Diagnostic Green

IC-Flow™ Imaging System:
Instructions for Use

www.diagnosticgreen.com

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1. General information

1.1. INTENDED USE

The IC-Flow Imaging System is used to capture and view fluorescent images for various indications such as:

- Visual assessment of blood flow
- Visual assessment of lymphatic system
- Organ transplant procedures
- Plastic micro-reconstructive surgery
- Visual assessment of hepatobiliary system (liver tumours and liver metastases)
- Visual assessment of bile ducts during hepatobiliary surgery

The IC-Flow™ Imaging System is used as an adjunctive method for visualisation of ICG fluorescent images.

The IC-Flow™ imaging system is intended for near-infrared fluorescence imaging in adult and pediatric patients one month of age and older.

The IC-Flow™ Imaging System is intended for use by qualified surgeons/physicians or healthcare professionals in doctors' offices and hospitals.

1.2. OPERATION

The IC-Flow™ Imaging System (hereafter referred to as IC-Flow) facilitates visualisation of the distribution and intensity of the fluorescent ICG dye.

The IC-Flow has a medical, near-infra red (NIR) Camera which emits a light (approx. 780 nm) to excite the ICG molecules and view ICG emitted fluorescence (approx. 830 nm). The captured fluorescent image data is displayed on the controller and/or connected monitor.

Images and videos are recorded using buttons located on the Camera and icons on the Controller. The NIR illumination (excitation light) and Camera sensitivity can also be adjusted using controls on either the Camera or Controller. Images and videos are stored in the Controller but can easily be transferred to a USB memory device, Cloud Drive or an external mass storage device.

1.3. SAFETY INSTRUCTIONS

CAUTION: Read this Instructions For Use (IFU) Manual carefully before working with the IC-Flow. Failure to read this IFU can endanger the lives of humans and may damage machines and buildings. Keep this IFU as a reference.

Warnings

European regulations require that this device be purchased only by a physician or person acting on behalf of a physician.

1. General information

Change of device

Device modifications are not permitted. The IC-flow may not be modified without permission from the manufacturer. If the device is modified, suitable inspections and tests must be carried out to ensure continued safe use.

Operation

To avoid the risk of electric shock, this appliance must only be connected to a supply main with a protective earth conductor.

Optical radiation

Although the emitted light (optical radiation) meets safety requirements, both medical personnel and the patient should avoid looking directly into the light source in order to minimise eye exposure. Avoid holding the Camera in front of the patient's eyes. Shut the Camera off or put it in standby mode when not in use.

Sterility and patient safety

The IC-Flow is not designed for direct patient contact. If the Camera is used close to the patient within a sterile field, it must be covered with a sterile drape. Do not bring the Camera into direct contact with the patient.

Electrical safety

Only connect the IC-Flow with the supplied power unit (Article number: ATM065T-P120 Section 2). Any other power unit can damage the IC-Flow and cause an electrical shock or fire.

This IC-Flow has not been tested in conjunction with high frequency surgical equipment (e.g. electrocautery) and should not be used with such equipment.

Do not touch the plug with wet hands. This could cause an electric shock. Always pull on the plug and never the cable when disconnecting it. Pulling on the cable could cause damage to it, causing an electric shock or fire.

Avoid mechanical shocks

If the IC-Flow is visibly damaged, stop using it and return to your Diagnostic Green distributor for inspection.

Ambient and storage conditions for IC-Flow

The IC-Flow is not designed for use in an oxygen-rich environment.

⚠ Cautions

Electrical safety

Disconnect the power unit from the wall socket if the IC-Flow is not to be used for an extended period of time. Always turn off the IC-Flow before connecting or disconnecting cables. Never touch the plug contacts of the IC-Flow and the patient at the same time as it can result in dangerous discharge currents.

Electromagnetic compatibility

Use this product as described in Section 3 to minimise risks related to the electromagnetic compatibility of this product with other products. The device is not suitable for magnetic resonance and not suitable for use in living or domestic areas.

Cables

Do not stress or place any heavy object on the cables. This could damage the cables and cause an electric shock or fire.

When handling the IC-Flow, make sure cables are not left in walkways or areas where they can be tripped over and cause injury or damage to the cable.

1. General information

If irregularities occur

If the image suddenly disappears, or an unusual sound, smell or smoke is emitted from the IC-Flow, switch device off immediately. Remove plug from socket and contact your Diagnostic Green distributor.

Never try to repair the IC-Flow yourself, as there are no user serviceable components. Attempting to repair the IC-Flow will void the warranty.

Do not open

Do not, at any time, try to take apart or modify the IC-Flow. This could damage the IC-Flow or even lead to injuries. Use the external components only as described in this IFU.

Foreign objects

Foreign objects or substances, such as flammable liquids, metal objects, or other liquids can damage the IC-Flow and cause an electric shock or fire.

Avoid mechanical shocks

The front side of the Camera is especially sensitive to mechanical shocks.

Notes

Camera cable

Check the cable before and after each use.

Ensure that the cable has no cracks or sharp kinks.

Ensure that plug connections are not bent or otherwise deformed.

Ensure that there are no signs of faulty cable connections (e.g. flickering monitor images).

Avoid mechanical shocks

Do not expose the IC-Flow to severe mechanical socks, for example, by dropping it as this may damage the device. If the device is dropped, inspect it thoroughly prior to use.

Avoid electrostatic discharged

Use caution to prevent damage on IC-Flow components from electrostatic discharge – i.e. avoid direct and indirect contact between metallic IC-Flow components, drapes, carpets or other synthetic materials prone to electrostatic build-up.

Electromagnetic compatibility

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 reorienting the equipment. No special precautions with regard to electromagnetic disturbances are necessary to maintain basic safety and the technical specifications over the expected service life.

1. General information

Do not expose IC-Flow to strong magnetic or electromagnetic fields. To prevent negative electromagnetic compatibility (EMC) impacts or situations, do not stack the IC-Flow or place it nearby emitting devices.

Avoid vibrations.

Prevent contact with strong corrosive gases (such as chlorine or fluorine gases).

Protect from dust and excessive moisture.

For a high-contrast image including the body contours, additional light with an infrared component is needed. Artificial ambient light sources exclusively based on LEDs are insufficient.

Temperature fluctuations

Avoid broad temperature fluctuations. If the IC-Flow is brought from a cold room (e.g. operating room) to a warm room, the Camera window may fog up resulting in blurred images or display artifacts. Wait until the image becomes clear before using.

Cleaning/disinfecting

Follow the cleaning and disinfecting instructions (see Section 4.1).

This IC-Flow cannot be sterilised.

Repairs/service

IC-Flow is a maintenance and calibration free device, as there are no user serviceable components in the device. Inspect visually on a regular basis (see Section 4.2). In the event of an error, read Section 4.3 and try to solve the problem. Alternatively, contact your Diagnostic Green distributor.

