Diagnostic Green

IC-Flow™ 2.0 Imaging System:
User Manual

www.diagnosticgreen.com

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1. General Information

1.1. INTENDED USE

IC-Flow™ 2.0 Imaging System, used in conjunction with Indocyanine Green for Injection (ICG), is indicated for fluorescence imaging of blood flow, tissue perfusion, and the lymphatic system in both adult and pediatric patients one month of age and older. Upon intravenous administration of ICG, the IC-Flow™ 2.0 Imaging System is used for fluorescence angiography before and after vascular, and plastic, micro-, and reconstructive procedures.

Additionally, upon subcutaneous administration, the system is used for fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels.

1.2. OPERATION

The IC-Flow™ 2.0 Imaging System (hereafter referred to as IC-Flow 2.0) facilitates visualization of the distribution and intensity of the fluorescent dye, Indocyanine Green for Injection (ICG), dye.

The IC-Flow 2.0 has a medical, near-infrared (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 captured using buttons located on the Camera or icons on the Controller. The NIR light source illumination (excitation light) and Camera sensitivity can be adjusted using controls on either the Camera or Controller. Images are stored in the Controller but can easily be transferred to a USB memory device, Cloud Drive or an external mass storage device.

WARNING: The IC-Flow 2.0 shall be operated by physicians and healthcare professionals at hospital outpatient clinics.

1.3. SAFETY INSTRUCTIONS

 1.3.1. Warnings

Read this User Manual carefully before working with the IC-Flow 2.0. Failure to read this User Manual can endanger the lives of humans and may damage machines and buildings. Keep this User Manual as a reference.

Federal law restricts this system to sale by or on the order of a licensed physician.

Device Modifications

Device modifications are not permitted.

Operation

To avoid the risk of electric shock, the IC-Flow 2.0 must only be connected to a main power supply.

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 minimize eye exposure. Avoid holding the Camera in front of the patient's eyes. Shut the camera off or put it in standby mode if not in use.

1. General Information

Sterility and Patient Safety

The IC-Flow 2.0 is not designed for direct or indirect patient contact. The camera may be used in close proximity to a patient in a non-sterile environment.

The IC-Flow 2.0 is not sterilized and cannot be reprocessed. The IC-Flow 2.0 is not intended for use in a sterile field.

DO NOT bring the Camera into contact with the patient.

Follow the cleaning and disinfecting instructions in Section 4.1.

Avoid Mechanical Shocks

If the IC-Flow 2.0 is visibly damaged or damage is suspected, stop using the system and contact the manufacturer or US Distributor.

Ambient and Storage Conditions for the IC-Flow 2.0

The IC-Flow 2.0 is not designed for use in an oxygen-rich environment.

Electromagnetic Compatibility and Electrical Safety

IC-Flow 2.0 complies with IEC 60601-1 safety requirements for medical electronic equipment.

IC-Flow 2.0 is powered via a power cable unit.

WARNING: Equipment NOT suitable for use in the presence of a flammable anesthetic mixture of air or with oxygen or continuous flow of Nitrous Oxide. Prevent contact with strong corrosive gases (such as chlorine or fluorine gases).

WARNING: DO NOT touch the plug with wet hands. This could cause an electric shock. Always pull on the plug and never pull the cable when disconnecting it. Pulling on the cable could cause damage to the IC-Flow 2.0, causing an electrical shock or fire.

WARNING: Only connect the IC-Flow 2.0 with the supplied Power Unit (Article Number: ATM065T-P120 Section 2).

Use only the AC adaptor provided by the manufacturer. Use of an unauthorized power supply may result in risk of electric shock, fire, damage, or malfunction.

WARNING: The equipment must be connected to a mains supply with protective earth (ground). Disconnect the system from the power supply before cleaning.

WARNING: Do not expose IC-Flow 2.0 to strong magnetic or electromagnetic fields. To prevent negative electromagnetic compatibility (EMC) impacts or situations, do not stack the IC-Flow 2.0 or place it nearby emitting devices.

WARNING: Protect from dust and excessive moisture. For Indoor use only. Avoid vibrations.

1. General information

1.3.2. Cautions

Electrical Safety

Disconnect the power unit from the wall socket if the IC-Flow 2.0 is not used for an extended period.

Always turn off the IC-Flow 2.0 before connecting or disconnecting the cables.

Never touch the plug contacts of the IC-Flow 2.0 and the patient at the same time as it can result in dangerous discharge currents.

Electromagnetic Compatibility

Use the IC-Flow 2.0 as described in Section 5.3 EMC, to minimize risks related to the electromagnetic compatibility of this system with other products.

Cables

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

When handling the IC-Flow 2.0, make sure cables are not left in walkways or areas where they can be tripped over and cause injury to the operators or damage to the cable.

If Irregularities Occur

If the image suddenly disappears, or you notice an unusual sound, smell, or smoke emitted from the IC-Flow 2.0, immediately turn off the device using the main switch. Pull the plug from the socket and contact the US Distributor.

Never try to repair the IC-Flow 2.0 yourself, as there are no user serviceable components in the device. Attempting to repair the device will void the warranty.

Do Not Open

Never attempt to disassemble or alter the IC-Flow 2.0 under any circumstances, as this may cause damage to the device or result in injury. Use only the external components as outlined in this User Manual.

Foreign Objects

Foreign objects or substances, such as flammable liquids, metal objects, or liquids can damage the IC-Flow 2.0 and cause an electric shock or fire.

Avoid Mechanical Shocks

The front side of the Camera is especially sensitive to mechanical shocks. Do not hit the Camera against a hard surface. Do not drop the Camera.

Do not drop the Controller. Do not hit the Controller against a hard surface.

1.3.3. NOTES

Camera Temperature

The intended use time at maximum brightness is 30 minutes. Do not operate the IC-Flow 2.0 at maximum brightness for more than 30 minutes.

Using the camera at maximum brightness for more than 30 minutes may result in overheating. Reduce the brightness after 30 minutes of operation to avoid overheating. If necessary, the camera should be turned off to cool down.

