



QUEST SPECTRUM[®] 3.0

Instructions for Use



Intraoperative Fluorescence Imaging
Open and Minimally Invasive Surgery



QUEST SPECTRUM® 3.0

Intra-operative Fluorescence Imaging

Open and Minimal Invasive Surgery





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1 Health and Safety Compliance

1.1 Important Information



WARNING: Read Before Use



This instruction manual contains essential information on using the QUEST SPECTRUM® 3.0 safely and effectively. Before use, thoroughly review this manual and use the system as instructed.

Keep this manual in a safe, accessible location. Questions or comments about any information in this manual should be sent to Quest Medical Imaging B.V.

The following signal words serve to distinguish between warning notes according to the type of danger:



WARNING: indicates risks to the safety of the patient or user. Failure to follow warnings may result in injury to the patient or user.



CAUTION: indicates risks to the equipment. Failure to follow cautions may result in product damage.



Note: provides special information to clarify instructions or present additional useful information.

1.2 Indication for Use

The QUEST SPECTRUM® 3.0 is intended for intraoperative and minimal invasive visual assessment of blood vessels and related tissue perfusion, by enabling surgeons to observe fluorescent images of blood vessels and related tissue.



WARNING: The QUEST SPECTRUM® should be used according to its approved Indication for Use.

1.3 User Qualifications

This manual is addressed exclusively to qualified and trained personnel (licensed physician, medical assistants supervised by a licensed physician). The QUEST SPECTRUM® 3.0 is to be used exclusively by qualified personnel to carry out clinical applications.



WARNING: This manual does not explain or discuss clinical procedures. The qualified personnel is responsible for correct execution of clinical procedures.

1.4 Repair and Modification



WARNING: The QUEST SPECTRUM® 3.0 does not contain any user-serviceable parts. On a yearly basis a preventive inspection or maintenance is recommended. Do not disassemble, modify or attempt to repair it. Patient or user injury and/or instrument damage can result

Minor problems that appear can be solved by Troubleshooting, refer to 10 Appendix A: Trouble Shooting. If a problem cannot be resolved, contact Quest Medical Imaging. Before sending it back:

- ❖ Clean, disinfect and sterilize the light guide cable and laparoscope thoroughly prior to returning for repair.
- ❖ Clean and disinfect the QUEST SPECTRUM® 3.0 and its camera and ring light.
- ❖ Return the part in its original packaging. If this is not possible, package the part to secure it for transport.
- ❖ Quest Medical Imaging is not liable for damage resulting from improper shipping.



Note:

The QUEST SPECTRUM® 3.0 and its separate components are backed by a warranty period according to the national regulations on parts and labor, starting from the moment that the product is dispatched from Quest Medical Imaging B.V. The warranty covers defects in parts as described in the Terms and Conditions.

2 System Overview

2.1 Components

The QUEST SPECTRUM® 3.0 is a Fluorescent Imaging System designed and developed to assist in open and minimally invasive fluorescence image-guided surgery and consists of the following components shown in Figure 1.



Figure 1: Overview of the QUEST SPECTRUM® 3.0. 1) 4K Monitor, 2) Sensitive camera, 3) Interactive touchpad, 4) Trolley



WARNING: Do not use the QUEST SPECTRUM® 3.0 with components that have not been clearly identified for use with the system



WARNING: Do not exchange components of the QUEST SPECTRUM® 3.0 between devices.



Note: The QUEST SPECTRUM® 3.0 can be used for minimal invasive surgeries by connecting the QUEST SPECTRUM® Laparoscope to the QUEST SPECTRUM® Camera.

2.2 Imaging Agent

- ❖ The Indocyanine Green (ICG) imaging agent is a sterile, water-soluble lyophilized green powder. ICG contains not more than 5.0% sodium iodide.
- ❖ ICG for Injection USP is dissolved using Sterile Water for Injection, and is to be administered intravenously.
- ❖ Instructions for preparation, handling and administration of ICG imaging agent are provided in Chapter 4 ICG Safety.

2.3 Article List

Table 1: Overview of all articles sold with the QUEST SPECTRUM® 3.0. ¹Laparoscopes have a separate manual, ²Drapes have a separate manual, ³USA only.

Article Number	Item Name
System	
ART-SYS-0029	QUEST SPECTRUM® 3.0 for VIS/ICG/MB 115V
ART-SYS-0030	QUEST SPECTRUM® 3.0 for VIS/ICG/MB 230V
Included components	
ART-HH-0016	QUEST SPECTRUM® Camera
ART-LE-0016	QUEST SPECTRUM® Light Engine
ART-MC-0004	QUEST SPECTRUM® IPC
ART-MC-A01-0012	Barco Branded 4K UHD surgical display
ART-CS-0100	QUEST SPECTRUM® Capture Suite
Optional components	
ART-RL-0012	QUEST SPECTRUM® Ring Light & Lens
ART-LAP-0008	QUEST SPECTRUM® Laparoscope 30° ¹
ART-LAP-0008S	QUEST SPECTRUM® Laparoscope 30° Short ¹
ART-LAP-0009	QUEST SPECTRUM® Laparoscope 0° ¹
ART-LAP-0009S	QUEST SPECTRUM® Laparoscope 0° Short ¹
ART-OP-0007	QUEST SPECTRUM® Light Cable ¹
Drapes	
ART-DRP-0-004	QUEST SPECTRUM® one-piece drape for Open Surgery ^{2,3}
ART-DRP-1-000	QUEST SPECTRUM® two-piece drape for Open Surgery ²
ART-DRP-1-001	QUEST SPECTRUM® two-piece drape Laparoscopic Surgery ²
Kits	
ART-ICG-0001	QUEST SPECTRUM® Kit for open surgery ³
ART-ICG-0002	QUEST SPECTRUM® Kit for laparoscopic surgery ³

3 General System Safety

3.1 Electrical Safety – General

-  **WARNING:** To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth.
-  **WARNING:** Do not use the system adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, observe to verify normal operation in the configuration in which it will be used.
-  **WARNING:** Do not connect multi-socket extension cords to QUEST SPECTRUM® 3.0. Connecting additional devices may overload the power supply of the QUEST SPECTRUM® 3.0.
-  **WARNING:** Do not connect devices to QUEST SPECTRUM® 3.0 that are not compliant with IEC 60601-1. Non-compliant devices may cause the QUEST SPECTRUM® 3.0 to stop functioning or show abnormal behavior.
-  **CAUTION:** Do not use or store liquids around the QUEST SPECTRUM® 3.0. If liquid enters components of the QUEST SPECTRUM® 3.0, immediately turn system off and unplug it from the power outlet.
-  **CAUTION:** Do not insert objects into the ventilation holes of QUEST SPECTRUM® 3.0 enclosure.
-  **CAUTION:** Do not connect or disconnect the camera cable while QUEST SPECTRUM® 3.0 is powered on.

3.2 Electrical Safety – Power

-  **WARNING:** Do not connect any devices to the power connectors inside the QUEST SPECTRUM® 3.0. Connecting additional devices may overload the power supply of the QUEST SPECTRUM® 3.0.
-  **WARNING:** Do not use the QUEST SPECTRUM® 3.0 if the power cord or plug is damaged or modified in any way.
-  **WARNING:** Do not remove or override the ground connection on the power cords.
-  **CAUTION:** Unplug power cords by grasping the plug. Do not unplug power cords by pulling on the cable.