Connecting a monitor

Only connect the monitor MEDDP-722-G1-A1-0010 or use a HDMI cable with a medically approved HDMI isolator when connecting any other external monitor compliant with the EN 60601-1 standard!

Anyone connecting other devices to the video signal input or output of this device is assembling a system used for medical purposes and is therefore responsible for compliance with the requirements of the system standard for medical products. Assembly of medical electrical systems and modifications during the actual service life require evaluation to the requirements of EN 60601-1.

Note the permissible environmental conditions of use of an external monitor including conditions for transport and storage. These must match the conditions permitted for the IC-Flow.

Read Verdye (ICG) package insert

Carefully read the Verdye (ICG) package insert for information regarding indications, contraindications and side effects.

Stored pictures and videos

The stored pictures and videos found on the IC-Flow are for demonstration purposes only. Additional information such as patient data, etc., are not stored on this device.

External devices

Do not connect any external devices to IC-Flow that are not specified in this Instructions for Use.

Device operator is responsible for ensuring that the overall system meets the requirements of IEC 60601-1 when external devices are connected.

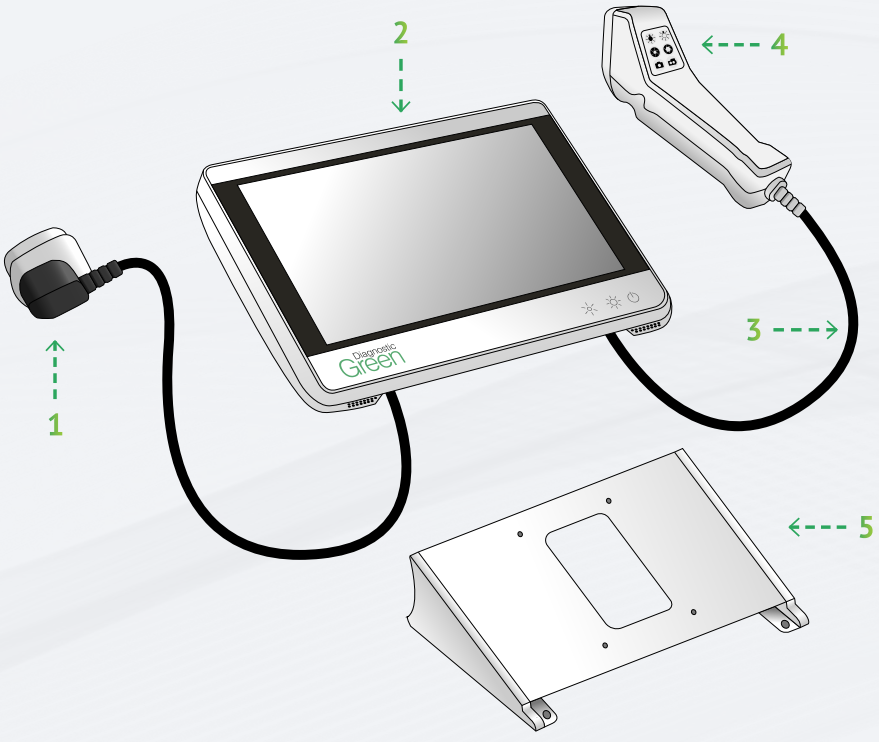
2. Set-Up

2.1. PACKAGE CONTENTS

When you open the package, please ensure that all items listed below are included. If the contents are incorrect, insufficient or damaged in any way, contact your Diagnostic Green distributor without attempting to operate the system.

2.1.1. IC-Flow Components

IC-Flow Components	# Reference	# Accessory
Power unit, cable, universal adapter with plug. (ATM065T-P120, Adapter Technology Co.)	1	PC6301
Controller	2	PC6302
Camera cable	3	PC6303
Camera	4	PC6304
Stand	5	PC6305
Documentation:	IC-Flow™ Imaging System IFU (this document)	



IC-Flow Controller

1. Power Unit
2. Controller
3. Camera Cable
4. Camera
5. Stand

2. Set-Up

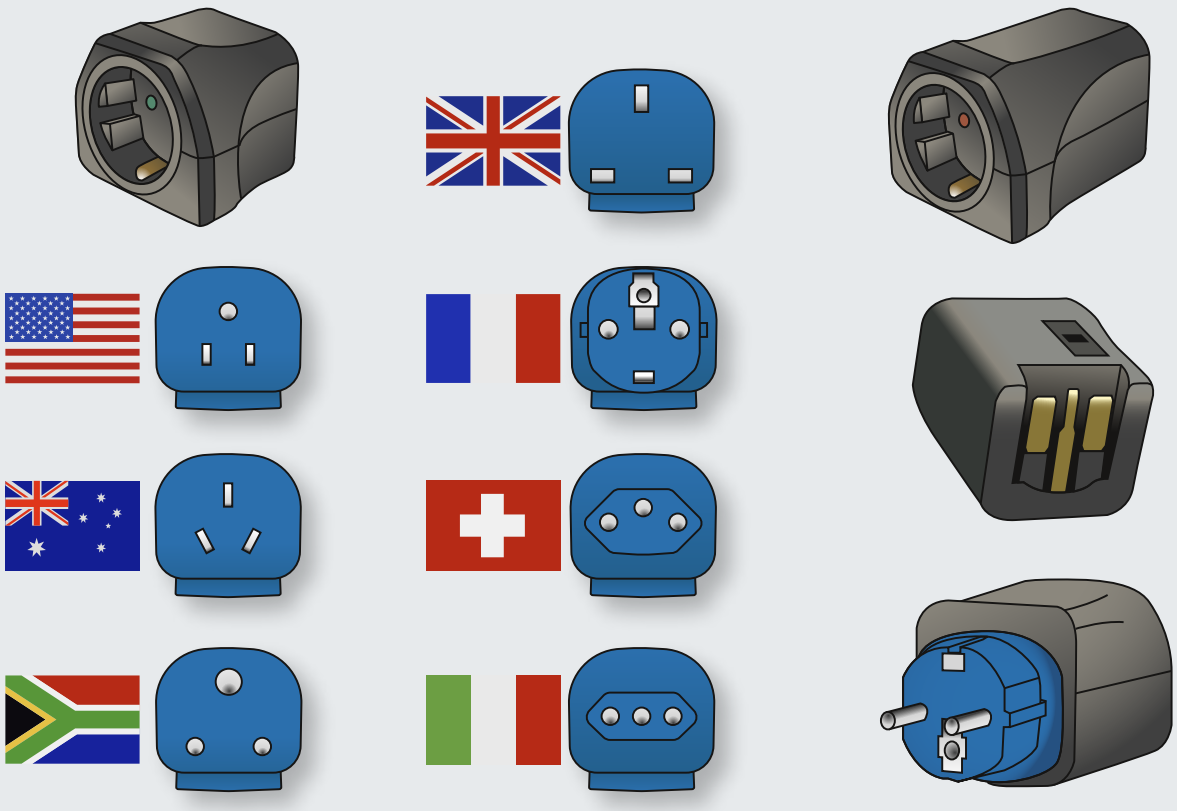
2.1.2. Select adapter plug

The IC-Flow is equipped with a power unit and an additional universal adapter. Use the appropriate plug for each country by sliding onto the universal adapter unit. To switch plugs, slide off the current plug on the adapter unit and slide on the required plug.