1. General information

Camera Cable

Inspect the Camera 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 2.0 to severe mechanical shocks, for example, by dropping it, as this may damage the device.

If the IC-Flow 2.0 falls or is dropped, inspect the IC-Flow 2.0 thoroughly prior use.

Avoid Electrostatic Discharge

Use caution to prevent damage on IC-Flow 2.0 components from electrostatic discharge – i.e. avoid direct and indirect contact between metallic device 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). See Warnings above.

Ambient and Storage Conditions for the IC-Flow 2.0

Protect the IC-Flow 2.0 from sunlight and heat.

Store the IC-Flow 2.0 in a dry place.

Ambient conditions for storage are -20°C to +60°C (-4°F to +140°F) and use is +15°C to +30°C (+59°F to + 86°F).

Temperature Fluctuations

Avoid broad temperature fluctuations. If the IC-Flow 2.0 is brought from a cold room to a warm room, the Camera window can fog up causing pictures to be blurred or show artifacts. Wait until the picture becomes clear before using it.

Cleaning and Disinfecting

Follow the cleaning and disinfecting instructions in Section 4.1.

The IC-Flow 2.0 cannot be sterilized.

Repairs/Service

IC-Flow 2.0 is a maintenance and calibration free device, as there are no user serviceable components in the IC-Flow 2.0. Merely inspect visually on a regular basis (see Section 4). In the event of an error, read Section 4 and try to solve the problem. Alternatively, contact the US Distributor. Contact information is provided on pages 31 and 46 of this manual.

Connecting a Monitor

Only connect the MEDDP-722-G1-A1-0010 monitor 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 the IC-Flow 2.0 device is assembling a system intended for medical purposes and is therefore responsible for ensuring compliance with the requirements of the system standard for medical products. The assembly of medical electrical systems as well as modifications during the service life must be evaluated according to the requirements of IEC 60601-1.

1. General information

Be sure to adhere to the allowable environmental conditions for using an external monitor, including the specified conditions for transport and storage which must match the requirements for transport and storage of IC-Flow 2.0.

Stored Pictures and Videos

The stored pictures and videos found on the IC-Flow 2.0 are for demonstration purposes only.

External Devices

Do not connect any external devices to IC-Flow 2.0 that are not specified in this User Manual.

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

2. IC-Flow 2.0 Set-Up

2.1. PACKAGE CONTENT

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

WARNING: If any component is missing or damaged, do not use the IC-Flow 2.0 and contact a Diagnostic Green GmbH representative.

2.2. IC-FLOW 2.0 COMPONENTS

Label	Component	Quantity	Item Number
1	Power Unit, Cable	1	PC6306
2	Controller	1	PC6309
3	Camera Cable	1	PC6303
4	Camera	1	PC6304
5	Stand (plus 4 screws)	1	PC6305
6	HDMI Cable	1	PC6308
–	IC FlowTM 2.0 Imaging System, User Manual (this document)	1	79021

IC-Flow Controller

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

Figure 1: IC-Flow 2.0 Imaging System Components

2. IC-Flow 2.0 Set-Up

2.3. DESCRIPTION OF COMPONENTS

1. Power Unit, Cable – connects the Controller to a main power source (Knurled sleeve)
2. Controller – A flat monitor control unit with command buttons for the Camera operation, data storage, and visualization of the ICG dye during the procedure.
3. Camera Cable – Connects the Camera to the Controller.
4. Camera – The handheld camera unit for visualizing the ICG in the body tissues.
5. Stand – For securing the Controller to a base or trolly for improved stability during the IC-Flow 2.0 operation.
6. Screws – For securing the Controller to the stand
7. HDMI Cable – For connecting the Controller to a larger monitor and projecting the images during the camera operation.

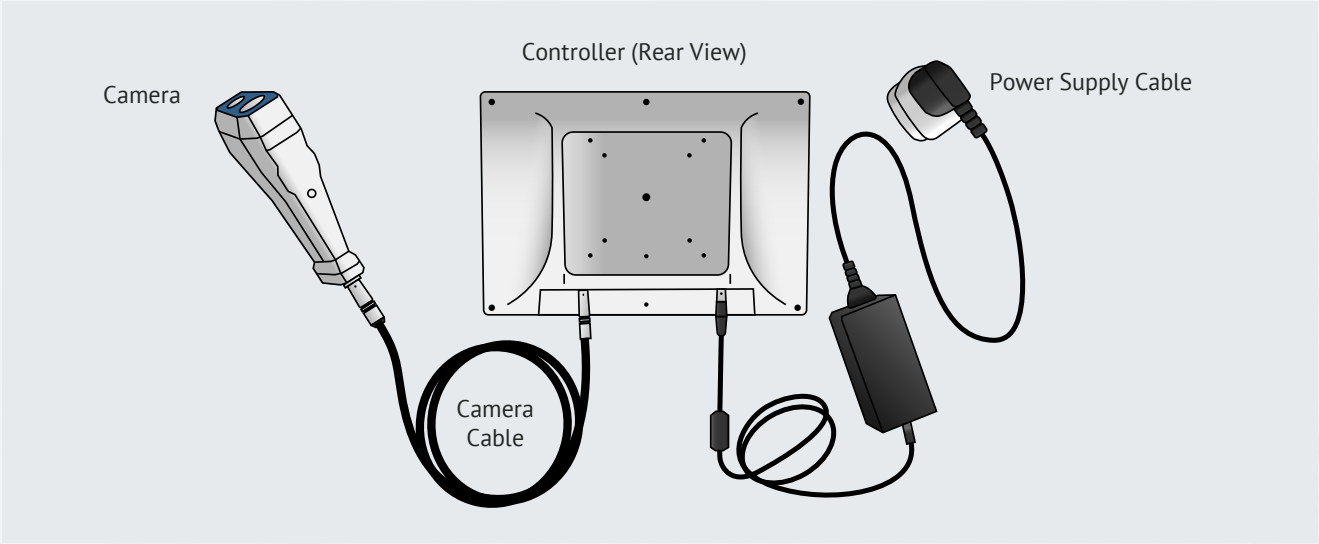
2.4. IC-FLOW 2.0 ASSEMBLY

Please follow the instructions for IC-Flow 2.0 assembly carefully to avoid any damage to the system and ensure proper operation.

