

# IC-Flow™ Imaging System

**USER MANUAL  
& PRODUCT INFORMATION**

## About This Manual



**CAUTION:** Read this user manual carefully before working with IC-Flow Imaging System!

Failure to read this User Manual can endanger the lives of humans, machines and buildings. Keep this user manual as a reference.



**WARNING:** Important items of information, i.e. activities where operating personnel must proceed with extreme caution in order to avoid injury to themselves or the patient. These items of information are always shown in **BOLD**.



**CAUTION:** Items of information for which careful attention must be paid in order to avoid damage to the equipment or inaccurate data as well as operational errors. These items of information are always shown in **BOLD**.



**NOTES:** Provided notes enable optimal operation by the user.

All information in this manual is subject to change without notice.

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# A General Information

## 1. Intended Use

IC-Flow™ Imaging System is indicated to visualize on a screen the flow, the distribution and/or the accumulation of Indocyanine Green (ICG) before, during and after surgery for the indications such as:

- visualization of the blood flow,
- visualization of the lymphatic flow,
- visualization of the bile ducts during hepatobiliary surgery,
- visualization of primary liver tumors and/or hepatic metastases.

The IC-Flow Imaging System is used as an adjunctive method for the visual assessment.

### Intended Use:

The device is used by surgeons or trained health care professionals within a doctor's office environment and in hospital settings.

## 2. Operation

The IC-Flow Imaging System provides for visualization of the distribution and intensity of the fluorescent dye, Indocyanine Green for Injection (ICG) in human tissue.

The IC-Flow Imaging System is a medical infrared camera for viewing fluorescent images of ICG dye in the patient's body. It has a light source (excitation light) and camera for creating and viewing the ICG dye fluorescence.

The image data is displayed on the integrated touchscreen and/or on a connected monitor.

Pictures and videos are recorded using button controls located on the IC-Flow Camera and/or Controller. The light source intensity (illumination) and camera sensitivity can also be adjusted using controls on either the Camera or Controller. Image data may be stored in the IC-Flow Controller but can easily be transferred to a USB stick or an external memory device.

## 3. Safety Instructions



**CAUTION:** Read this user manual carefully before working with the IC-Flow™ Imaging System. Failure to read this User Manual can endanger the lives of humans, machines and buildings. Keep this User Manual as a reference.



### WARNINGS:

- European regulations require that this device be purchased only by a physician or person acting on behalf of a physician.
- **Training and Operation**

Training on use of the IC-Flow Imaging System is required for all users prior to operation. This device should only be used by qualified medical personnel who have been instructed on how to use it.

- **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 IC-Flow Camera in front of the patient's eyes. Shut the camera off or put it in standby mode if it is not being used.

- **Sterility and Patient Safety**

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

- **Electrical Safety:**

- Only connect the IC-Flow™ Imaging System with the supplied IC-Flow Power Unit (see B2.5). Any other power-supply unit can damage the device and cause an electrical shock or fire.
- This device 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 damage it, causing an electric shock or fire.

- **Avoid Mechanical Shocks**

If the device is visibly damaged, stop using it and send it to the manufacturer or your Diagnostic Green distributor for inspection.

- **Ambient and Storage Conditions for the IC-Flow™ Imaging System**

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



**CAUTIONS:**

- **Electrical Safety:**

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

- **Electromagnetic Compatibility**

Use this product as described in Appendix E4 to minimize risks related to the electromagnetic compatibility of this product with other products.

- **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 this device, make sure cables are not left in walkways or areas where they can tripped over and cause injury or damage to the cable.

- **If Irregularities Occur**

- If the image suddenly disappears, you notice an unusual sound or smell, or if smoke comes from this device, switch the device off using the main switch, pull the wall plug transformer from the socket, and contact your distributor.
- Never try to repair the device yourself, as there are no user serviceable components in the device.

- **Do Not Open**

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

- **Foreign Objects**

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

- **Avoid Mechanical Shocks**

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



## **NOTES:**

- **Read the ICG Dye Package Insert:**

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

- **Stored Pictures and Videos**

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

- **Overheating**

To prevent the Controller Unit from overheating, do not cover with a cloth, film or similar material.

