturbance testing, the only relevant essential performance is supporting a PATIENT without unwanted movement in a SINGLE FAULT CONDITION (IEC 60601-2-46:2016)
2. Describe the compliance (pass/fail) criteria for each test:
   No permanent degradation or loss of function or OPERATOR settings (table memory positions such as "Level"-position) which are not recoverable shall be observed;

   No unintended movement of the table shall be observed.
   Functional disturbances corresponding to the inability to use built in motors is acceptable for up to 15 s.

   Within 15 s after the immunity test the OPERATING TABLE shall resume normal operation in the previous operating mode, without loss of any OPERATOR settings or stored data, and shall continue to perform its intended function as described in the ACCOMPANYING DOCUMENTS. Can for example be verified through the hand control button for "Level"-position 15 s after test completion, with the expected result of the table reaching the same position as before the test was initiated. Prior testing, the table shall be brought to a different position than "Level"-position, i.e. "Trend"-position.

TECHNICAL INFORMATION

Environment and recycling

Environment

- Follow local laws and regulations issued by the local government and environmental protection authority.
- Do not dispose of discharged batteries in ordinary household waste, in water, or in an open fire.
- Drain the operating table of hydraulic oil before sending it for recycling.

Replacing the Batteries and Electrical Components

EU Waste Electrical and Electronic Equipment (WEEE) Directive

In August of 2005, the European Union (EU) implemented the EU WEEE Directive 2002/96/EC and later the WEEE Recast Directive 2012/19/EU requiring Producers of electronic and electrical equipment (EEE) to manage and finance the collection, reuse, recycling and to appropriately treat WEEE that the Producer places on the EU market after August 13, 2005. The goal of this directive is to minimize the volume of electrical and electronic waste disposal and to encourage re-use and recycling at the end of life.

Battery recycling

- Lithium-ion batteries are to be recycled at battery recycling facilities, follow local laws and regulations.

All components of the battery can be recycled and/or recovered. Damaged batteries should be replaced and handled according to safety regulations for batteries.

- Do not place damaged replaced batteries in the regular trash or recycling container, local laws apply.
- Always wear protective gloves and eye wear when working with the batteries.
- Risk for fire or explosion.

Replacing electrical components

- If an electrical component is replaced, it shall be handled as electronic waste and be recycled, check local laws and regulations.
- If you have purchased STILLE-branded electrical or electronic products and are intending to discard these products at the end of their useful life, please do not dispose of them in household or municipal waste.

Replacing the hydraulic oil

- If the hydraulic oil is replaced, the waste oil should be handled as chemical waste and should be contained and recycled, check local laws and regulations.
- Always wear protective gloves and eye wear.
- For further details regarding recommendations for recycling of the device, see the service manual.

Technical / Standard

Standards
- IEC 60601-1:2005+A1:2012+A2:2020, Medical electrical equipment – Part 1: General Requirements for basic safety and essential performance.
- IEC 60601-2-46:2016, third edition, Medical electrical equipment - Part 2-46: Particular requirements for the basic safety and essential performance of operating tables.
- IEC 60601-1-2:2014, fourth edition, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests.
- CAN/CSA C22.2 NO. 60601-1:14 (R2018), 3rd edition (2014-03-01) Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (Adopted IEC 60601-1:2005, third edition, 2005-12, including amendment 1:2012, with Canadian deviations)
- Medical Electrical Equipment, Part 1: General Requirements For Basic Safety And Essential Performance (R2012) [AAMI ES60601-1:2005+C1;A2]
- Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (R2018) [CSA C22.2#60601-1:2014 Ed.3]
- Medical Electrical Equipment - Part 2-46: Particular Requirements for the Basic Safety and Essential Performance of Operating Tables [CSA C22.2#60601-2-46:2018 Ed.3]

Applied Part
- The Type B applied part is the mattresses/pads.

Essential Performance
- Essential performance of the table is the Trendelenburg function. The function allows for positioning of the patient in position for emergency treatment. The function can be activated by the use of the hand control and can manually be achieved as an emergency function in cases of power failure.

Definitions/ Classifications
- ME equipment classified Group 1, Class A according to CISPR 11
- The definition Technical Lifetime is the same as Expected Service Life 10 years.
- The technical life time of the batteries is 5 years if they are well maintained and charged regularly. The technical lifetime for the mattress/pads is 3 years.
- The definition of maximum patient weight is the same as Maximum Safe Work Load (SWL).
- The Maximum Safe Work Load is the maximum weight of the patient and attached accessories.
- The potential equalization conductor is the zero potential connector.