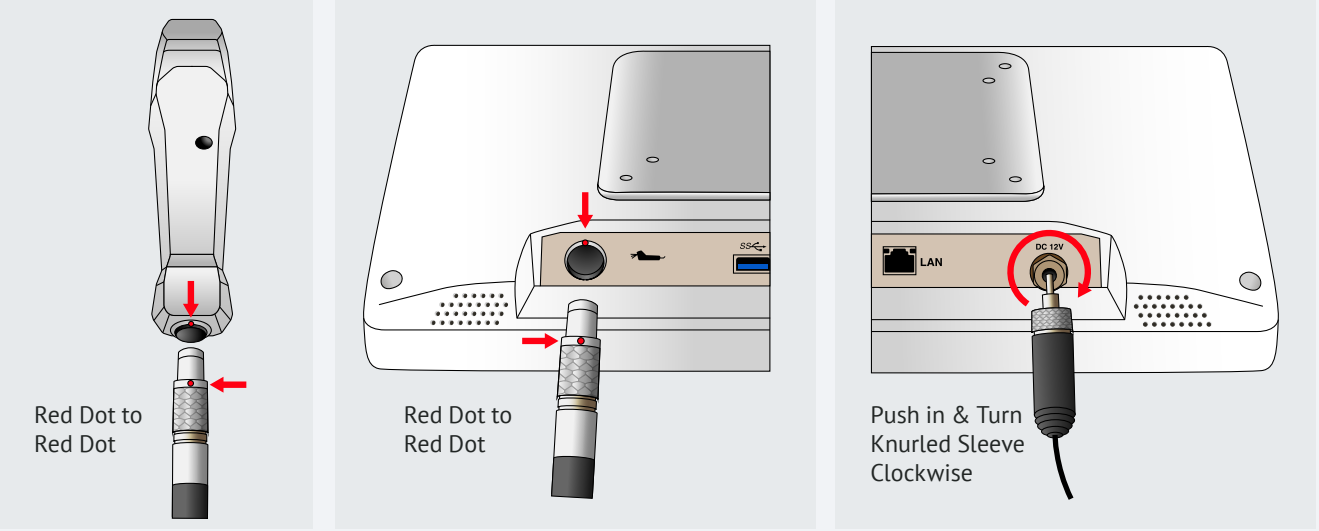
Insert the Camera Cable plugs directly into the slots. Align the red dots on the Camera Cable with the red dots on the Camera and Controller plugs.

Ensure the Camera cable plugs are fully pushed in on the Camera and Controller. **Do not twist the plugs which could result in damage.**

Connect the power cable to the Controller, rotate the knurled sleeve clockwise.



2. IC-Flow 2.0 Set-Up



Notes:

- Ensure the Camera cable plugs are fully pushed in on the Camera and Controller, **DO NOT** twist these plugs.
- Connect the power unit (cable) to the Controller, rotate the knurled sleeve clockwise to secure in place.
- Attach the stand to the Controller using the 4 screws.

2.4.1. Attach Controller to Stand

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

Notes:

- The IC-Flow 2.0 should only be used when mounted on the stand.

CAUTION: The rear side of the IC-Flow 2.0 can get warm. When moving the IC-Flow 2.0, it is recommended that it is done by gripping the stand.

2.4.2. Compatible Products

Indocyanine Green (ICG)

The following Indocyanine Green (ICG) products are compatible for use with IC-Flow 2.0:

Product Name	Manufacturer
IC-Green®, 25 mg	Renew Pharmaceuticals Ltd.
Spy Agent Green®, 25 mg	Stryker
Indocyanine Green for Injection, 25 mg	Renew Pharmaceuticals Ltd.

3. Usage

3.1. OPERATION

WARNING: Do not position equipment so that it is difficult to disconnect the IC-Flow 2.0.

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

WARNING: Magnetic and electrical fields can affect the function of the device. Maintain a safe distance between IC-Flow 2.0 and other devices that emit HF radiation, otherwise malfunctions may occur.

Note:

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

3.1.1. Switch On

Press and hold the main power button for three (3) seconds to switch on the Controller.

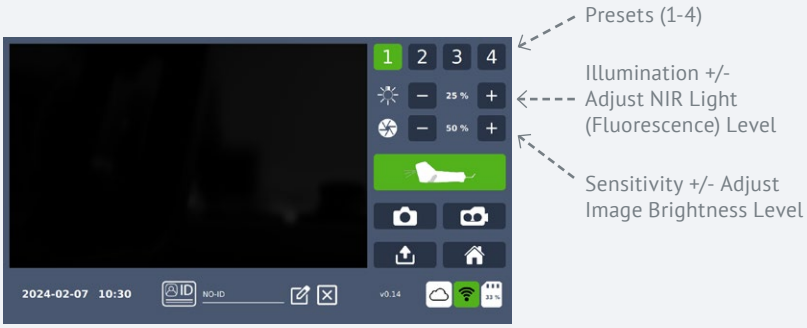
The panel buttons light up green; the Standby Screen appears (approx. 45 seconds).

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.

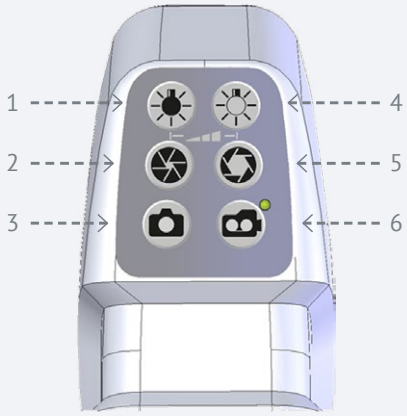
3. Usage

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, Setting can be adjusted on Camera.