3.3 Damaged or Malfunctioning Equipment

-  **WARNING:** Do not use QUEST SPECTRUM® if any part of the system is damaged or does not function properly. Failure to follow this warning may lead to injury.

3.4 Light Safety

 **WARNING:** Do not detach the optical fiber from the ring light or laparoscope when the excitation light source is enabled. Without qualified optical components ring light or laparoscope, the excitation light source must be considered class 3B and corresponding precautions must be taken.

LASER RADIATION
DO NOT VIEW DIRECTLY WITH OPTICAL INSTRUMENTS
CLASS 1M LASER PRODUCT WHEN USED WITH
QUALIFIED RING LIGHT AND LAPAROSCOPE

 **WARNING:**

 **WARNING:** Do not view the beam with magnifying optical instruments (e.g. a loupe).

 **WARNING:** Do not look in the QUEST SPECTRUM Light Engine's exit port (see 7.2.2 for the exact location of the exit port).

 **WARNING:** Do not stare into the output of the light engine. The brightness of this light source is higher than most commercial lighting fixtures and is intended to couple directly into a lighting cable.

 **CAUTION:** Do not open the unit. There are no serviceable parts inside and opening the Light Engine enclosure will void the manufacturer's warranty.

 **CAUTION:** Do not shine Light Engine beam in the direction of other people or at reflective surfaces.

3.5 Cleaning and Disinfecting

 **WARNING:** Follow the instructions in Chapter 9 to clean, disinfect and/or sterilize the QUEST SPECTRUM® 3.0 components and accessories.

 **WARNING:** Do not sterilize the Ring Light with Lens.

4 ICG Safety

4.1 Clinical Pharmacology

Following intravenous injection, Indocyanine Green (ICG) is rapidly bound to plasma protein, of which albumin is the principle carrier (95%). ICG undergoes no significant extrahepatic or enterohepatic circulation; simultaneous arterial and venous blood estimations have shown negligible renal, peripheral, lung or cerebral-spinal uptake of the dye. ICG is taken up from the plasma almost exclusively by the hepatic parenchymal cells and is secreted entirely into the bile. After biliary obstruction, the dye appears in the hepatic lymph, independently of the bile, suggesting that the biliary mucosa is sufficiently intact to prevent diffusion of the dye, though allowing diffusion of bilirubin. These characteristics make ICG a helpful index of hepatic function.

The plasma fractional disappearance rate at the recommended 0.5 mg/kg dose has been reported to be significantly greater in women than in men, although there was no significant difference in the calculated value for clearance.

4.2 Contraindications

ICG for Injection USP contains sodium iodide and should be used with caution in patients who have a history of allergy to iodides.

4.2.1 General

ICG Powder and Solution: ICG is unstable in aqueous solution and must be used within 6 hours. However, the dye is stable in plasma and whole blood so that samples obtained in discontinuous sampling techniques may be read hours later. Sterile techniques should be used in handling the dye solution as well as in the performance of the dilution curves.

ICG powder may cling to the vial or lump together because it is freeze-dried in the vials. This is not due to the presence of water - the moisture content is carefully controlled. The ICG is suitable for use.

4.2.2 Drug Interactions

Heparin preparations containing sodium bisulfite reduce the absorption peak of ICG in blood and, therefore, should not be used as an anticoagulant for the collection of samples for analysis.

4.2.3 Drug/Laboratory Test Interactions

Radioactive iodine uptake studies should not be performed for at least a week following the use of ICG.

4.2.4 Carcinogenesis, Mutagenesis, Impairment of Fertility

No studies have been performed to evaluate the carcinogenicity, mutagenicity, or impairment of fertility.

Pregnancy Category C: Animal Reproduction studies have not been conducted with ICG. It is not known whether ICG can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. ICG should be given to a pregnant woman only if clearly indicated.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when ICG is administered to a nursing woman.

4.2.5 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

4.2.6 Geriatric Use

No overall differences in safety or effectiveness have been observed between elderly and younger patients.

4.3 Adverse reactions

Anaphylactic or urticarial reactions have been reported in patients with or without history of allergy to iodides. If such reactions occur, treatment with the appropriate agents (e.g., epinephrine, antihistamines, and corticosteroids) should be administered.

4.4 Overdosage

There are no data available describing the signs, symptoms, or laboratory findings accompanying overdosage. The LD 50 after I.V. administration ranges between 60 and 80 mg/kg in mice, 50 and 70 mg/kg in rats and 50 and 80 mg/kg in rabbits.

Under sterile conditions, the ICG for Injection USP powder should be dissolved with Sterile Water for Injection, *USP*. Exactly 5 mL of Sterile Water for Injection, *USP*, should be added to the 25-mg vial, giving 5 mg of dye per mL of solution.

5 Symbols and indicator Lights

Table 2: General Symbols and Signs

	Article number
	Serial number
	Applied part Class 1 BF type
	Manufacturer
	Follow instructions for use

Table 3: Symbols and Signs IPC

	On/ off button with blue light indicator
---	--

Table 4: Symbols and Signs Trolley

	Aperture Warning: Do not view the beam with magnifying optical instruments (e.g. a loupe).
	Laser warning indications

6 Disposal

The QUEST SPECTRUM® components and consumables should be disposed of in compliance with local, regional and national regulations.

- ❖ Single use or consumable components and accessories such as the QUEST SPECTRUM® Drapes should be disposed in compliance with the regulatory regulations.
- ❖ Other QUEST SPECTRUM® 3.0 components should be returned to Quest Medical Imaging B.V. for disposal.

7 Unpacking and Setting Up

7.1 Unpacking the System



WARNING: Check according to Table 5 below if all components are complete and undamaged before proceeding installing the QUEST SPECTRUM® 3.0. Contact Quest Medical Imaging B.V. or representative if components are missing or damaged.



Note: The QUEST SPECTRUM® Drapes are purchased separately.

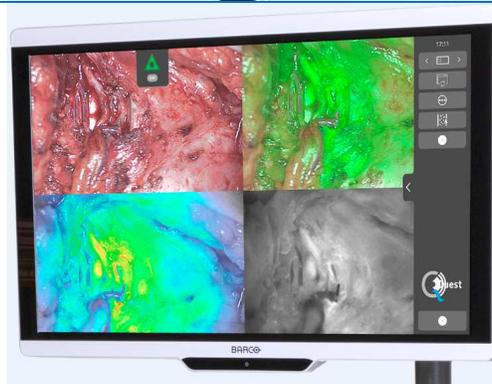
Table 5: Component summary

Description	Component
<p>QUEST SPECTRUM® Camera</p> <p>+</p> <p>QUEST SPECTRUM® Ring Light (optional)</p>	
<p>QUEST SPECTRUM® Camera</p> <p>+</p> <p>QUEST SPECTRUM® Laparoscope (optional)</p>	
<p>QUEST SPECTRUM® IPC</p>	

Trolley



Barco Branded 4K UHD surgical display



Instructions for Use



<p>Draping Instructions</p>	
<p>Quick Start</p>	

7.2 Setting Up QUEST SPECTRUM® 3.0

7.2.1 Installation of components

Quest Medical Imaging or a qualified representative will install the components.



CAUTION: Installation by personnel that is not qualified by Quest Medical Imaging can result in damage or failure of the device. Quest Medical Imaging is not liable for damage caused by installation by unqualified personnel.

7.2.2 Main power supply

In **Error! Reference source not found.** the main power supply of the QUEST SPECTRUM® 3.0 is shown. Make sure both cables are connected to ensure power supply and protective earth.