CAUTION: Do not use force when switching between country specific plugs. This can cause mechanical damage and is electrically hazardous.

WARNING: Use the correct adapter plugs for connecting to the wall socket. Use only the adapter provided by Diagnostic Green. The plug must fit into the socket easily. Do not use force when connecting the power cord. This is electrically hazardous.

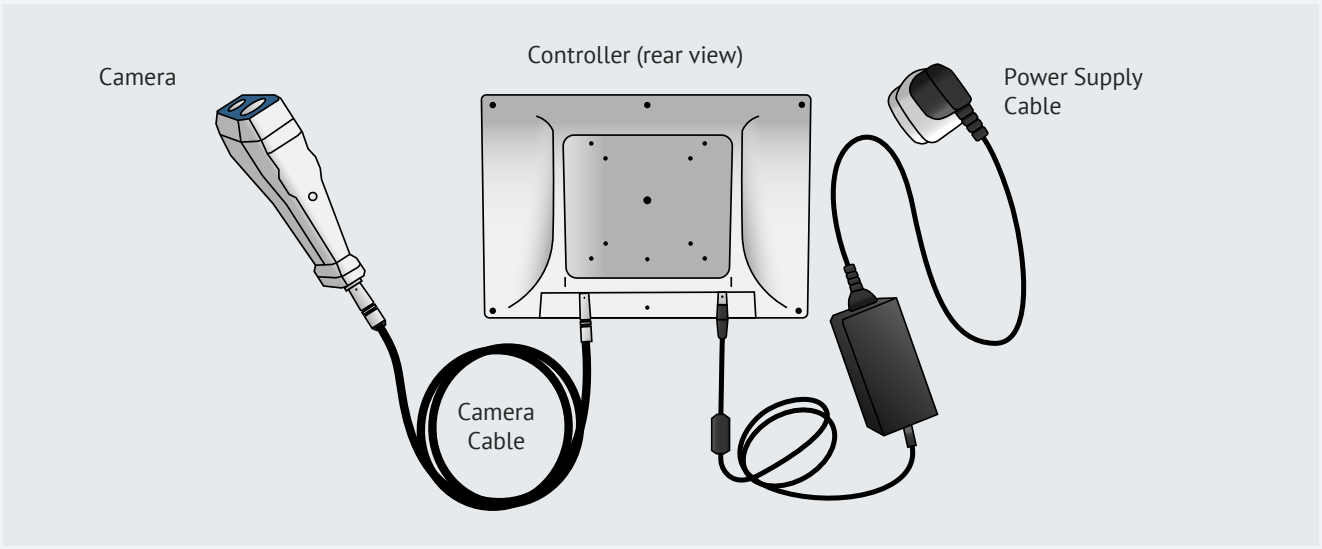
WARNING: If nonmedical compliant components are connected to this device, it could result in EMC or electrical damage to other equipment.

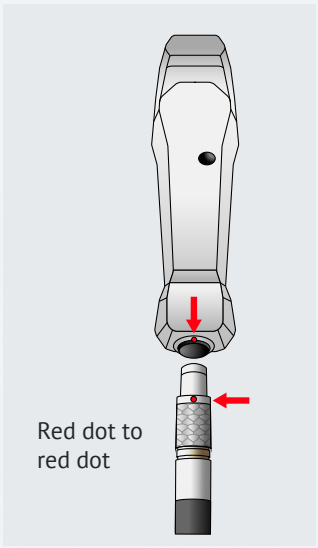


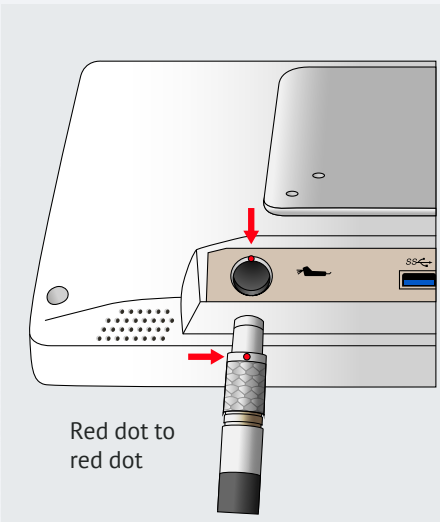
2. Set-Up

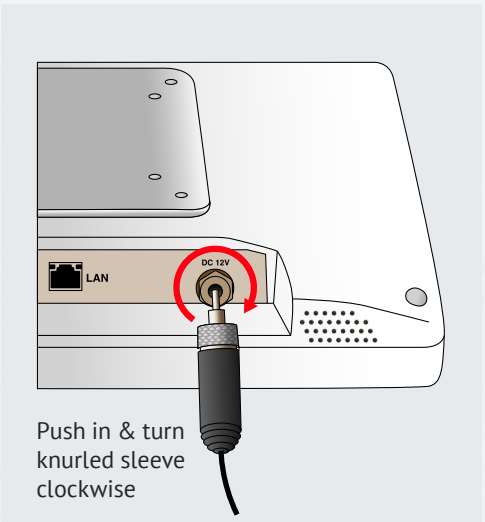
2.1.3. Assemble IC-Flow

To assemble, insert the plugs in the designated sockets as outlined below. To operate, insert the power plug into power supply connection.









Notes

- Ensure the Camera cable plugs are fully pushed in on the Camera and Controller, do not twist these plugs.
- Connect the power cable to the Controller, rotate the knurled sleeve clockwise.
- Attach the stand to the Controller.

2. Set-Up

2.1.4. Attach controller to stand

To attach, place Controller face down on a table so that rear view is visible. Place the stand on the backplate and adjust to facilitate insertion of screws. When completed, screw the stand to the controller using the four screws provided.

Notes

- The IC-Flow shall only be used when mounted on the stand.

CAUTION: The rear side of the IC-Flow can get warm. Best to move IC-Flow by gripping the stand.

2.1.5 Accessories and compatible products

The following IC-Flow accessories are available:

• IC-Flow Camera Cover (Premier Guard, PV6241S)

The IC-Flow is compatible with ICG for injection.