- **IC-Flow Camera Cable**

- Check 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 this device to severe mechanical shocks, for example, by dropping it. This might damage the device. Inspect this device in the event that it falls or is dropped.
- **Avoid Electrostatic Discharge**
  - Use caution to prevent damage on device components from electrostatic discharge – i.e. avoid direct and indirect contact between metallic device components, carpets or other synthetic materials prone to electrostatic build-up.
  - Use of the IC-Flow potential equalization pin reduces the risk of electrostatic discharge.
- **Ambient and Storage Conditions for the IC-Flow Imaging System**
  - Protect the IC-Flow Imaging System from sunlight and heat! Do not cover any part of the device or fan.
  - Refer to the ambient conditions for storage and use as defined in Appendix E2.
  - Do not expose IC-Flow Imaging System to strong magnetic or electromagnetic fields. To prevent negative EMC impacts or situations, do not stack the device or place it nearby emitting devices.
  - Avoid vibrations.
  - Prevent contact with strong corrosive gases (such as chlorine or fluorine gases).
  - Protect from dust.
  - For a high-contrast image including the body contours, additional light with an infrared component is needed. Artificial ambient light sources exclusively based on LED's are insufficient.
- **Temperature Fluctuations**

Avoid great temperature fluctuations. If the device 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.
- **Cleaning and Disinfecting**

Follow the cleaning and disinfecting instructions (see section D1)  
This device cannot be sterilized.
- **Repairs and Service**

IC-Flow is a maintenance and calibration free device, as there are no user serviceable components in the device. Merely inspect visually on a regular basis (see D2). In the event of an error, read section D3 and try to solve the problem. Alternatively, contact your Diagnostic Green distributor or Diagnostic Green directly.

## B Installation

### 1. Unpackaging and Checking

Upon delivery, immediately check the IC-Flow™ Imaging System for completeness and possible damage. Immediately inform your Diagnostic Green distributor if you have any issue.

#### 1.1 IC-Flow Imaging System – Basic Equipment

- Controller (A)
- Power Unit (B)
- Camera Cable (C)
- Camera (D)
- Monitor Cable
- Quick Start Guide and User Manual

For additional optional accessories, contact Diagnostic Green directly.

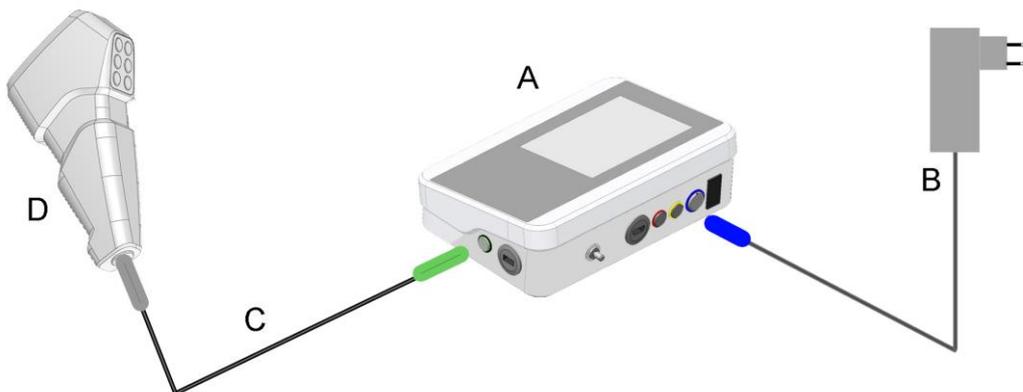
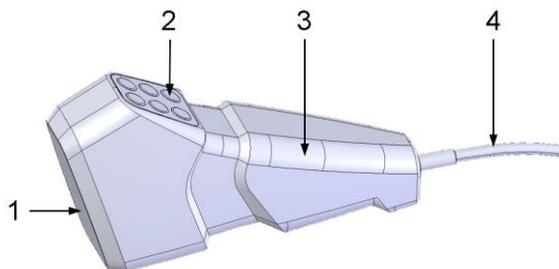


Figure 1: IC-Flow Imaging System Basic Equipment

## 2. Components

### 2.1 Design of the IC-Flow™ Camera



- 1 Camera lens**  
with lighting and lens
- 2 Operating panel**  
Membrane keypad
- 3 Grip**
- 4 Camera Cable**  
to connect to the controller unit