Figure 2: Main power supply



Note:

The yellow-green cable is omitted in the USA version. The protective earth is incorporated in the black cable.



Note:

Make sure to use the metal frame above the power supply in order to prevent accidental disconnection of the cables which can result in undesired power loss.

7.2.3 Camera and Light Connector

In Figure 3, the Camera and Light connection are shown. The camera adapter has a magnetic lock mechanism that eases the connection. The Ring light or the Laparoscope adapter can be connected to the Quest Spectrum®. Make sure the adapter is in the locked position: **push & click**



Figure 3: Camera and Light Connection



CAUTION:

Connecting devices can cause failure to the QUEST SPECTRUM® 3.0. Quest Medical Imaging B.V. is not liable for any resulting damage.

7.2.4 Connecting Ring Light or Laparoscope to the Camera

Depending on the procedure a laparoscope or ring light needs to be attached to the camera. The fully assembled camera consists of two parts: the camera & the ring light/laparoscope. When assembling, make sure that the three pins on the ring light/laparoscope fit into the camera.



Figure 4: Connecting the ring light/Laparoscope to the camera

Assembly:

- 1) Unlock the camera by turning the lens adapter clockwise (from the user's perspective)
- 2) Insert the ring light/ laparoscope into the camera
- 3) Make sure the lens adapter is back in the locked position:
 - a. Check if you hear a click
 - b. Check if rotation of the laparoscope/ring light is possible

8 Operation

8.1 Preparing the QUEST SPECTRUM® 3.0

Take the following into consideration before moving the QUEST SPECTRUM® 3.0.

1. If the Trolley is equipped with an arm onto which the camera or a monitor is mounted, the arm should be folded away before the Trolley is moved.
2. Ensure that objects being transported on the Trolley are properly attached.
3. Cables must be securely rolled away.
4. Before moving the Trolley, release the brakes of all wheels.

5. Use the side handles to push the Trolley.
6. Adjust your speed to the immediate circumstances.
7. Drive cautiously over inclines and obstacles such as cables and thresholds (elevator). If this is necessary, do it slowly by at least two persons.
8. Be aware that the Trolley always has a certain brake path.
9. If you plan to move backwards, watch out that you do not become trapped between the Trolley and obstacles.
10. When the Trolley is equipped with an arm to which the camera is attached, make sure that when moving (swivelling or lifting) the arm, trolley or camera, neither hit any objects or persons. Do not pull or push the arm to move the Trolley!
11. Make sure to fold the IPC back in its closed position before moving the trolley.
12. Before use, select a stable location with sufficient space.
13. Use the Trolley only with the wheels in their fixed position (brakes applied).
14. The Trolley is usually placed on the other side from where the surgeon is positioned but can be placed in a different position if preferred.
15. The equipment on the Trolley needs a power supply to function. The Trolley is equipped with a medical isolation transformer located below in the Trolley that is connected with the 5 m (16.4 ft) mains cable to the mains power supply. Always plug into an electrical socket with Protective Earth. Do not lay the mains cable over pathways and prevent persons from tripping over the cable.
16. All devices are to be connected via a potential compensation cable with the potential compensation bar. First connect the potential compensation (potential equalization) with the corresponding plug pin and then connect the mains plug. During electric safety measurements and tests (leakage currents, etc.) the potential equalization cable has to be disconnected temporarily.
17. When all components of the QUEST SPECTRUM® 3.0 are connected and the Trolley is plugged into the mains power supply.



WARNING: The QUEST SPECTRUM® 3.0 needs to be draped prior clinical usage. The Draping procedure is explained in its own manual.



WARNING: The QUEST SPECTRUM® Laparoscopes needs to be sterilized prior usage. The sterilization procedures are explained in its own manual.

8.2 Brake instructions

The QUEST SPECTRUM® 3.0 can be put on the brakes by using the buttons on the side of the trolley.



Figure 5: Brake control centre

 **CAUTION:** Before lowering the brakes, make sure no cables or other objects are underneath.

8.3 Powering on and Shutting the QUEST SPECTRUM® 3.0 down

The QUEST SPECTRUM® 3.0 can be powered on with the On / Off button which can be found on the IPC. The on/off button only needs to be pressed once. After having pressed once the blue light indicator should light up as an indicator that the system is starting up. This light will stay on until the system has been shut down.

The shutting down process also includes pressing the On / Off button once. As a result, the blue light indicator will start flickering as an indicator that the system is shutting down. The system has been shut down when the button stopped flickering

8.4 Starting surgery

The QUEST SPECTRUM® 3.0 will load into the start surgery screen immediately after powering on (see figure 8). For the surgery to commence, the right surgeon and surgery type need to be selected (see figure 8 & 9). Also, an option is given to insert the patient's data (see figure 7). However, this step is not mandatory, it can be skipped. After all this, the surgery and imaging can start. The next pages give a more detailed explanation about the imaging.

The arrow in the upper left corner can be selected in both figure 7 and 8 when not wanting to start surgery. The user will then return to the home screen (see figure 6: Home screen). For more information about the home screen see chapter 8.6 "pin code" up till and including chapter 8.9 "help".

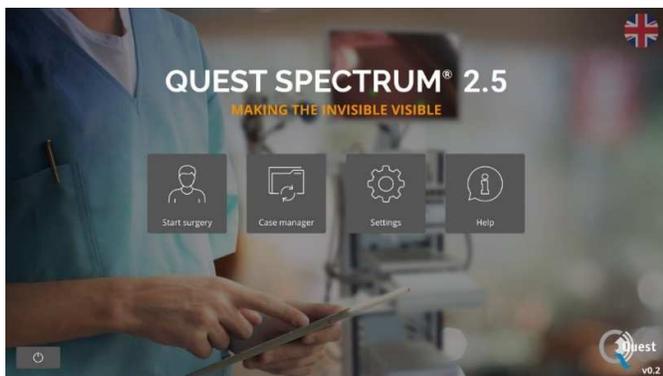


Figure 6: home screen

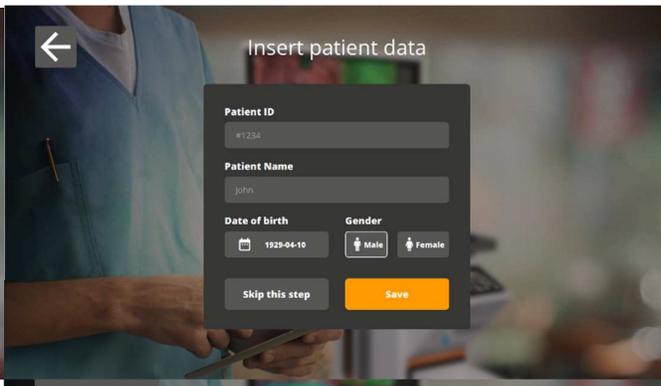


Figure 7: insert patient data

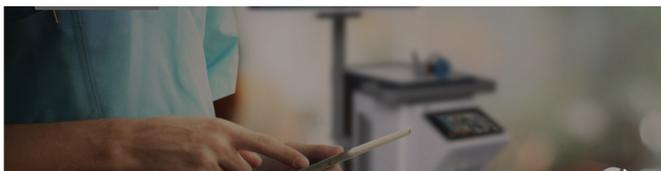


Figure 9: Select surgery

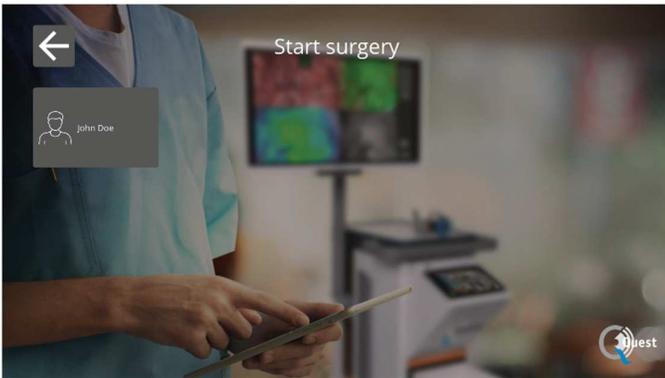


Figure 8: Start Surgery



Focus

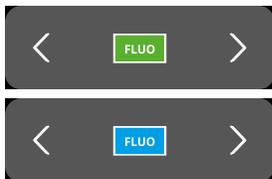
The camera can be focused manually by using the following options:

- By using the camera (see chapter 8.2 “using the camera”)
- By using the touchpad

When focussing, the icon will be set to MF (Manual Focus), when done this will be set to the other icon.

Using the touchpad to focus

Select the icon on the touchpad (see the first image on the left). When selected, the icon will transform into an icon as shown on the left. Focussing can be done by selecting the arrows on the side. When done focussing, select the icon again and it will transform back into his previous form.



Mode

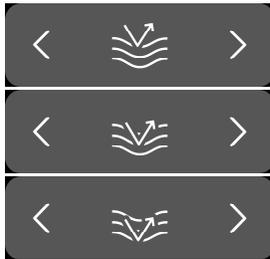
When starting surgery, the correct mode needs to be selected otherwise no fluorescent overlay can be seen. There are two modes:

- Green icon: the 800 nm channel (supports the use of ICG)
- Blue icon: the 700 nm channel

It is important to know what kind of fluorescence is used before starting surgery in order for the correct mode to be selected.



Note: Only the ICG mode is activated for USA purposes.



Sensitivity

The sensitivity can be increased by use of this function. When unable to clearly visualise the fluorescence during the procedure, this setting can be adjusted to improve the device’s sensitivity. The sensitivity has three different modes, the arrow represents the sensitivity of the device within tissue, by increasing the sensitivity the arrow “penetrates” deeper through the tissue to symbolise the increase of the sensitivity



Note: Consequently, when increasing the sensitivity, the real-time behaviour decreases and the image noise increases. This may possibly result in a lower quality image.



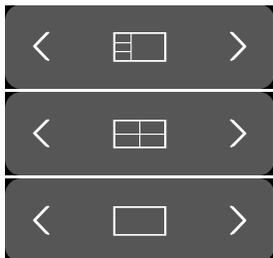
180° turn

When wanting to rotate the image a complete 180° this function can be used. The whole image will rotate 180° by simply selecting the icon on the side. The icon will also automatically transform into an 180° icon. By selecting the 180° icon the image will rotate back.



Total light output

By using this function, the total light output can be switched on and off with only one click. Both the laser and visible light output can be turned off or on by selecting the icon.



Viewing Modes

By using the arrows on the side of the icon, the monitor can be adjusted to the user’s preferred settings. The different viewing possibilities of the monitor are shown on the left:

- 3x1 screen
- 2x2 screen
- 1x full screen

Rotating screens

There are 4 different screens (see table below). By using the arrows on the side of the icons the user can rotate through these various screens.

Table 6: overview different screens

Icon	Definition	Explanation
	<i>Red/Green/Blue</i>	Natural image that can be seen by the eye in colour.
	<i>Near infra red</i>	Fluorescent response in grayscale
	<i>Overlay</i>	Overlay of fluorescent image in green with the Colour image
	<i>Gradient</i>	Overlay of the fluorescent response in Colour (Blue to Red) on the Colour image in grayscale



Second menu

When selecting this icon, another menu will appear. With these extra settings the imaging can be perfected to create the best possible image. Further explanation about these options and possibilities can be found below.



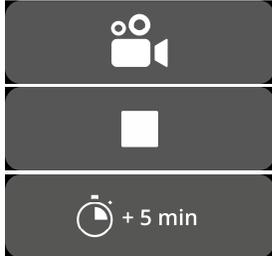
Exit

When wanting to end surgery this icon needs to be selected. A question will come up to ask for confirmation. After having verified to end the surgery a new interface will show up: the Case view. See chapter 8.2 “Case view” for a more detailed explanation about this interface.



Snapshot

By pressing this icon, a snapshot will be made. The snapshot can be retrieved during surgery by selecting the “Timeline” icon (see 8.4.4 timeline). When wanting to access the snapshot after surgery, go to the case manager (see chapter 8.4)



Recording

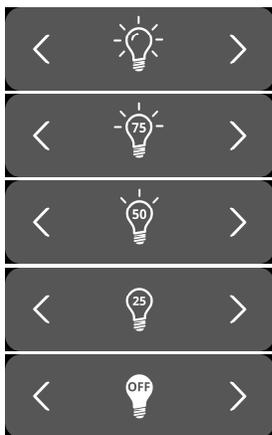
By pressing the left camera icon, a live recording will be made. By pressing the square icon, the recording will be stopped. The recording can be retrieved during surgery by selecting the “timeline” icon (see 8.4.4 timeline). After surgery, the recording can be accessed by going to the case manager (see chapter 8.4)

When recording a red coloured circle will turn up next to the laser safety tag as an indicator that the recording has started, also a timer will show the user how much time of recording is left. Recording time starts off with 5 min. However, when wanting to record for a longer time press the “+ 5 min” icon and an additional 5 minutes will be added to the recording time.



Timeline

During surgery, snapshots can be retrieved by selecting this icon. They will be stored in chronological order with time stamps. For more information about retrieving recordings and snapshots after surgery see 8.4 Case manager.

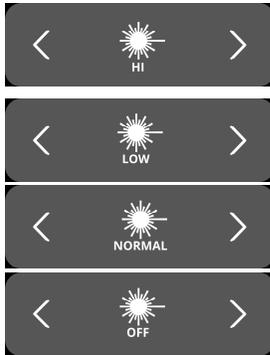


Visible light

The amount of visible light can be adjusted by use of these icons. Increasing the amount of visible light has no influence on the fluorescence. Furthermore, increasing or decreasing the light is advised depending on the situation and personal preferences of the user. However, keep in mind: no visible light means no fluorescent overlay

As shown on the left there are 5 different settings. By using the arrows on the side, the user can scroll through these settings. Each next setting increases or decreases the visible light output by 25%. When wanting to turn the light output off completely without scrolling through all the settings, see *Total light output*.

Laser



The amount of laser light can be adjusted by use of these icons. Increasing the amount of laser light results in a greater fluorescent response. By default, the laser setting is at its highest level.

As shown on the left, there are 4 different settings. Scrolling through the settings is possible by using the arrows on the side. Each next setting increases or decreases the laser output by 33,3%. When wanting to turn the light output off completely without scrolling through all the settings, see *Total light output*.



Save settings

Personal preferred settings can be saved by using this function. The next surgery will then start with the same setting so no time needs to be spend on finding the best settings again.



Back

By selecting this arrow, the user will return to the previous menu.