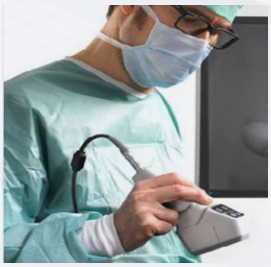
1. Less light illumination – reduces the fluorescence intensity level
2. Less sensitivity – increases the overall image brightness of the camera
3. Take a picture
4. More light illumination – increases the fluorescence intensity level
5. More sensitivity – reduces the overall image brightness of the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

3.1.3. Administration of ICG

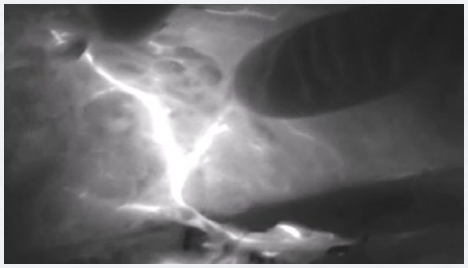
When ICG injection is administered, Near Infra-Red (NIR) light is applied to tissue/organ of interest. ICG emits fluorescence and is detected by the Camera with images displayed on the Controller.

3.1.4. Capture Image / Record Video

Hold the Camera between 17 cm - 20 cm (6.8 in – 7.9 in) above tissue / organ of interest.

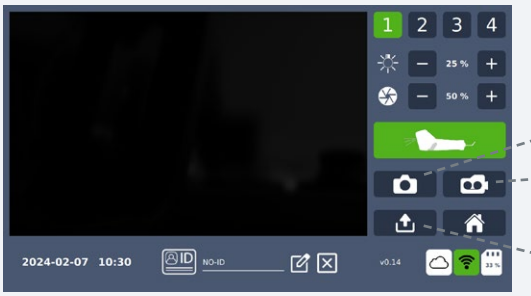


Adjust settings to ensure high contrast image capture.



3. Usage

3.1.5. Capture Image / Record Video



- Select Photo icon to take a photo of an image.
- Select video icon to start recording and once again to stop the recording.

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		Arrange multiple recorded images / videos by Patient ID

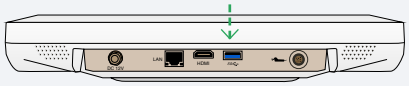
3. Usage

Icon	Display	Action
 Individual Data View		Permit individual Patient ID view of images / videos*

*Automatically displays the last Patient IDs images/videos captured (when IC-Flow 2.0 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 sec (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 2.0, select small circle beside folder.

  OR
- (ii) Copy image/video select small circle beside copy folder.

i) 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 2.0 folder on the USB.

  In the IC-Flow 2.0 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 of 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 analysis 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)

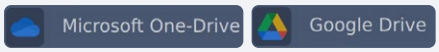
- Select Wi-Fi (Home Screen). 
- Select Wi-Fi provider. 
- Use keyboard to enter Wi-Fi password and then select accept.  
- Successful connection indicated by green Wi-Fi symbol. 
- Close screen to return to Home or Transfer screens. 
- The Wi-Fi button will change to green when Wi-Fi is connected. 

Connect to Cloud (Initial Set-up)

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

3. Usage

- Choose Cloud service provider.



- Use keyboard to create unique IC-Flow 2.0 user ID, then select accept.

  Note: User ID required when there are multiple users of the device. This ensures each user's captured data is protected.

- Sign-in to selected drive with relevant.

  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 2.0 users to send images/videos to this account..

- The next screen displays a 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.

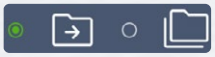
- Press and hold image/video for two sec (green outline appears).

  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 2.0, select small circle beside folder.



OR

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

3. Usage

- Select IC-Flow 2.0 user ID Cloud button.

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

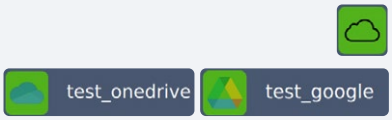
  Images/videos are saved in an IC-Flow 2.0 folder on the Cloud Drive.

  In the IC-Flow 2.0 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 the Cloud Drive,** select the green Cloud button on the Home screen and then press the green Drive connection button beside the unique IC-Flow 2.0 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

Connect to Cloud (Initial Set-up)

- Select Transfer Screen or turn Camera off.

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

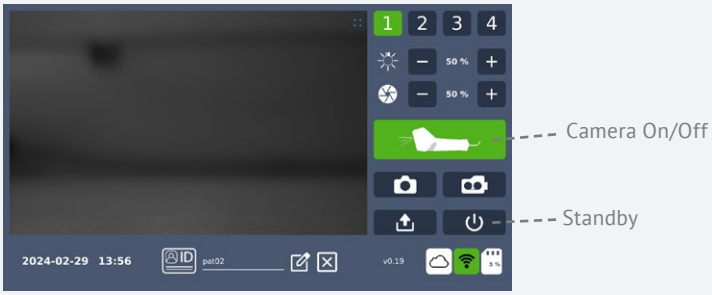
  Note: All images/videos can be deleted by selecting photo/video icon.

- 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 minutes, Camera may exceed 43°C/109.4°F).

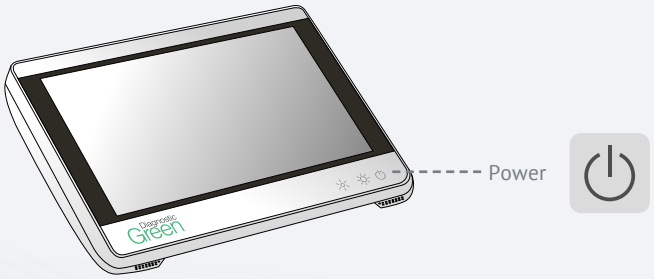


Home Screen

Standby Screen

3.1.12. Switch Off

Press and hold Power button (1) for three seconds, then select Power-Off button to confirm.



3.1.13. Disassemble IC-Flow 2.0

1)

Once IC-Flow 2.0 is powered off, remove power supply plug from socket.