3. Usage

3.1. OPERATION

WARNING: Do not position equipment so that it is difficult to disconnect the IC-Flow.

WARNING: No modification of this equipment is allowed. Do not modify this equipment without authorisation of the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.

CAUTION: Magnetic and electrical fields can affect the function of the device. Maintain a safe distance between IC-Flow and other devices that emit HF radiation, otherwise malfunctions may occur.

Note

Only connect the monitor MEDDP-722-G1-A1-0010 or use a HDMI cable with a medically approved HDMI isolator when connecting any other external monitor compliant with the EN 60601-1 standard!

3.1.1. Switch on

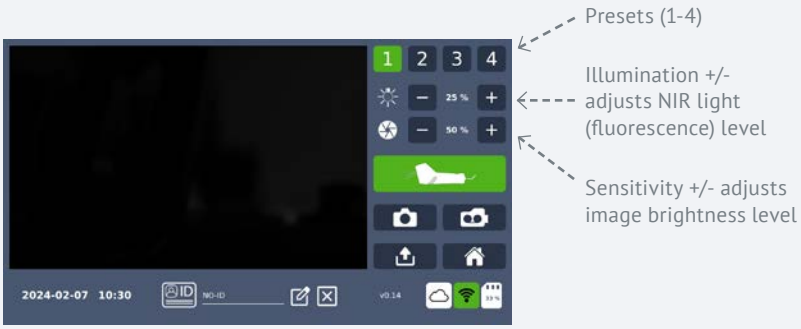
Press and hold the main power button for three seconds to switch on the Controller. The panel buttons light up green and Standby Screen appears (approx. 45 seconds).

Select Patient ID, enter details (if required), then ☑ to complete entry and close keyboard (alphanumeric allowed).

Select start on the Standby Screen to enter the Home Screen.

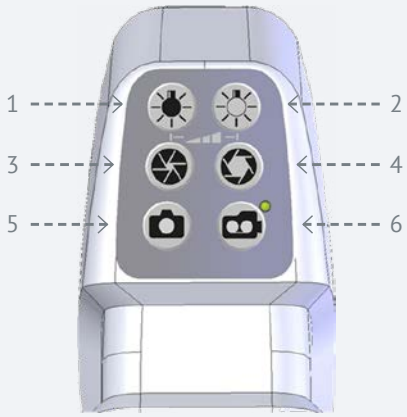
3. Usage

3.1.2. View/adjust presets



Select Preset buttons to view associated illumination and sensitivity settings.

- To adjust settings, press – or + (Single tap 1% or Hold 5% adjustments).
- To save, press and hold selected preset for two seconds.



Alternatively, settings can be adjusted on Camera.

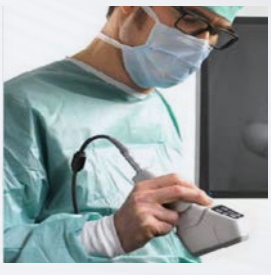
1. Less light illumination - reduces the fluorescence intensity level
2. More light illumination - increases the fluorescence intensity level
3. Less sensitivity - reduces the overall image brightness of the camera
4. More sensitivity - increases the overall image brightness of the camera
5. Take picture
6. Start/Stop video

3.1.3. Administer ICG (Verdye)

When ICG injection is administered, Near Infra-Red (NIR) light is applied to tissue/organ of interest. ICG emits fluorescence and is detected by the Camera with images displayed on the Controller.

3.1.4. Capture image/record video

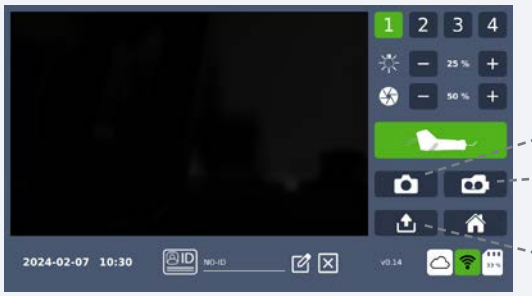
Hold the Camera between 15-20 cm above tissue/ organ of interest.



Adjust settings to ensure high contrast image capture.

3. Usage

3.1.5. Capture Images/Video



- Select photo icon to take image.
- Select video icon to start recording and once again to stop.

3.1.6. View/Transfer data

- Select Transfer or turn Camera off

Image

Video

- Select image/video (use scroll bar to view all)

To return to Transfer Screen:

- Close image/video (bottom right hand corner) or select Transfer

3.1.7. Filter data

Icon	Display	Action
 Multiple data view		Arranges multiple recorded images/videos by Patient ID

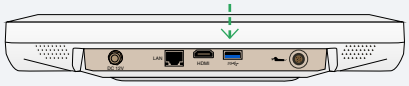
3. Usage

Icon		Display	Action
	Individual data view		Permits individual Patient ID view of images/videos*

* Automatically displays the last Patient IDs images/videos captured (when IC-Flow was last switched on).

3.1.8. Transfer data (USB)

- Insert USB (Controller port located underneath).



- Select Transfer or turn Camera off.

- Press and hold image/video for two seconds (green outline appears).

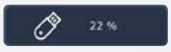
  Note: All images can be transferred by selecting the checkbox beside the photo or video icon.

- Select JPEG/MPEG or DICOM button.

- **Options:**
- (i) Transfer image/video and delete from IC-Flow, select small circle beside folder. i)
- OR
- (ii) Copy image/video select small circle beside copy folder.

ii)

- Select the USB button.



- Wait for the progress bar to turn fully green, this indicates transfer completed and confirmed by auditory chime.

  Images/videos are saved in an IC-Flow folder on the USB.

  In the IC-Flow folder the images/videos are saved in Patient ID folders named with the unique Patient ID followed by the timestamp of when they were taken in the format:

  patient id_YYYYMMDD_HHMMSS.

  If multiple images/videos are saved for each patient the Patient ID folder assumes the timestamp of the first captured image/video.

3. Usage

3.1.9. Transfer data (Cloud)

Note

The characteristics to be provided for the integration in the Wi-Fi network are provided in the technical data section.

CAUTION: Connecting the device to the cloud for the purpose of transferring data creates a two-node IT-network.

Changes to the IT network made by the user can entail risks and require additional analyses by the user.

Changes to the IT-network include:

- Changes in the IT-network configuration;
- Connection of additional items to the IT-network;
- Update of equipment connected to the IT-network; and upgrade of equipment connected to the It-network

CAUTION: The user is responsible for data security and risk evaluation in case of changes to the IT-network.

Connect to Wi-Fi (initial set-up)

- Select Wi-Fi (Home Screen). 
- Select Wi-Fi provider. 
- Use keyboard to enter Wi-Fi password and then select accept.  
- Successful connection indicated by green Wi-Fi symbol. 
- Close screen to return to Home or Transfer screens. 
- The Wi-Fi button will change to green when Wi-Fi is connected. 