8.5 Case View

After having ended the surgery the Case view screen will turn up (see figure 10). In this screen an overview is given of all taken snapshots and recordings. They are all organised in chronological order with timestamps beneath them. It is also possible to re-watch the snapshots and recording just by selecting them. By selecting the top right icon, the patient data can be accessed. When done, select the top left arrow and you will return to the home screen.

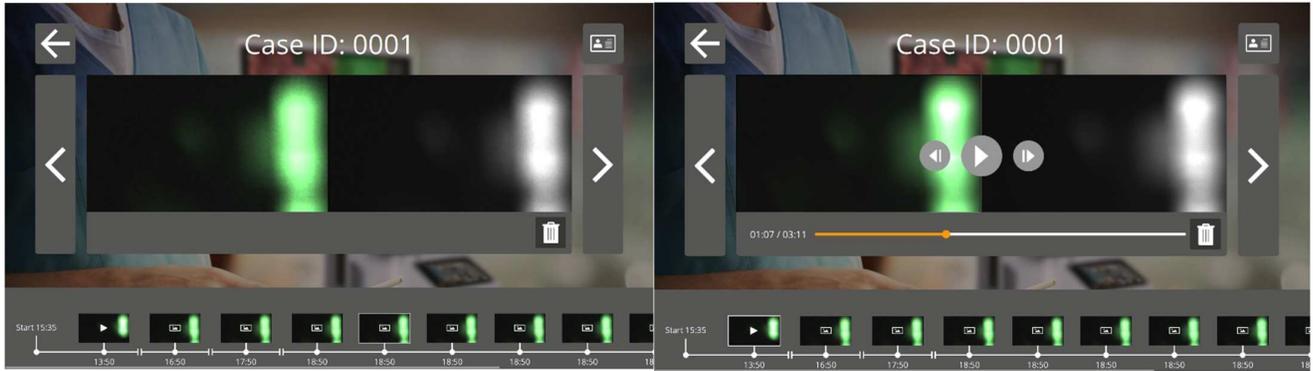


Figure 10: Case view

8.6 Using the Camera



Figure 11: camera

The tables below give an overview of all the options and functions of the camera. There are two different tables, the first one showcases all the options and functions when the menu is closed and the second table shows the various camera options when the menu is open. Each table has also been divided into two parts: “No focus” and “MF” (manual focus). “No focus” symbolises all the functions and options when the manual focus has not been selected and MF symbolises the opposi

Table 7: overview camera functions

		Menu Closed	
		No focus	MF
	Long press	start video/end video	start video/end video
	Short press	snapshot	snapshot
		Turn Manual Focus on	Turn manual focus off
		<i>Not applicable</i>	<i>Not applicable</i>
	Long press	open menu	open menu
	Short press	<i>Not applicable</i>	<i>Not applicable</i>
		Menu Open	
		AF	MF
	Long press	start video/end video	start video/end video
	Short press	snapshot	snapshot
		Turn Manual Focus on	Turn manual focus off
		Scrolling through menu	Manual focussing
	Long press	Closes menu	Closes menu
	Short press	Selecting an icon	Selecting an icon

8.7 Pin code

Each surgeon is given a personal four-digit pin code. This pin code is requested when wanting to access the “case manager” and the “settings”. First, the correct surgeon needs to be selected. Thereafter, the surgeon’s correct pin code needs to be entered (see figure 12).

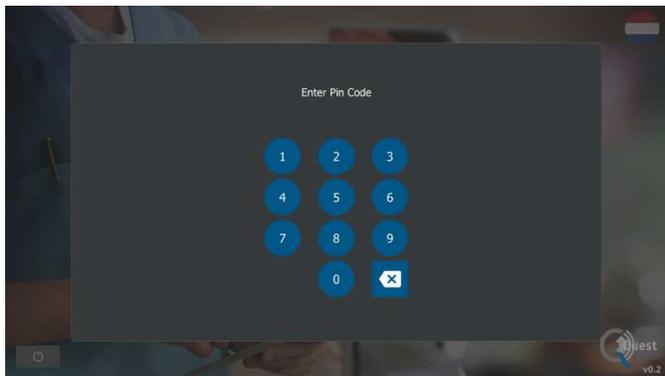


Figure 12: Pin code

**Note:**

Please note that a surgeon can never be logged in. Every time a user wants to access the “case manager” or “settings”, the pin code is requested. Sharing the pin code with third parties is not advised.

8.8 Case manager

All the taken recordings are stored in the “case manager”. The Case manager can be found on the home page (see figure 6). After selecting the “case manager” icon, a surgeon must be selected. Accessing the recordings can only be done by entering the surgeon’s personal pin code. After having entered the code, an interface as shown in figure 13 will appear. Now, all the recordings and snapshots taken by the surgeon can be accessed. All the snapshots and recordings can be filtered on date by selecting the calendar icon. The search bar can be used as well to search a specific patient for example.

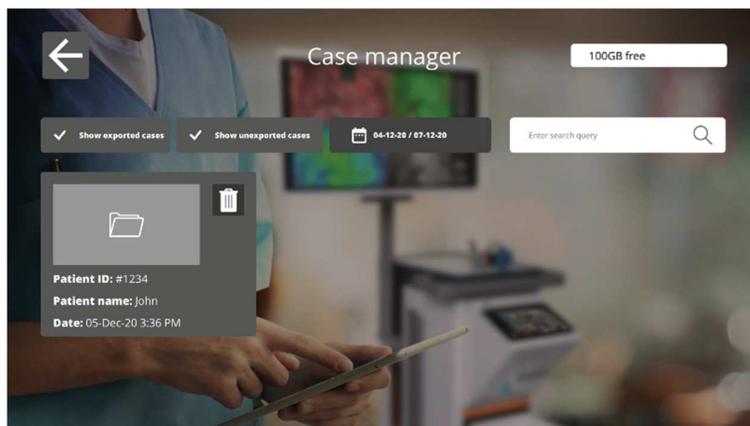


Figure 13: Case manager

**Delete**

By selecting this icon, recordings and snapshots can be deleted.

**Export**

When wanting to export a recording or snapshot, this icon should be selected. After having selected this icon, the correct device needs to be selected and all content can be exported to this device. Devices can be connected by using the USB ports on the IPC.

8.9 Settings

After selecting the settings icon on the home page (see figure 6) an interface similar to figure 14 will appear. The user has two access options:

- Access the surgeon’s settings (by selecting the surgeon and entering the correct pin code see 8.6)
- Access the technical staff’s settings (see figure 15 and figure 16 and further explanation below)