Figure 2: IC-Flow Camera

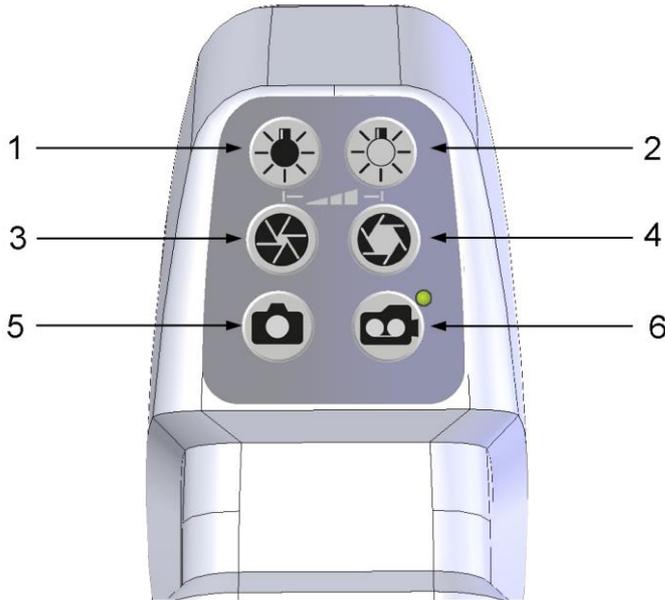


Figure 3: Camera Operating Panel

- 1. Less intensity**  
reduces the illumination level of the camera unit
- 2. More intensity**  
raises the illumination level of the camera unit
- 3. Less sensitivity**  
reduces the sensitivity of the camera
- 4. More sensitivity**  
heightens the sensitivity of the camera
- 5. Take picture**
- 6. Start/Stop video**

## 2.2 Design of the IC-Flow™ Controller

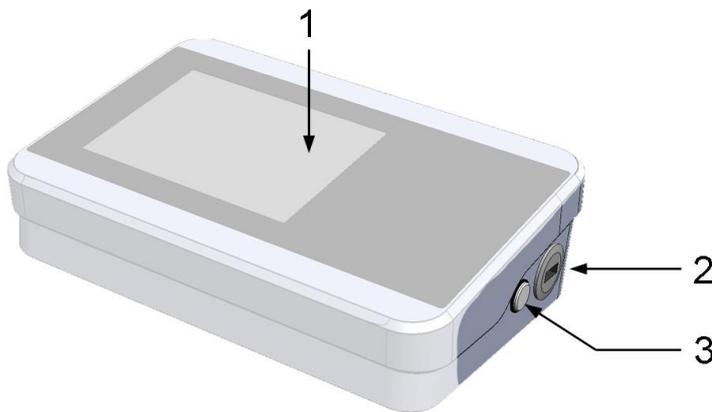


Figure 4: IC-Flow Controller Front Side

- 1. Touchscreen**  
operation of device
- 2. USB Connection**  
for exporting pictures and videos
- 3. Camera Connection Socket**  
green socket

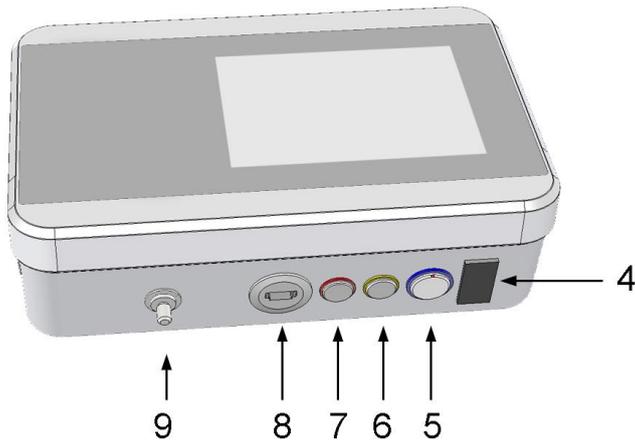


Figure 5: IC-Flow Controller Back Side

- 4. Main Switch Button**
- 5. 24V Power Cord Connection**  
blue socket
- 6. Optional Connection**  
yellow socket, for optional devices
- 7. Connection for Control of External USB300 Memory Unit**  
red socket
- 8. HDMI Connection**  
for monitor
- 9. Connection for Potential Equalization**