2)

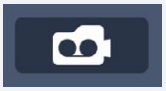
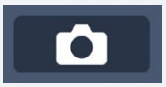
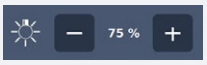
Disconnect mains AC power cable from the IC-Flow 2.0 by turning counterclockwise, then remove the mains plug.

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 (without turning).

3. Usage

3.1.14. Icons

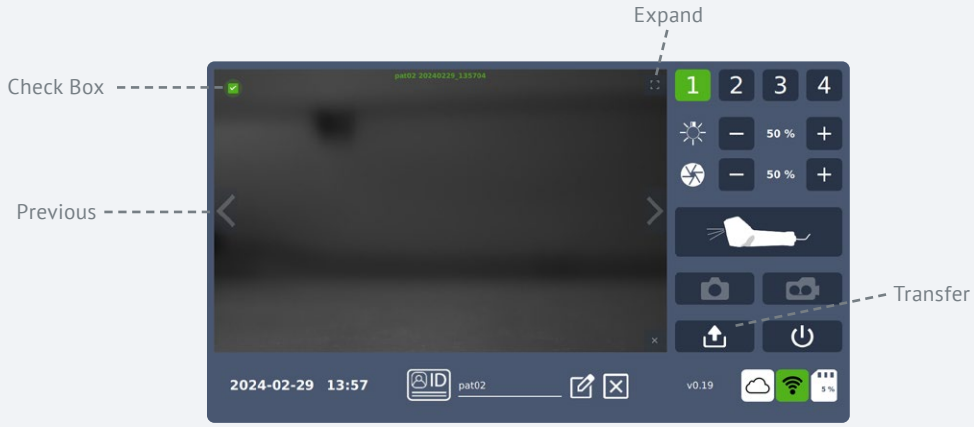
Icon	Description	Action
	Standby	Standby Screen Turns Camera off
	Transfer	Captured images & videos for viewing, transfer or deletion
	Patient ID	Patient ID Creation
	Cloud	Connection to Cloud Drive Server
	Wi-Fi	Connection to Wi-Fi
	IC-Flow 2.0 memory	IC-Flow 2.0 – % Memory Used
	Video	Records video
	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 a USB memory device or as per Section 3.1.8 above. 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 a 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 a USB memory device or Cloud Drive as per Section 3.1.9 above. 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 the 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 the view returns to the 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, optimize ambient light so that body contours are visible using the IC-Flow 2.0, to ensure ideal lighting for visualization/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 the ambient light is indirect. For example, switch off the overhead light and switch on 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 is completely switched OFF and position the overhead lights 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 sunlight might obstruct the visualization 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 2.0. Check if the Camera cable plug is connected to the Camera and Controller. Check the Camera cable for damage.
Failed to delete file.	Restart system. Contact support if restarting 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 refreshing 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 is 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 the 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.

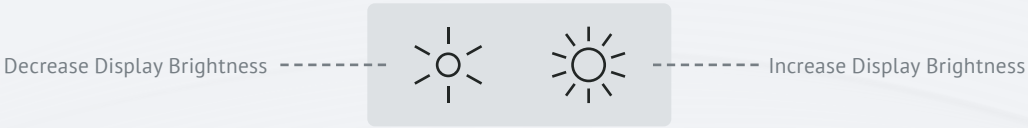
3.4.2. Set Time

- 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.

3.4.3. Set Display Screen Brightness

Increase or decrease the brightness of the IC-Flow 2.0 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 2.0 switches to sleep mode after 20 minutes of inactivity.

If Controller or Camera activity is absent for 20 minutes, the IC-Flow 2.0 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 the Standby Screen.

4. Maintenance / Service

Note: The IC-Flow 2.0 switches have a service life of 5 years.

WARNING: Do not open the IC-Flow 2.0 Camera or Controller. Do not attempt to make any repairs yourself. The IC-Flow 2.0 is a maintenance and calibration free device.

4.1. CLEANING AND DISINFECTING

WARNINGS:

The IC-Flow 2.0 cannot be sterilized. Turn the IC-Flow 2.0 off and disconnect the cable connectors prior to cleaning and disinfecting. Failure to power off the IC-Flow 2.0 prior to cleaning may expose personnel to unsafe conditions and result in damage to the device.

For cleaning or disinfecting medical devices only specifically formulated cleaning agents and/or disinfectants should be used.

Prevent the inside of the IC-Flow 2.0 from getting wet.

4.1.1. Cleaning IC-Flow 2.0 Components

WARNING: Turn the IC-Flow 2.0 off. Disconnect the cable connectors and disconnect the device from the main power supply.

WARNING: Prevent the interior of the IC-Flow 2.0 from becoming wet. Do not immerse the IC-Flow 2.0 in liquid.

NOTE: The front glass of the Camera is made of perspex and is sensitive to chemical – cleaning agents (e.g., ethanol, acetone, methanol).

NOTE: Staff should use suitable protective clothing and equipment at all times. Take note of the instructions provided by the cleaning agent manufacturer for correct handling and use of the product.

NOTE: The guidance concentrations in the cleaning solutions and/or disinfectants contact time given by the detergent manufacturers should be observed. If these concentrations and times are exceeded significantly, discoloration or corrosion could occur with some materials.

Use soft, non-scratching disposable cloths for cleaning the IC-Flow 2.0 moistened with a mild detergent solution. It is best to use soft cloth material with a non-aggressive soap solution for the sensitive components (e.g. Camera front glass, Controller touchscreen). Remove all residual cleaner from the components surfaces.

Do not use caustic, corrosive, or abrasive cleaning agents.

4. Maintenance / Service

4.1.2. Disinfection of the IC-Flow 2.0 Components

Use soft, non-scratching disposable cloths for disinfecting the IC-Flow 2.0. Disinfect the metal housing of the camera with 70% 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 appropriate for the materials used on the IC-Flow 2.0.

In case of unknown combinations, ask the manufacturer or the US Distributor about using the correct disinfection agent.

Dry all component surfaces following cleaning and disinfection.