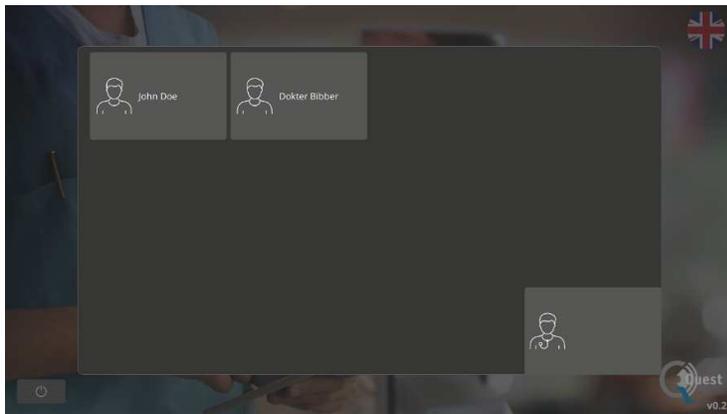
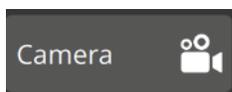
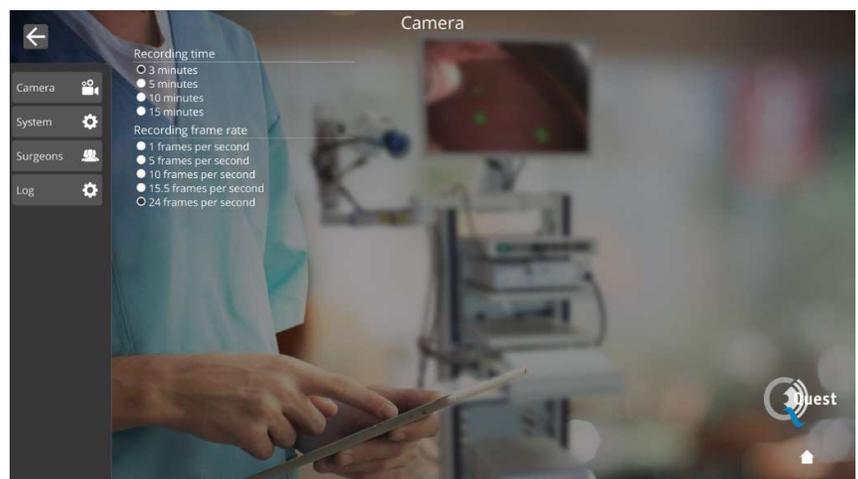


Figure 14: Settings

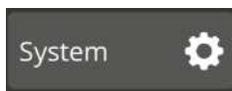
Technical service settings

When having entered the correct pin-code after selecting the option Technical service, an interface as shown in figure 19 will appear. See an explanation about the setting options below.

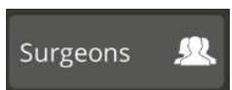
Figure 15: Technical service settings



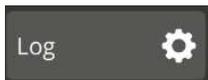
By selecting this icon, the recording time and the frame rate during recording can be changed to the user’s preferences.



The language and pin code settings can be changed by selecting this icon.



When wanting an overview of all registered surgeons this icon should be selected.



After pressing this icon, a log of all activities is given. The log includes time stamps of the activities and names of the active users.

Surgeon's settings

After having selected the surgeon and correct pin code, an interface as shown in figure 16 will appear.

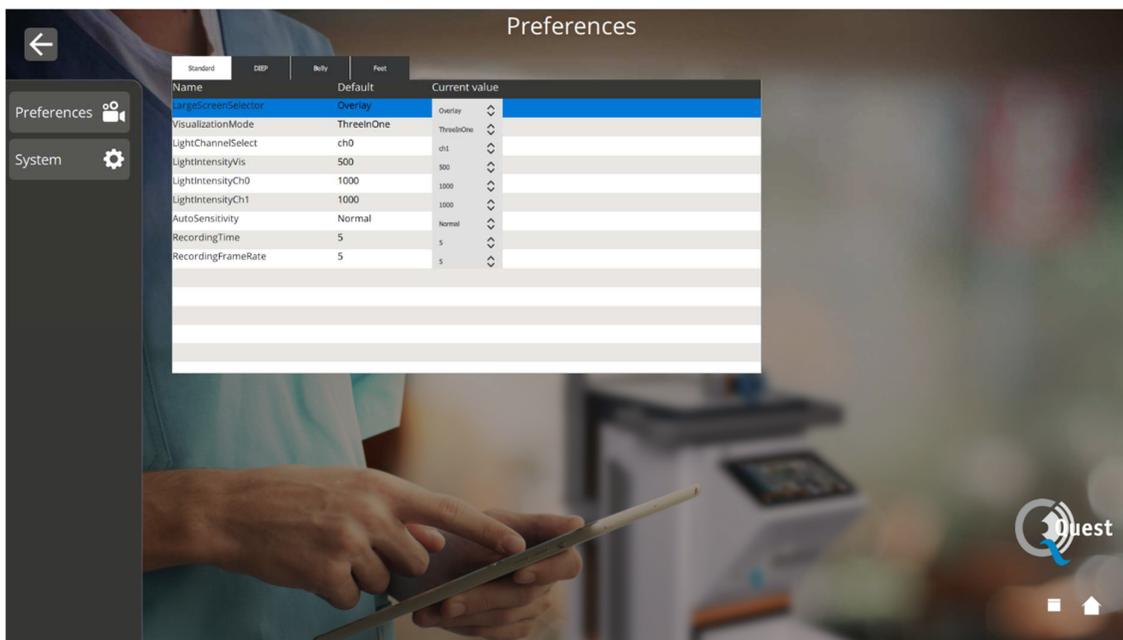
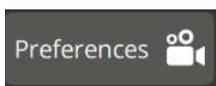
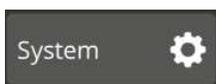


Figure 16: surgeon's settings



By selecting this icon, settings can be set to the surgeon's preferences. Advised is not to change much, by default the best settings have been set.



The language and pin code settings can be changed by selecting this icon.

8.10 Help

The "help" icon on the home page can be selected when experiencing trouble with the system (see figure 17). Advised is first to try and solve the problem by using the appendix trouble shooting (see appendix A: trouble Shooting). When still experiencing trouble, the "help" icon

should be selected. After selecting this icon an interface like figure 9 will appear containing all contact details for help. Depending on what country the user is in, different contact details are needed. This information can be retrieved by selecting the correct country on the left-hand side of the screen.

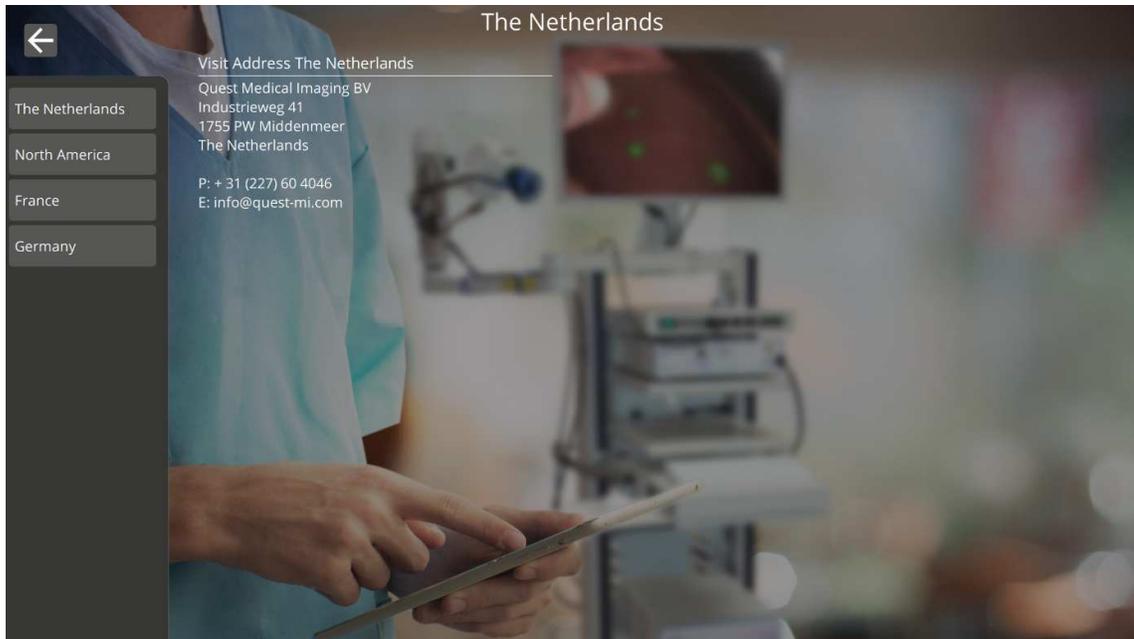


Figure 17: Help

9 Cleaning, Disinfection and Sterilization

9.1 Cleaning Instructions

Cleaning:

- ❖ Make sure to unplug the main power supply before cleaning
- ❖ Use a slightly moistened lint free soft cloth material. Do not soak in cleaning fluids as liquid ingress into unit may result in damage of the electronics. A mild detergent is permissible.
- ❖ Wipe down the system with a dry, lint free cloth.
- ❖ Wipe off water drops immediately

Disinfection:

- ❖ Wipe the QUEST SPECTRUM® 3.0
- ❖ with a soft and lint free cloth moisturized with 70% IPA solution.