Technical Lifetime (Expected service life)
- This product has a technical lifetime, which by STILLE AB is considered to be 10 years. At the time of delivery the product fulfils the existing regulations and standards but as all other electromechanical products.
- The imagiQ3 table is subjected to age and wear, and even though the product undergoes regular and prescribed maintenance, STILLE AB can not guarantee the product's safety after the expiry of the technical lifetime.
- STILLE AB recommends that the product is taken out of service after latest 10 years.
- Spare parts and service provided by STILLE AB after the expiry of the specified technical lifetime does not mean an extension of STILLE AB's liabilities.
- Some components of the product have a shorter technical lifetime, and should be replaced once the technical lifetime has expired.
- Technical lifetime of the batteries (if well maintained and charged regularly) is 5 years.
- Technical lifetime of the mattress is 3 years.
- Technical lifetime of the hydraulic pump is 5 years.
- Technical lifetime of the Trendelenburg actuator is 6 years.
- Technical lifetime of the lift actuator is 7 years.
- The use of the device after its technical lifetime has expired is done solely on the user's responsibility.
- Only cleaned and disinfected parts may be disposed.

California Proposition 65

What is this warning?

The following warning is associated with our product, as well as on many other products purchased from other manufacturer´s:

WARNING: This product can expose you to chemicals which are known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

The warning does not mean our products will necessarily cause cancer or other harm. Moreover, a Proposition 65 warning does not mean a product is in violation of any product-safety standards or requirements. In fact, the California government has clarified that "the fact that a product bears a Proposition 65 warning does not mean by itself that the product is unsafe." The government has also explained, "You could think of Proposition 65 more as a 'right to know' law than a pure product safety law."
While we believe our products are not harmful when used as designed, we choose to provide the warning as a result of this California law.

What is Proposition 65?

Proposition 65 is a broad law that applies to any company operating in California, selling products in California, or manufacturing products that may be sold in, or brought into, California. Proposition 65 mandates that the Governor of California maintain and publish a list of chemicals that are known to cause cancer, birth defects and/or other reproductive harm. The list, which must be updated annually, includes a wide variety of chemicals that can be found in many everyday items, such as dyes, solvents, drugs, food-additives, by-products of certain processes, pesticides, and tobacco products.

The purpose of Proposition 65 is to ensure that people are informed about exposure to these chemicals. Proposition 65 also requires warnings to be placed on any product, or product packaging, or literature accompanying a product that contains or may contain any of the more than 800 chemicals that the California Air Resources Board considers harmful. As noted above, many of the elements listed under Proposition 65 have been routinely used in everyday consumer items for years without documented harm.

A warning must be given if the listed chemical is merely present in a product unless a business demonstrates that the exposure it causes poses "no significant risk". With respect to carcinogens, the "no significant risk" level is defined as the level that is calculated to result in not more than one excess case of cancer in 100,000 individuals exposed over a 70-year lifetime. In other words, if you are exposed to the chemical in question at this level every day for 70 years, theoretically, it will increase your chances of getting cancer by no more than 1 case in 100,000 individuals so exposed. With respect to reproductive toxins, the "no significant risk" level is defined as the level of exposure that, even if multiplied by 1,000, will not produce birth defects or other reproductive harm. In other words, the level of exposure is below the "no observable effect level," divided by 1,000. (The "no observable effect level" is the highest dose level that has not been associated with observable reproductive harm in humans or test animals.)

A Proposition 65 warning generally means one of two things: (1) the business has evaluated the exposure and has concluded that it exceeds the "no significant risk level"; or (2) the business has chosen to provide a warning simply based on it's knowledge about the presence of a listed chemical without attempting to evaluate the exposure.

STILLE has chosen to provide a warning based on it's knowledge about the presence of one or more listed chemicals without attempting to evaluate the level of exposure, as not all of the listed chemicals provide exposure limit requirements. With STILLE products, the exposure may be negligible or well within the "no significant risk" range. However, out of an abundance of caution, STILLE has elected to provide the Proposition 65 warnings.

Why does STILLE include this warning?

The penalties for not complying with Proposition 65 are high. As a result of the potential penalties, and because there is no penalty for providing an unnecessary warning, STILLE, as well as many other manufacturer´s, have elected to provide the Proposition 65 notice on our products out of an abundance of caution in order to avoid the potential for liability. I purchased this product outside of California; why is it included? STILLE products are sold World Wide. It would be extremely difficult and costly to determine which products will be ultimately sold or brought into California. Therefore, to ensure compliance with Proposition 65 requirements, STILLE has decided to include these warnings on our product, regardless of origin and location sold.

For more information go to: http://www.p65warnings.ca.gov/
For more information about Proposition 65 visit: http://www.oehha.ca.gov/prop65/getNSRLs.html

TECHNICAL INFORMATION

Revision history

Version	Date	Reason for update	Updated by
01	2024-10-18	Official release	Ralph Tamm

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imagiQ3™ Legacy

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