Special attention should be paid to cleaning the Camera front glass and Controller touchscreen carefully to avoid scratches. If the front glass of the Camera requires cleaning, use a small amount of glass cleaner and a soft cloth or gauze. Do not use abrasive cleaners or solvents.

Avoid over disinfecting the Camera front glass as it may damage the glass over time.

4.2. IC-FLOW 2.0 COMPONENTS INSPECTION

After cleaning and/or disinfection, inspect all components for corrosion, damaged surface, chip, or contamination. Components that appear to be contaminated must be cleaned and low-level disinfected again following the procedures described in Sections 4.1.1 and 4.1.2 above.

Check all cables for damage, 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 2.0. Check the Camera front glass for scratches and irregularities. Check all the components for damage, sharp edges, rough surfaces, loose or missing parts, residue from cleaner and disinfectant (remove residues if needed) Check all text and labels attached to the IC-Flow 2.0 for legibility. Replace them if necessary.

Contact the Diagnostic Green GmbH or US Distributor for new labels.

4.3. TROUBLESHOOTING

4.3.1. Common Errors

Error	Cause	Action
IC-Flow does not react	Cable incorrectly connected	Turn off IC-Flow 2.0. Check and re-connect all cables (see Section 2.4).
	Damaged cables	Contact your Diagnostic Green distributor.
	IC-Flow 2.0 not switched on	Turn IC-Flow 2.0 on (see Section 3.1).
	Software crash	Turn IC-Flow 2.0 off, then restart (hard reset).
No image visible	Monitor and/or Camera unit is off or in standby mode	Check devices and turn them on.
	Cable incorrectly connected	Turn IC-Flow 2.0 off. Check and re-connect all cables (see Section 2.4).
	Damaged cables	Contact your Diagnostic Green GmbH or US Distributor.

4. Maintenance / Service

Error	Cause	Action
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 2.0'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 2.0'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 2.0 off. Check and re-connect all cables (see Section 3.1).
Cannot project the images on the larger screen	HDMI Cable connected to the wrong port on TN monitor	Disconnect and connect the cable and ensure the connection is to right portal in the large screen.
	HDMI Cable does not work	Discontinue the use and select another compatible HDMI Cable if possible or continue using the smaller monitor.

4.3.2 Additional Information

For irregularities during operation, state condition during which the error occurred. Contact the US Distributor with the details or contact Diagnostic Green GmbH directly:

Manufacturer

Diagnostic Green GmbH
Feldkirchener Str. 7c
85551 Kirchheim b. München
Germany

E-Mail: info@diagnosticgreen.com

www.diagnosticgreen.com

US Distributor

Ultragreen Data Systems Inc.
2501 Jackson Avenue, Suite 1810
Long Island, NY 11101

www.diagnosticgreen.com

1-646-8931395

4. Maintenance / Service

4.3.3. Repair / Return IC-Flow 2.0

Should you notice any irregularities, perform troubleshooting (see Section 4.3) to establish if defect is present.

Should this procedure be unclear to you or if you notice other problems not mentioned in this User Manual, contact the US Distributor, HUB Pharmaceuticals. Please have product information, serial number, and a detailed description of the problem on hand. As soon as the problem has been identified as a defect, a determination will be made to have the IC-Flow 2.0 returned for repair.

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

WARNING: Always switch the IC-Flow 2.0 off prior to cleaning, disinfection or inspection.

4.3.4. Warranty

In observance of the described purposes and indications, and in compliance with the guidelines of the User Manual, Diagnostic Green GmbH guarantees the proper functioning of the IC-Flow 2.0 for the duration of the legal warranty period from the date of purchase. If the IC-Flow 2.0 is not used in accordance with the requirements outlined in this User Manual, the warranty claim becomes invalid and is no longer in effect. Any service or repair work may only be carried out by Diagnostic Green GmbH.

Disclaimer

Diagnostic Green GmbH does not assume any liability if the IC-Flow 2.0 has been changed or modified without the manufacturer's consent. Diagnostic Green GmbH does not assume any liability in the event of improper or unintended use. Diagnostic Green GmbH does not assume any liability for the use of accessories or spare parts not released by Diagnostic Green GmbH.

4.4. DISPOSAL

NOTE: The owner of the IC-Flow 2.0 is responsible for the safe and environmentally conforming disposal of the system after its service life.

The IC-Flow 2.0 is an electrical and electronic product. Its individual components must be disposed of separately and not in household or domestic garbage.

Please note, the IC-Flow 2.0 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
	Part Number
	Name and Address of the Manufacturer
	Date Manufactured (Year/Month)
	Distributor
	Serial Number
	Consult User Manual
	Caution Symbol
	Warning Symbol
	Note Symbol
	Keep Away From Sunlight
	Quantity
	Keep Dry
	Prescription Only
	Do Not Use if the Package is Damaged and Consult the User Manual

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Symbol	Description
	Fragile, Handle with Care
	Indicates that the product is not sterile
	Not suitable for normal waste
	Do not immerse in any liquid
	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.
	Electromagnetic Interference
	IEC 60601, Class I, Protective Earth

5. Appendix

5.2. TECHNICAL DATA

Classification in Accordance with IEC 60601-1	
Electrical Protection Class	I
IP Class	IP 20
Sterility	Non-sterile, cannot be sterilized
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	60 VA
Electric Fuses	FUSE T 5A, L 125V

Operation and Display	
Touchpad on IC-Flow 2.0 Unit	29.5 cm color
Membrane Keypad on Camera Unit	Can be wiped clean with specified cleaning agents
Monitor Output on IC-Flow 2.0 Unit	HDMI 2.3
Working Distance	17-20 cm, optimum at 18 cm
Image Field of View	Approx. 7 x 11 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 not suitable.