Connect to Cloud (initial set-up)

- Select Cloud (Home Screen). 
- Select add Cloud. 

3. Usage

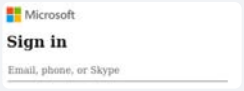
- Choose Cloud drive provider.

- Use keyboard to create User ID, select accept.

  Note: User ID is required when there are multiple device users. This ensures each users captured data is protected.

- Sign in to selected drive.

  Note: Successful sign is indicated by 'Success' message, followed by appearance of keyboard.



- Create password for User's account

  Important! Not entering a password here will allow other IC-Flow users to send images/videos to this account.

- The next screen displays unique User ID beside a green drive showing a live connection.

- Close screen to return to Home or Transfer Screens.

- Cloud and Wi-Fi icons change to green.

- **Note:** To sign back in to Cloud Drive, select Cloud icon from Home Screen, select User ID, enter password and close screen.

- Select Transfer Screen or turn Camera off.

- Press and hold image/video for two seconds (green outline appears).

  Note: All images can be transferred by selecting the checkbox beside the photo or video icon.

- Select JPEG/MPEG/DICOM.

Options:

- Transfer image/video and delete from IC-Flow, select small circle beside folder.

OR

- Copy image/video select small circle beside copy folder.

3. Usage

- Select IC-Flow user ID Cloud button.

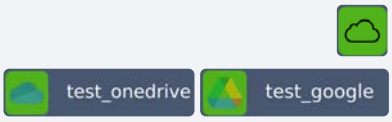
- Wait for the progress bar to turn fully green, indicates transfer completed and confirmed by auditory chime.
  Images/videos are saved in an IC-Flow folder on the Cloud Drive.

  In the IC-Flow folder the images/videos are saved in Patient ID folders named with the unique Patient ID followed by the timestamp of when they were taken in the format:

  patient id_YYYYMMDD_HHMMSS.

  If multiple images/videos are saved for each patient the Patient ID folder assumes the timestamp of the first captured image/video.

- **To sign out of Cloud Drive** select the green Cloud button on the Home Screen and then press the green Drive connection button beside the unique IC-Flow user ID to deselect it.



- The Home Screen Cloud button will no longer be highlighted green indicating connection has ceased.

3.1.10. Delete image/videos

- Select Transfer Screen or turn Camera off.

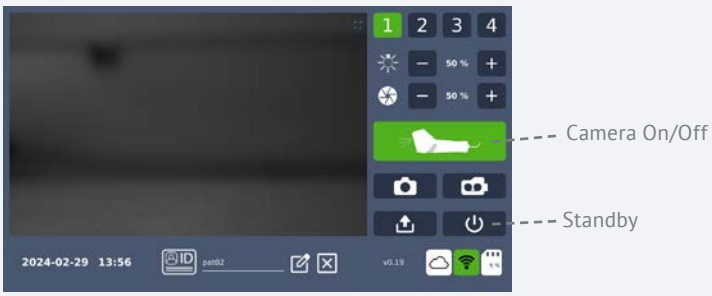
- Press and hold image/video for two seconds (green outline appears).
  Note: All images/videos can be deleted by selecting photo/video icon.

- Select Delete, repeat to confirm deletion.

3. Usage

3.1.11. Standby mode/turn Camera off

When not in use, turn the Camera off by pressing the On/Off button. Alternatively, activate standby mode by pressing the standby button on the Home Screen. (After 30 min, Camera may exceed 43°C).

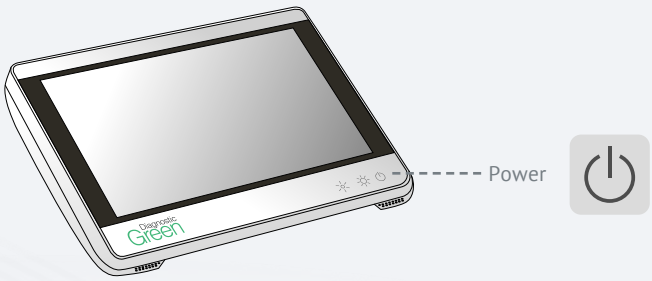


Home Screen

Standby Screen

3.1.12. Switch off

Press and hold Power button for three seconds, then select Power-Off to confirm.



3.1.13. Disassemble IC-Flow

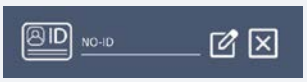
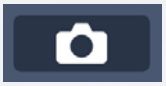
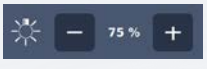
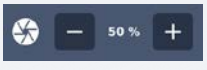
1)
Once IC-Flow powered off, remove power supply plug from the socket.

2)
Disconnect mains cable from the IC-Flow by loosening the nut, then remove the mains plug.

3)
To disconnect the camera cable from the controller and camera, hold the plug by the grooved area and pull the plug out of the device.

3. Usage

3.1.14. Icons

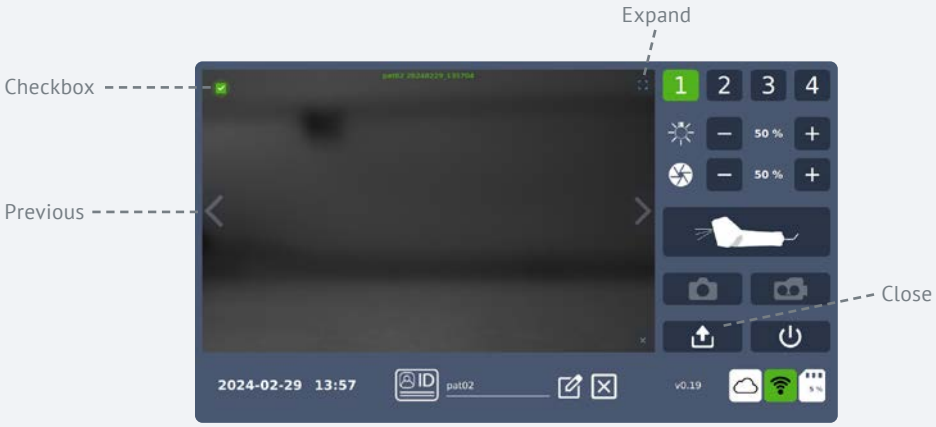
Icon	Description	Action
	Standby	Standby Screen Turns Camera off
	Transfer	Captured images & videos for viewing, transfer or deletion
	Patient ID	Patient ID Creation
	Cloud	Connection to Cloud Drive Server
	Wi-Fi	Connection to Wi-Fi
	IC-Flow memory	IC-Flow - % Memory Used
	Video	Records video
	Photo	Captures image
	Camera	Camera On/Off
	Adjust illumination	Increase/decrease fluorescence
	Adjust sensitivity	Increase/decrease Camera brightness
	Multiple data filter	Arranges multiple recorded images/videos by Patient ID
	Individual data filter	Permits individual view of images/ videos
	Presets	Preset (1-4) illumination and sensitivity levels

3. Usage

3.2. EXPANDING DISPLAY TO FULL SCREEN

To expand images/videos to full size screen, select the expand icon and return to normal size again by selecting the collapse icon.