External housing materials of the device are powder coated or anodized aluminium.

9.2 Sterilization

Laparoscopes and their Lighting Cables are compatible with conventional sterilization methods. The operating facility is responsible for the sterility of the Laparoscopes and Optical Fibre Cables.

For cleaning and sterilization of your Laparoscope and Optical Fibre Cables, see its Instructions for Use.



CAUTION: Do not sterilize the Lens with Ring Light.

9.3 Maintenance

The QUEST SPECTRUM® 3.0 does not contain any user-serviceable parts. On a yearly basis a preventive inspection or maintenance is recommended.

Refer all repairs, maintenance or service work to the Quest Medical Imaging.

10 Appendix A: Trouble Shooting

10.1 Trouble shooting

Table 8: Trouble shoot overview

Situation	Recommended action
System does not start after pressing the On / off button	<ul style="list-style-type: none"> Check whether the on/off button lights blue (if not press the on/off button till it turns blue) Restart the system after 1 minute Try other socket Replace fuses (see 10.2)
Monitor is black while other components are working	<ul style="list-style-type: none"> Check if all cables are connected. Check if monitor is turned on.
Images in Surgical App are black	<ul style="list-style-type: none"> Check if all cables are connected Turn off device as described in section 8.3. Restart System after 1 minute.
Image flickers 'on and off' within one second	<ul style="list-style-type: none"> Turn all surgical lights off, with exception of the light generated by the QUEST SPECTRUM® 3.0.
No fluorescence appears	<ul style="list-style-type: none"> Check that the laser is turned on. Check that the system illuminates light. Check that the injected product is fluorescent Check that the injected dose is appropriate Check that the right fluorescent tracer is selected.
Unexpected bright areas	<ul style="list-style-type: none"> Check that all surgical lights are turned off. Check if the fluorescent tracer can accumulate or leak to those areas Check if the tissue could fluoresce by itself Check if the light is not reflected by other medical equipment.
The contrast of the fluorescent image is too low	<ul style="list-style-type: none"> Check that all surgical lights are turned off. Move the camera closer to the tissue. Increase the light intensity of the laser.
The image appears to bright	<ul style="list-style-type: none"> Decrease the intensity of the light source.
No laser- or visible light	<ul style="list-style-type: none"> Check if the main power supply is connected Check if all cables regarding the camera are connected
Frozen screen	<ul style="list-style-type: none"> Check if all cables are connected Turn off device as described in section 8.3 Restart the system after approximately 1 minute

10.2 Fuse Replace Procedure



Note: If a fuse needed to be replaced make sure that both fuses are replaced at the same time.

To replace the fuses unscrew the fuse holder as shown in Figure . The fuses can be found just above the main power supply.



Figure 18: Replacement of the fuses

Pull out the fuse from the fuse holder (see Figure 19) and replace it with a new fuses.

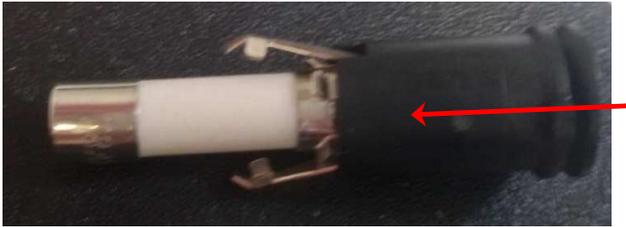


Figure 19: Pull out the fuse

Screw the fuse holder back in place.

11 Appendix B: Technical Specifications

Table 9: Technical specifications

Item	Value		Remark
	EU	US	
Input voltage	230V AC	115V AC	
Input frequency	50Hz	60Hz	
Power dissipation	520 W	520 W	
Current consumption	2.2A	4.4A	
Fuse rating	2 x 4A (in series) p/n ART-ETC-0007	2 x 8A (in series) p/n ART-ETC-0008	Ceramic or sand filled
Device classification	Class 1 BF type		
Maximum installation height	1000 m		
Temperature range	10 - 30 °C		Operating
	0 - 50 °C		Storage
Humidity range	30 - 80% R.H.		Non-condensing
IP class	20		
Laser class	Class 1		See chapter 3.4 for details
Dimensions	55 x 85 x (between 165 and 190) cm		
Weight	162.5 kg		

Table 10: Cable specifications

Item	Max. length	Remark
Power cord	5 m	
Camera cable	3 m	

12 Appendix C: EMC and Environmental Safety

The QUEST SPECTRUM® 3.0 has been tested and found to comply with electromagnetic compatibility (EMC) limits for medical devices to IEC/EN 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The QUEST SPECTRUM® 3.0 does not have Essential Performances as referred to in IEC 60601-1 and ISO14971 standards.

12.1 Electromagnetic interference

Medical electrical equipment requires special precautions regarding EMC and must be installed and operated according to these instructions. It is possible that high levels of radiated or conducted radio-frequency electromagnetic interference (EMI) from portable and mobile RF communications equipment or other strong or nearby radio-frequency sources could result in performance disruption of the imaging system. Evidence of disruption may include image degradation or distortion, erratic readings, equipment ceasing to operate, or other incorrect functioning. If this occurs, survey the site to determine the source of disruption, and take the following actions to eliminate the source(s).

- ❖ Turn equipment in the vicinity off and on to isolate disruptive equipment.
- ❖ Relocate or re-orient interfering equipment.
- ❖ Increase distance between interfering equipment and your imaging system.
- ❖ Manage use of frequencies close to ultrasound system frequencies.
- ❖ Remove devices that are highly susceptible to EMI.
- ❖ Lower power from internal sources within facility control (such as paging systems).
- ❖ Label devices susceptible to EMI.
- ❖ Educate clinical staff to recognize potential EMI-related problems.
- ❖ Eliminate or reduce EMI with technical solutions (such as shielding).
- ❖ Restrict use of personal communicators (cell phones, computers) in areas with devices susceptible to EMI.
- ❖ Share relevant EMI information with others, particularly when evaluating new equipment purchases which may generate EMI.
- ❖ Purchase medical devices that comply with IEC 60601-1-2 EMC Standards (3V/meter EMI immunity, limit interference level to 0.0014 V/meter).
- ❖ Always use and plug in the Potential Equalizer Conductor for safe use according to 60601-1 standard.