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 Unit	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. ESSENTIAL PERFORMANCE

IC-Flow 2.0 has three essential performances (EPs):

IC-Flow 2.0 Essential Performance (EP)		
No	**Essential Performance**	**Description**
EP1	Image Visualization	No change in contrast and brightness on display
EP2	Image Visualization	Image display does not flicker of shifted
EP3	Image Visualization	The brightness changes of the camera LED are in the range of less than +/-5%

5.4. EMC REQUIREMENTS

IC-Flow 2.0 complies with IEC 60601-1 Medical Electrical Equipment Classification for safety and IEC 60601-1-2 for electromagnetic emission and immunity.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
IC-Flow 2.0 is intended for use in the electromagnetic environment specified below. The customer or the user of the IC-Flow 2.0 should ensure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF Emissions CISPR 11	Group 1 Class A	The IC-Flow 2.0 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 CISPR 11	Group 1 Class A	The IC-Flow 2.0 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. ⚠ **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 2.0 or shielding the location.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Class A	

5. Appendix

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	Main 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	Main 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% UT (>95 % dip in UT) for 0,5 cycle	<5% UT (>95 % dip in UT) for 0,5 cycle	Main power quality should be that of a typical commercial or hospital environment. If the user of the IC-Flow 2.0 requires continued Operation during mains power interruptions, it is recommended that IC-Flow 2.0 be powered from an uninterruptible power supply.
	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	30 A/m	30 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.			
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 the IC-Flow 2.0, including cables, then the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF	3 V/m	3 V/m	

5. Appendix

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
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: 
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.			
*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 2.0** is used exceeds the applicable RF compliance level above, the **IC-Flow 2.0** 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 2.0**.			

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Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the IC-Flow 2.0

The IC-Flow 2.0 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the IC-Flow 2.0 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the IC-Flow 2.0 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 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection of structures, objects and people.

WARNING: Electromagnetic Interference Risk

- The IC-Flow 2.0 is subject to specific precautions related to electromagnetic compatibility (EMC) and must only be installed and operated in accordance with the EMC guidance provided in this User Manual.
- The IC-Flow 2.0 complies with IEC 60601-1-2 EMC requirements; however, medical electrical equipment may still be susceptible to electromagnetic interference.
- The device is intended for use only in electromagnetic environments specified in the accompanying documentation. It is the responsibility of the user to ensure the device is used in such environments.
- Portable and mobile RF communication devices (e.g., mobile phones, walkie-talkies) may interfere with the IC-Flow 2.0's performance. A minimum separation distance should be maintained between such RF devices and the IC-Flow 2.0.
- This device has not been tested for immunity to high-power RF sources (e.g., MRI systems or industrial emitters). Use in the vicinity of such equipment may cause unpredictable behavior, degraded performance, or failure of essential functions.
- Do not operate the IC-Flow 2.0 within the active field of RF-emitting devices.
- In clinical settings where high-powered RF devices are in use, implement mitigation strategies such as physical separation, RF shielding, or scheduling to avoid electromagnetic overlap.

5. Appendix

- If the device exhibits unexpected performance or behavior, relocate it or eliminate nearby RF sources (e.g., move it away from an MRI suite).
- Noncompliance with these EMC precautions may lead to degradation of essential performance or compromise of basic safety functions., performance degradation, data loss, or interruption of device functionality.
- If operation near RF sources is unavoidable, consult your facility's biomedical engineering or clinical safety personnel to assess risks and implement appropriate mitigation measures.

5.5. APPLIED STANDARDS

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

6. ICG Imaging Agent for the IC-Flow 2.0

The IC-FlowTM 2.0 Imaging System device uses Indocyanine Green for Injection (ICG) as the imaging agent.

The IC-Flow 2.0 does not include the ICG and sterile water. This User Manual provides instructions for preparation, handling and administration of the ICG imaging agent.

WARNING: Consult with ICG Instructions for Use prior to use or administration, dosage, warning, caution, contraindications, and patient population.

NOTE: ICG imaging agent should be acquired through normal supply channels.

6.1 CLINICAL PHARMACOLOGY

Following intravenous injection, ICG rapidly binds to plasma proteins, primarily lipoproteins with a lesser and variable binding to albumin (2-30% of total). Simultaneous arterial and venous blood estimations have shown negligible renal, peripheral, lung or cerebro-spinal uptake of the ICG. ICG is taken up from the plasma almost exclusively by the hepatic parenchymal cells and is secreted entirely into the bile. ICG does not undergo significant enterohepatic recirculation. ICG has a half-life of 2.5-3.0 minutes.

6.2 CONTRAINDICATIONS

ICG is contraindicated in patients with a history of hypersensitivity to indocyanine green. Reactions have included anaphylaxis.

ICG contains sodium iodide and should be used with caution in patients who have a history of allergy to iodides or iodinated imaging agents due to a risk of anaphylaxis. The IC-Flow 2.0 should not be used during procedures with patients who are known to be sensitive to iodides or iodinated imaging agents.

6.3 ICG WARNINGS

- Anaphylactic deaths have been reported following ICG administration during cardiac catheterization.
- Each vial of ICG and accompanying Sterile Water for Injection are intended for use with only 1 patient and within 6 hours of reconstitution. Discard any unused reconstituted ICG after each surgery is completed or 6 hours have lapsed since reconstitution. If a precipitate is present upon reconstitution, do not use and discard the solution.
- 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.
- The outside packaging of ICG vials, and the Sterile Water for Injection are NOT sterile. The contents of the ICG vial are sterile and must be handled aseptically to maintain the sterile field during surgery.
- Radioactive iodine uptake studies should not be performed for at least a week following the use of ICG for injection.
- 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.
- Only use ICG at indicated doses and concentrations as defined in the User Manual.

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- Do not use ICG vials, and Sterile Water for Injection that appear to have packaging or seals that are compromised or damaged in any way.
- ICG is generally injected through a shared intravenous line with no reported difficulties or unexpected results to date. However, drug / drug interactions have not been identified in the ICG Package Insert.
- Always have cardiopulmonary resuscitation personnel and equipment readily available and monitor all patients for hypersensitivity reactions.
- Because ICG contains iodine, the iodine-binding capacity of thyroid tissue may be reduced for at least one week following administration

6.4 GENERAL INFORMATION

6.4.1 General Description

ICG imaging agent is a sterile, water soluble tricarbocyanine dye with a peak spectral absorption at 800-810 nm in blood plasma or blood. Note that endogenous species have low light absorption in that range. ICG contains not more than 5.0% sodium iodide.