Images/videos may be viewed by using the arrow key forward or arrow key back, in standard or expanded screens.



Images/videos may be selected for transfer to USB, Cloud Drive or deletion while viewing:

- In standard screen size each image/video may be selected for transfer to USB memory device, Cloud Drive or deletion. Select image/video by ticking the small check box on the top left of the required file. When all required images/videos are selected, press the transfer icon to return to the Transfer Screen. All selected images/videos are highlighted green and may be transferred to USB memory device or as per Section 3. Images/videos may also be deleted by pressing delete and again to confirm deletion.

- In expanded screen size, each image/video may be selected for transfer to USB memory device or Cloud Drive. Select image/video by ticking the small check box on the top left of the required file. Select transfer icon to return to the Transfer Screen. All selected images/videos will be highlighted green and may be transferred to USB memory device or Cloud Drive as per Section 3. Images/videos may also be deleted by pressing delete and again to confirm deletion.

The Controller picture may be expanded to full display screen. With Camera on, select the expand button on the top right of the Controller image. All Camera adjustments mentioned in Section 3, are available when on this screen. Images /videos may be captured from this screen by activating the Camera/video buttons. The expanded screen may be collapsed again with the Camera remaining on. By closing the expanded screen, the Camera is turned off and view returns to transfer screen.

Note: In expanded screen the checkbox disappears after a few moments – touch the screen to reveal it again if image/video selection is required.

3. Usage

3.3. IMAGE CONFIGURATION

Prior to use, optimise ambient light so that body contours are visible using the IC-Flow, to ensure ideal lighting for visualisation/capture of ICG fluorescence images.

If the room has windows, switch off room lights and almost fully close window blinds. If it is sunny outside, close the window blinds completely. In rooms without windows, ensure there is indirect ambient light present. For example, switch off the operating lamp light and switch on the indirect room light including lights such as halogen lamps.

If the room light has insufficient NIR light, the ICG molecules may not fluoresce. Ensure the room light completely switched OFF and position the switched-on operating lamps away from the patient.

Note: In ambient light not containing infrared light (fluorescent or LED), the tissue contours will be less visible.

WARNING: Configure and check image quality before each use to avoid incorrect image interpretations.

WARNING: Please consider that direct sun light might obstruct the visualisation of fluorescence image.

3.3.1. Error messages - data transfer

Text	Action
Export to USB failed.	Replace the USB stick. Close the message and start the copying process again. Ensure the USB stick is formatted FAT32.
Not enough USB storage.	Replace the USB stick. Close the message and start the copying process again.
Export to Cloud failed.	Check Wi-Fi connection. Check login credentials are up to date.

3. Usage

3.3.2. Error Messages - Operation

Text	Action
Camera head disconnected unexpectedly.	Turn off IC-Flow. Check the Camera cable plug is connected to Camera and Controller. Check the Camera cable for damage.
Failed to delete file.	Restart system. Contact support if restart system does not work.
Error operating camera.	Reconnect Camera. Contact support if reconnecting camera does not work.
Cannot load camera driver.	Restart system. Contact support if restarting system does not work.
Out of memory.	Delete images/videos to free up memory.
Failed to activate video encoder/decoder.	Restart system. Contact support if restarting system does not work.
Out of video encoder/decoder memory.	Restart system. Contact support if restarting system does not work.
Video encoder/decoder internal error.	Restart system. Contact support if restarting system does not work.
Failed to open file.	Restart system. Contact support if restarting system does not work.
Failed to read file.	Restart system. Contact support if restarting system does not work.
Failed to write file.	Restart system. Ensure storage space available. Contact support if restarting system does not work.
Failed to create file system directory.	Restart system. Contact support if restarting system does not work.
Failed to save image.	Restart system. Contact support if restarting system does not work.
RClone error.	Check login credentials are up to date. Contact support if problem is not resolved.
Password error.	Ensure correct password entry. Contact support if problem is not resolved by password re-entry.
Certificate error.	Restart system. Contact support if restarting system does not work.

3. Usage

3.4. ADDITIONAL SETTINGS

3.4.1. Set date

Select date (where visible) on the touch screen.

A number-input field automatically opens for configuration in Year – Month – Day.

After setting the current date, close input field and the set date will be retained.

3.4.2. Set time

Select time (where visible) on the touch screen.

A number-input field automatically opens for configuration using 24 hour clock format.

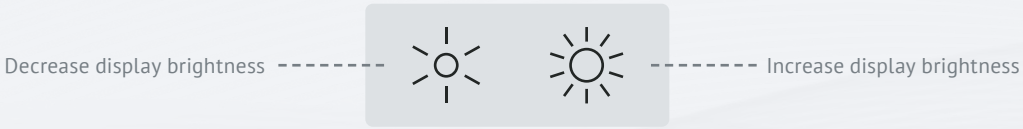
After setting the current time, close input field and the set time will be retained.

Please check and update the time regularly. Update the time manually for daylight saving time as appropriate.

3.4.3. Set display screen brightness

Increase or decrease the brightness of the IC-Flow display screen:

Press and hold the brightness buttons on the bottom of the screen front panel until desired brightness level is acquired.



3.5. SLEEP MODE

Note: The IC-Flow switches to sleep mode after 20 minutes of inactivity.

If Controller or Camera activity is absent for 20 minutes, the IC-Flow goes into sleep mode. The Camera switches off and the Controller display screen darkens. To exit sleep mode, touch the Controller display screen or press any Camera button to return to Standby Screen.

4. Maintenance/service

Note: The IC-Flow switches has a service life of 5 years.

WARNING: Do not open the IC-Flow. Do not make any repairs by yourself. The IC-Flow is a maintenance and calibration free device.

4.1. CLEANING/DISINFECTING

Only use the recommended and tested cleaning and disinfecting agents. Neither the IC-Flow, nor its accessories can be sterilised. Turn the IC-Flow off and disconnect the cable connectors. Prevent the inside of the IC-Flow from getting wet.

4.1.1. Cleaning/disinfection agents

Only use the recommended and tested cleaning and disinfecting agents. Neither the IC-Flow nor its accessories can be sterilised.

WARNING: Turn the IC-Flow off. Disconnect the cable connectors and device from power supply.

Prevent the interior of the IC-Flow from becoming wet.

Note: The front glass of the camera is made from Perspex and is sensitive to chemical cleaning agents (ethanol, acetone, methanol, etc.)