12.2 Electrostatic discharge

Electrostatic discharge (ESD), or static shock, is a naturally occurring phenomenon. ESD is common in conditions of low humidity, which can be caused by heating or air conditioning. Static shock is a discharge of the electrical energy from a charged body to a lesser or non-charged body. The degree of discharge can be significant enough to cause damage to a transducer or an imaging system. The following precautions can help reduce ESD: anti-static spray on carpets, anti-static spray on linoleum, and anti-static mats.

12.3 General notes and benefits of potential equalization

The voltage of a conductor or body to earth is called the "potential" of this conductor or body. The earth is electrically neutral and thus has the potential "zero". The unit of measurement for the potential is volt. A conductor or body has the potential "zero" (earth potential) if it is conductively connected with the earth. As a consequence of damage to the insulation, voltages may be transmitted to metal parts which do not belong to the service circuit. This causes the development of potentials between the metal parts which might be dangerous for man. If a man touches two different metal parts at a time - for instance an electrical device and a water pipe - he bridges the existing potential and current flows through his body. The flow of electric current through the body of a human being could be mortal. A remedy for this is a potential equalization to zero potential. Potential equalization therefore can be seen as an additional earthing (in addition to normal earthing included in power cords) and improves the safety standard of medical devices and medical systems. Potential equalization has the additional benefit of equal voltage potential on all involved metal housings of medical devices of a medical system. Different voltage potentials on housings could lead to false measurements during medical diagnosis, since the difference of voltage potential of the medical devices within a system would interfere with voltage measurements (ECG, EMG, etc.) of the human body. Thus, potential equalization is also important for correct and valid measurements.

13 Appendix D: Manufacturer’s declaration

The system is intended for use in the electromagnetic environment specified in the tables below. For maximum performance, ensure that the system is used in the environments described in these tables.

Table 11: Guidance and Manufacturer’s declaration-electromagnetic emissions

Guidance and Manufacturer’s declaration-electromagnetic emissions		
The QUEST SPECTRUM® 3.0 is intended for use in the electromagnetic environment specified below. The customer or the user of QUEST SPECTRUM® 3.0 should assure that it is used in the following environment:		
Emissions Test	Compliance	Electromagnetic Environment - guidance
RF emissions CISPR11	Group 1	The QUEST SPECTRUM® 3.0 uses RF energy only for its internal function Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class A	The QUEST SPECTRUM® 3.0 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

Table 12: Guidance and Manufacturer’s declaration-electromagnetic immunity

Guidance and Manufacturer’s declaration-electromagnetic immunity			
The QUEST SPECTRUM® 3.0 is intended for use in the electromagnetic environment specified below. The customer or the user of the QUEST SPECTRUM® 3.0 should assure that it is used in the following environment:			
Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be made of wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5% Un (>95% drop in Un) for 0,5 cycle 40% Un (60% drop in Un) for 5 cycles 70% Un (30% drop in Un) for 25 cycles <5% Un (>95% drop in Un) for 5 seconds	<5% Un (>95% drop in Un) for 0.5 cycle 40% Un (60% drop in Un) for 5 cycles 70% Un (30% drop in Un) for 25 cycles <5% Un (>95% drop in Un) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the QUEST SPECTRUM® 3.0 requires continued operation during power mains interruptions, it is recommended that the QUEST SPECTRUM® 3.0 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	NA	NA	The QUEST SPECTRUM® 3.0 does not contain any devices influenced by magnetic fields
NOTE Un is the a.c. mains voltage prior to application of the test level			

Table 13: Guidance and Manufacturer’s declaration-electromagnetic immunity

Guidance and Manufacturer’s declaration-electromagnetic immunity			
The QUEST SPECTRUM® 3.0 is intended for use in the electromagnetic environment specified below. The customer or the user of the QUEST SPECTRUM® 3.0 should assure that it is used in the following environment:			
Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment - guidance

<p>RF Common mode/ Conducted Susceptibility IEC 61000-4-6</p> <p>Radiated RF Electromagnetic Field IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz 6 Vrms Inside IMS bands</p> <p>3 V/m 80 MHz to 2.7 GHz</p>	<p>3 Vrms 150 kHz to 80 MHz 6 Vrms Inside IMS bands</p> <p>3 V/m 80 MHz to 2.7 GHz</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the QUEST SPECTRUM® 3.0, including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> <p>$d = 1,2 \sqrt{P}$</p> <p>$d = 1,2 \sqrt{P}$ 80 MHz to 800 MHz</p> <p>$d = 2,4 \sqrt{P}$ 800 MHz to 2,5 GHz</p> <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> <div style="text-align: center;">  </div>
<p>Proximity fields form RF wireless communications equipment</p>	<p>385 MHz 380 – 390 MHz</p> <p>430 – 470 MHz 28 V/m</p> <p>704 – 787 MHz 9 V/m</p> <p>800 – 960 MHz 28 V/m</p> <p>1700 – 1990 MHz 28 V/m</p> <p>2400 – 2570 MHz 28 V/m</p> <p>5100 – 5800 MHz 9 V/m</p>	<p>385 MHz 380 – 390 MHz</p> <p>430 – 470 MHz 28 V/m</p> <p>704 – 787 MHz 9 V/m</p> <p>800 – 960 MHz 28 V/m</p> <p>1700 – 1990 MHz 28 V/m</p> <p>2400 – 2570 MHz 28 V/m</p> <p>5100 – 5800 MHz 9 V/m</p>	
<p>NOTE These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the QUEST SPECTRUM® 3.0 is used exceeds the applicable RF compliance level above, the QUEST SPECTRUM® 3.0 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the QUEST SPECTRUM® 3.0.</p>			

Table 14: Guidance and Manufacturer’s declaration-electromagnetic immunity

Recommended separation distance between portable and mobile RF communications equipment and the QUEST SPECTRUM® 3.0			
The QUEST SPECTRUM® 3.0 is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the QUEST SPECTRUM® 3.0 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the QUEST SPECTRUM® 3.0 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		
	150 kHz to 80 MHz $d = 1,2 \sqrt{P}$	80 MHz to 800 MHz $d = 1,2 \sqrt{P}$	800 MHz to 2,5 GHz $d = 2,4 \sqrt{P}$
0,01	0,12	0,12	0,24
0,1	0,38	0,38	0,76
1	1,2	1,2	2,4
10	3,8	3,8	7,6
100	12	12	24
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watt (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Table 15: Laser safety classification.

Projection device	Basic standard	Compliance
QUEST SPECTRUM® Ring Light	EN 60285-1:2014	Class 1

Table 16: QUEST SPECTRUM® Capture Suite classification.

	Basic standard	Compliance
QUEST SPECTRUM® Capture Suite	Medical Device Directive 93/42/EEC-M5	Class 1

Declarations of Conformity

Manufacturer: Quest Medical Imaging B.V.
Industrieweg 41
1775 PW Middenmeer
the Netherlands

We declare under our sole responsibility that the QUEST SPECTRUM® 3.0 complies with the following directive:

Directive 93/42/EEC-M5 for medical devices



The individual components of your QUEST SPECTRUM® 3.0 bear the CE mark. Quest Medical Imaging B.V. herewith declares that:

- (a) We have verified the mutual compatibility of the devices of the QUEST SPECTRUM® 3.0 in accordance with the manufacturers' instructions and have carried out his operations in accordance with these instructions;
- (b) We have packaged the QUEST SPECTRUM® 3.0 and supplied relevant information to users incorporating relevant instructions from the manufacturers; and
- (c) We have subjected the whole activity to appropriate methods of internal control and inspection.