### 2.3 Design of the Touchscreen

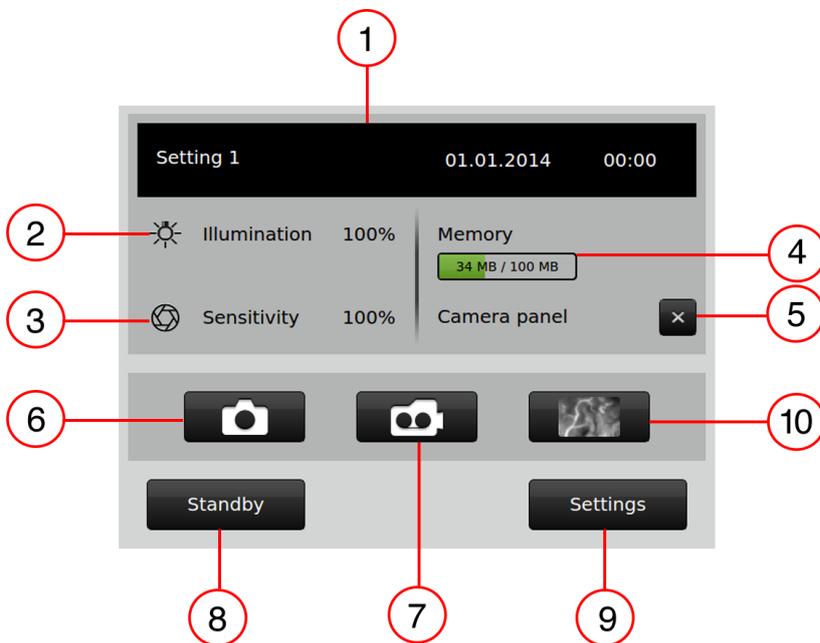


Figure 6: Main Screen

- 1. Settings, Date, Time**
- 2. Intensity of light source**  
between 0 and 100%
- 3. Sensitivity of camera**  
between 0 and 100%
- 4. Memory Used/Total Memory**
- 5. Operating panel of camera**



Figure 7: Video Screen Overlay

### 11. Deactivate Video Screen

Return to Main Screen

### 12. Image configuration

Setting sensitivity of the camera and illumination of fluorescence image

activated/  
deactivated

### 6. Take picture

activated/  
deactivated

### 7. Record video

activated/  
deactivated

### 8. Activate standby

camera unit,  
monitor, device  
unit standby

### 9. Set settings

### 10. Video Screen

Activate video  
output from the IC-  
Flow Camera to  
the Touchscreen

## 2.4 Connecting Cables and Monitor



**WARNING:** Make sure that the cables have no cracks, cuts or sharp kinks.



**CAUTION:** Cables other than specified can lead to negative EMC aspects.



**WARNING:** Never touch the plug contacts of the device and the patient at the same time as this can result in dangerous discharge currents.

The connection sockets of the IC-Flow™ Controller have the same colors as the plugs of the peripheral devices.