Use soft, non-scratching disposable cloths for cleaning the IC-Flow. In particular, clean the Camera front glass and touchscreen carefully to avoid scratches. It is best to use soft cloth material with a nonaggressive (avoiding caustic, corrosive, or abrasive cleaning agents) soap solution for the sensitive components (e.g. Camera front glass, touchscreen). Use soft, non-scratching disposable cloths for disinfecting the IC-Flow. Disinfect with ethanol or isopropyl alcohol (damp cloths) suitable for cleaning according to the hygiene guidelines of your practice/hospital and national disposable guidelines. Make sure your disinfection solution is suitable for the materials used on the IC-Flow. In case of unknown cleaning agents, ask the manufacturer or your local distributor about using the correct disinfection agent.

Avoid overly disinfecting the Camera front glass as it will become sensitive to disinfectants over time.

4.2. VISUAL INSPECTION

Check all cables for bulges, tears, cracks or twisting at regular intervals. The Camera cable is typically exposed to stress. Check it before and after each use of the IC-Flow. Check the Camera front glass for scratches and irregularities. Check all labels attached to the IC-Flow for legibility. Replace them if necessary. Contact your Diagnostic Green distributor for new labels.

4. Maintenance/service

4.3. TROUBLESHOOTING

4.3.1. Common Errors

Message	Cause	Action
IC-Flow does not react	Cable incorrectly connected	Turn off IC-Flow. Check and re-connect all cables (see Section 2.1)
	Damaged cables	Contact your Diagnostic Green distributor
	IC-Flow not switched on	Turn IC-Flow on (see Section 3.1)
	Software crash	Turn IC-Flow off, then restart (hard reset)
No image visible	Monitor and/or Camera unit is off or in standby mode	Check devices and turn on
	Cable incorrectly connected	Turn IC-Flow off. Check and re-connect all cables (see Section 2.1)
	Damaged cables	Contact your Diagnostic Green distributor
Picture too dark	Sensitivity set too low	Increase sensitivity (see Section 3.1) and/or increase illumination intensity
	Ambient lighting too low	Increase ambient lighting
	Ambient light without proportion of infrared light	Ambient light with a component of infrared light is required
Picture too bright	Sensitivity set too high	Decrease sensitivity (see Section 3.1) and/or decrease illumination intensity
	Ambient lighting too strong	Decrease ambient lighting
Fluorescent image too dark	Intensity too low	Increase illumination intensity (see Section 3.1) and/or increase sensitivity
	IC-Flow's light source damaged	Contact Diagnostic Green distributor
Fluorescent image too bright	Intensity too high	Decrease illumination intensity (see Section 3.1) and/or decrease sensitivity
	IC-Flow's light source damaged	Contact your Diagnostic Green distributor
Operation of Camera unit not possible	Camera operating panel is disabled	Enable the Camera unit operating panel (see Section 3.1)
	Cables incorrectly connected	Turn the IC-Flow off. Check and re-connect all cables (see Section 3.1)

4. Maintenance/service

4.3.2. Additional information

For irregularities during operation, state condition during which error occurred and contact your Diagnostic Green distributor with the details or contact Diagnostic Green directly:

Diagnostic Green GmbH

Feldkirchener Str. 7c
85551 Kirchheim b. Munich, Germany

E-Mail: info@diagnosticgreen.com
www.diagnosticgreen.com

4.3.3. Repairs/return IC-Flow

Should you notice any irregularities, perform troubleshooting (see Section 4.3) to establish if defect is present. To avoid misunderstandings, the user should first clarify the description error.

Should this procedure be unclear to you or if you notice other problems not mentioned in this IFU, contact your Diagnostic Green distributor. Please have product information, serial number, and a detailed description of the problem ready at hand. As soon as the problem has been identified as a defect, a determination will be made to have the IC-Flow returned for repair.

Service and repair measures may only be carried out by authorised Diagnostic Green personnel or authorised representatives.

Always switch the IC-Flow off prior to cleaning, disinfection or inspection measures.

4.3.4. Warranty

In observance of the described purposes and indications, and in compliance with the guidelines of the IFU, Diagnostic Green guarantees the proper functioning of the IC-Flow for the duration of the legal warranty period from the date of purchase. If the IC-Flow is not used in accordance with the requirements outlined in this IFU, the warranty claim becomes invalid and is no longer in effect. Any service or repair work may only be carried out by Diagnostic Green distributor.

Disclaimer:

Diagnostic Green does not assume any liability if the IC-Flow has been changed or modified without the manufacturer's consent. Diagnostic Green does not assume any liability in the event of improper or unintended use. Diagnostic Green does not assume any liability for the use of accessories or spare parts not released by Diagnostic Green.

4.4. DISPOSAL

Note: The owner of this IC-Flow is responsible for the safe and environmentally conforming disposal of the system after its service.

The IC-Flow is an electrical and electronic product according to the EU Directive 2012/19/EU. Its individual components must be disposed of separately and not in household or domestic garbage.

Please note, this IC-Flow does not contain any dangerous material. Its disposal will not damage the environment and will not put at risk the staff charged with the disposal itself.

5. Appendix

5.1. SYMBOLS

Symbol	Description
REF	Part number
	Name and address of the manufacturer
	Date manufactured (year/month)
SN	Serial number
CE	CE mark
	Follow the instructions for use
	Keep away from sunlight
	Protect from moisture Direct current
	Indicates that the product is not sterile
MD	This is a medical device
	Not suitable for normal waste
	Environmental conditions Air pressure limits, limit values for humidity, lower and upper temperature limits.
IP 20	IP20 IP Protection class. Protected against solid foreign objects of 12.5 mm Ø and greater, non-protected against water.

5. Appendix

5.2. TECHNICAL DATA

Classifications in accordance with IEC 60601-1	
Electrical protection class	I
IP Class	IP20
Sterility	Non-sterile, cannot be sterilised
Use in oxygen-rich environment	Not usable
Operating mode	Continuous

Electrical Connection	
Power-supply unit	AC adapter
Input voltage	AC 100 V to AC 240 V
Power frequency	50 Hz / 60 Hz (47-63 Hz)
Power consumption	1.6 – 0.7 A
Maximum secondary power	60 W

Operation and Display	
Touchpad on IC-Flow unit	29.5 cm colour
Membrane keypad on Camera unit	Can be wiped clean with specified cleaning agents
Monitor output on IC-Flow unit	HDMI 2.3
Working distance	15-20 cm, optimum at 18 cm (highest sharpness)
Image field of view	Approx. 8 x 10.5 cm (at 20 cm distance)

Memory	
Internal image memory	30 GB
USB stick	USB 3.1, FAT32 file system Socket on bottom of the Controller