ICG is supplied as a sterile powder (25 mg / vial) with sterile water for injection (10 mL) to reconstitute the ICG powder. These components are for single patient use only.

Before injection of ICG for each patient's imaging procedure, ICG must be reconstituted using Sterile Water for Injection.

Optical properties of ICG are as follows:

- Maximum absorption wavelength in blood: approx. 806 nm
- Peak wavelength of fluorescence: approx. 830 nm

6.4.2 Supplies

1. Depending on the number of images to be acquired, one or two 25 mg vials of ICG and one or two 10 mL vials of Sterile Water for Injection should be sufficient for each patient's imaging procedure.
2. One or two 10 mL syringes for the preparation of ICG with sterile water.
3. 100 mL of sterile normal saline for injection.
4. Depending upon the number of images being performed, usually three to four 3 mL syringes and up to three 5 mL syringes are required. Ensure adequate quantities of 3 mL or 5 mL syringes must be available, based on the number of imaging sequences required during the procedure, i.e., one syringe prepared for each imaging sequence.
5. Each ICG injection must be followed immediately with a 10 mL sterile saline injection bolus, which requires an adequate number of 10 mL syringes to be pre-filled with sterile saline for injection in advance of the IC-Flow imaging procedure(s) and available at the time of each imaging sequence.
6. For the administration of ICG, use of a 3-way stopcocks is recommended, one to facilitate ICG delivery, the other to facilitate the immediate injection of the saline flush. A dedicated line is not required for ICG injection.

6. ICG Imaging Agent for the IC-Flow 2.0

6.4.3 Preparation for General ICG Administration

ICG imaging agent can be reconstituted and prepared for injection at the beginning of the procedure but must be used within six hours of preparation.

WARNING: Do not use any ICG that has been reconstituted for more than 6 hours.

Discard any unused reconstituted ICG after each procedure is completed.

Prepare ICG for administration as follows:

1. Remove one (1) 25 mg vial of ICG and one (1) 10 mL vial of Sterile Water for Injection from the kit.
2. Reconstitute ICG under sterile conditions.
3. Reconstitute ICG with sterile water per the indication and according to dosage in Section 6.4.4 below.
4. Shake the ICG vial gently to mix.

Note: This yields a 2.5 mg/mL solution of reconstituted ICG.

5. Mix the contents of the ICG vial thoroughly and inspect the reconstituted vial for precipitation. If precipitation is noted, continue to gently shake until all ICG is dissolved in solution. The reconstituted solution should be a clear, green solution.
6. Prior to the imaging procedure, withdraw the desired volume of ICG solution for each imaging sequence into separate 3 mL or 5 mL syringes.
7. With a single use 10 mL syringe, withdraw 10 mL of sterile saline, and place the prepared syringes in an accessible and sterile location for use at the time of imaging.
8. There should be either the same number of, or more, sterile saline syringes as the prepared ICG syringes for flushing the infusion line.

WARNING: If a precipitate exists, do not use the mixture. Discard the reconstituted vial and prepare a new vial, as described above.

WARNING: The total dose of ICG injected should be kept below 2 mg/kg of patient body weight. Prescribed dosages are at the medical discretion of the prescribing physician.

To ensure that the reconstituted solution is used within six hours from the time of reconstitution, it is recommended that the second vial of ICG be reconstituted only after the first reconstituted vial has been used up.

If necessary, repeat the steps above with a second sterile water and a second ICG vial, to ensure an adequate amount of reconstituted ICG is prepared for the imaging procedure.

6. ICG Imaging Agent for the IC-Flow 2.0

6.4.4 Dosage

See table below for recommended dosage per procedure.

Note: For each procedure, dosing may vary and is determined at the discretion of the imaging surgeon.

Recommended dosage Per Procedure for Indicated Uses with ICG Concentration of 2.5 mg/mL	
Procedure	**Dosage**
Blood Flow and Tissue Perfusion	
- Adult – Single Image sequence	1.25 mg to 5.0 mg (0.5 mL to 2.0 mL of a 2.5 mg/mL solution)
- Adult – visualization of perfusion in extremities through the skin	3.75 to 10 mg (1.5 – 4.0 mL of a 2.5 mg/mL solution).
- Pediatric age 1 month and older	1.25 mg to 5 mg
Assess Lymphatic flow in extremities	
- Recommended Dose	0.1 to 0.2 mL (2.5 mg/mL) subcutaneous into bilateral interdigit hand or foot

6.4.5 Intravenous Administration of ICG

1. Select the illumination and sensitivity settings on IC-Flow 2.0 for visualization.
2. Administer ICG via a central or peripheral venous line. Use a three-way stopcock attached to an injection port on the infusion line. Attach one prepared 3 mL syringe of ICG solution and one prepared 10 mL syringe of saline solution.
3. Inject the prepared 2.5 mg/mL ICG solution into the line as a tight bolus.
4. Immediately switch access on the stopcock to the syringe containing sterile saline and quickly flush the ICG bolus through the line with 10 mL of sterile saline.

6.4.6 Timing of ICG Administration

ICG injection should occur after the Camera Unit of the IC-Flow 2.0 device is positioned as to display the area to be observed on the Controller or monitor. To capture initial ingress, begin recording prior to injection the ICG.

Note: A fluorescence response time depends on the administration site.

6.4.7 Disposal of the ICG and Consumables

Discard any unused reconstituted ICG after the procedure is complete.

Prepared or partially used ICG should be disposed of in compliance with regulations for the disposal of such items.

6.4.8 Storage

The ICG vials and sterile water vials should be stored at ambient room temperatures of 20 °C to 25 °C (68 °F to 77 °F) or as listed in the ICG Instructions for Use.

7. Manufacturer

Manufacturer

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