5. Appendix

Image Data	
Formats	Pictures: JPEG Videos: MPEG1
Image size for pictures	1920 x 1200 pixels
Image size for videos	1920 x 1200 pixels

Operating Conditions	
Operating temperature	+15 °C to +30 °C (+59 °F to +86 °F)
Operation humidity	20 % to 70 % (non-condensing)
Operation air pressure	700 hPa to 1060 hPA (10.153 psi to 15.374 psi)
Ambient light	Daylight or artificial light with a component of IR light. LED lighting without a component of IR light is unsuitable

Storage Conditions	
Storage temperature	-20 °C to +60 °C (-4 °F to +140 °F)
Storage humidity	20 % to 70 % (non-condensing)
Storage air pressure	700 hPa to 1060 hPA (2.248 psi to 15.374 psi)

Transportation Conditions	
Transportation temperature	-20 °C to +60 °C (-4 °F to +140 °F)
Transportation humidity	10 % to 95 % (non-condensing)
Transportation air pressure	700 hPa to 1060 hPA (2.248 psi to 15.374 psi)

Dimensions and Weight	
Camera	Metal housing 53 mm x 212 mm x 90 mm (2.087 in x 8.346 in x 3.543 in) (width x depth x height) Weight: 0.74 kg (1 lb 7.3 oz) (without cable) Cable length: about 5 m (5.5 yd)
Controller	Plastic housing Touchscreen 300 mm x 208 mm x 47 mm (11.811 in x 8.189 in x 1.85 in) (width x depth x height) Weight: 1.5 kg (3 lb 5 oz) (without cable or accessories)

5. Appendix

Optics	
Radiation class in accordance with IEC 62471 and 2006/25/EU	Continuous wave lamp (CW) No photo-biological danger
Wavelength range	670 – 780 nm (26.4 – 30.7 in)
Peak wavelength	740 nm
Camera LED service life	> 10,000 h

5.3. EMC REQUIREMENTS

Guidance and manufacturer's declaration – electromagnetic emissions		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1 Class A	The IC-Flow System PC6300 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Group 1 Class A	The IC-Flow System PC6300 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. **WARNING:** This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re- orienting or relocating the IC-Flow System PC6300 or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Class A	

Guidance and manufacturer's declaration – electromagnetic immunity			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV contact discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode voltage ± 2 kV common mode voltage	± 1 kV differential mode voltage ± 2 kV common mode voltage	Mains power quality should be that of a typical commercial or hospital environment.

5. Appendix

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% UT (>95 % dip in UT) for 0,5 cycle	< 5% UT (>95 % dip in UT) for 0,5 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the IC-Flow System PC6300 requires continued Operation during power mains interruptions, it is recommended that the IC- Flow System PC6300 be powered from an uninterruptible power supply or a battery.
	40% UT (60 % dip in UT) for 5 cycles	40% UT (60 % dip in UT) for 5 cycles	
	70% UT (30 % dip in UT) for 25 cycles	70% UT (30 % dip in UT) for 25 cycles	
	< 5% UT (> 95% dip in UT) for 5 s	< 5% UT (> 95% dip in UT) for 5 s	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the A.C. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Veff 150 kHz to 80 MHz	3 Veff	Portable and mobile RF communications equipment should be used no closer to any part of IC-Flow System PC6300, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF	3 V/m	3 V/m	
IEC 61000-4-3	80 MHz to 2.5 GHz		Recommended separation distance:
			d = 1,17 1/V * √'P
			d = 1,17 m/V * √'P for 80 MHz to 800 MHz
			d = 2,33 m/V * √'P for 800 MHz to 2,5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field 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: 

5. Appendix

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection of structures, objects and people.

[a] Field strength 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 IC-Flow System PC6300 is used exceeds the applicable RF compliance level above, the IC-Flow System PC6300 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the IC-Flow System PC6300.

Recommended separation distances between portable and mobile RF communications equipment and the IC-Flow System PC6300

The IC-Flow System PC6300 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the IC-Flow System PC6300 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the IC-Flow System PC6300 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W Electrical fast transient/ burst IEC 61000-4-4	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz d = 1,17 1/V * √'P	80 MHz to 800 MHz d = 1,17 1/V * √'P	800 MHz to 2.5 GHz d = 2,33 1/V * √'P
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.3

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency applies.

NOTE 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection of structures, objects and people.

CAUTION: The IC-Flow System PC6300 is subject to specific precautions concerning EMC (Electromagnetic compatibility) and is only allowed to be installed and used according the EMC advice contained in this user manual.

Portable and mobile high frequency communication devices may influence the IC- Flow System PC6300.

When high frequency devices are used during surgery, the applying standards for high frequency devices for surgery must be followed.

5. Appendix

5.4. APPLIED STANDARDS

Safety	EN 60601-1
Electromagnetic Compatibility	EN 60601-1-2: 2014
Labelling	EN 60601-1, ISO 15223-1, EN 1041
Potential equalisation	DIN 42801
Safety of lamps	IEC 62471:2006 (+A1:2008)

5.5. DECLARATION OF CONFORMITY

- Declaration of Conformity for devices in accordance with the Medical Device Regulation 2017745.
- Declaration of Conformity for optical radiation in accordance with 2006/EG.
- Declaration of Conformity for Restriction of Hazardous Substances (RoHS) in accordance with 2011/65/EU.

Manufacturer

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IC-FLOW™ IMAGING SYSTEM REGISTRATION & DISTRIBUTION

IC-Flow™ Imaging System is currently available in all territories where CE is recognised as follows:

- Austria
- Belarus
- Belgium
- Bulgaria
- Croatia
- Cyprus
- Czechia
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Iceland
- Ireland
- Italy
- Latvia
- Liechtenstein
- Lithuania
- Luxembourg
- Malta
- Montenegro
- Netherlands
- Norway
- Poland
- Portugal
- Romania
- Serbia
- Slovakia
- Slovenia
- Spain
- Sweden
- Switzerland
- United Kingdom

IC-Flow™ Imaging System Intended Use

IC-Flow™ Imaging System received CE mark as a Medical Device Class I

The IC-Flow Imaging System is used to capture and view fluorescent images for various indications such as, visual assessment of blood flow, visual assessment of lymphatic system, organ transplant procedures, plastic micro-reconstructive surgery, visual assessment of hepatobiliary system (liver tumours and liver metastases), visual assessment of bile ducts during hepatobiliary surgery.

The IC-Flow™ Imaging System is used as an adjunctive method for visualisation of ICG fluorescent images.
The IC-Flow™ imaging system is intended for near-infrared fluorescence imaging in adult and pediatric patients one month of age and older. The IC-Flow™ Imaging System is intended for use by qualified surgeons/physicians or healthcare professionals in doctors' offices and hospitals.

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