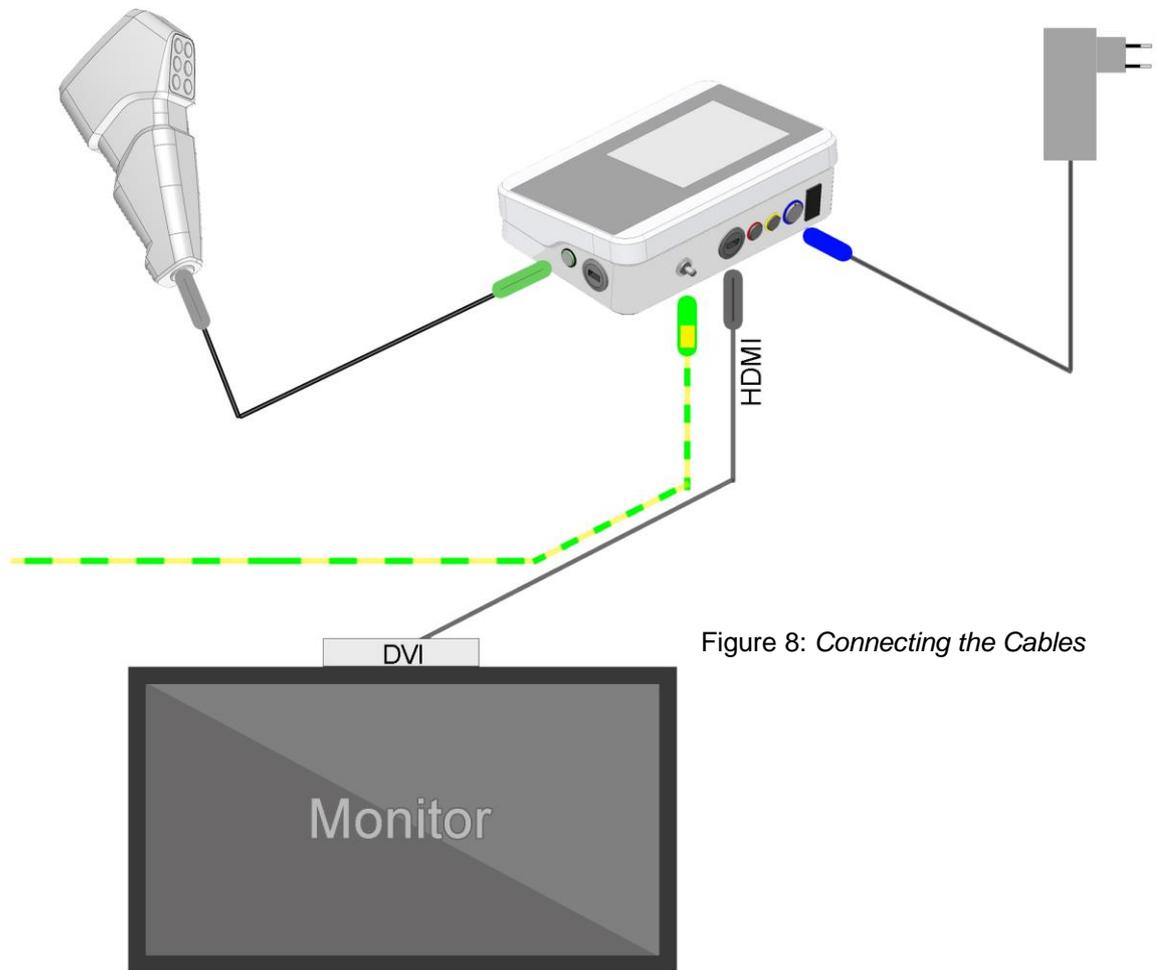


Figure 8: Connecting the Cables

1. Connect the green plug of the camera cable with the green socket.
2. Connect the gray plug of the camera cable with the camera unit.
3. Connect the blue plug of the power unit with the blue socket.
4. Connect the monitor cable with the HDMI socket



**WARNING:** Anyone connecting another monitor is configuring a system used for medical purposes and therefore responsible for compliance with the requirements of the EN 60601-1 system standard.

## 2.5 Selecting a Power Unit Adapter

The IC-Flow Imaging System is equipped with the IC-Flow Power Unit. Since there are different types of sockets, the power unit is provided with different adapters.

The adapter smoothly connects to the power unit and can be easily removed.

To switch adapters, push the adapter off of the power unit and connect another.



**WARNING:** Do not use force when switching adapters. This can cause mechanical damage and is electrically hazardous.



**WARNING:** Use the correct adapter for connecting to the wall socket. Use only the adapters 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.



Figure 9: IC-Flow Power Unit and adapters



Figure 10: Adapter E (British 3 Pin)



Figure 11: Adapter A (USA 2 Pin)



Figure 12: Adapter U (Europe 2 Pin)



Figure 13: Adapter S (Australia 2 Pin)

## 2.6 Connecting USB Storage Stick

You can save all pictures and videos on a USB stick.



**NOTE:** The USB stick must be formatted with FAT32



Figure 14: Connecting the USB Stick

1. Connect the USB stick to the device via the USB socket.
2. Wait until the device unit has installed the new data-storage device.
3. Data transfer is described in section C3 (Recording).



**NOTE:** For problems with the USB stick, see troubleshooting in section D3 and technical data on the USB stick in Appendix E2.

## C Usage

### 1. Switching On

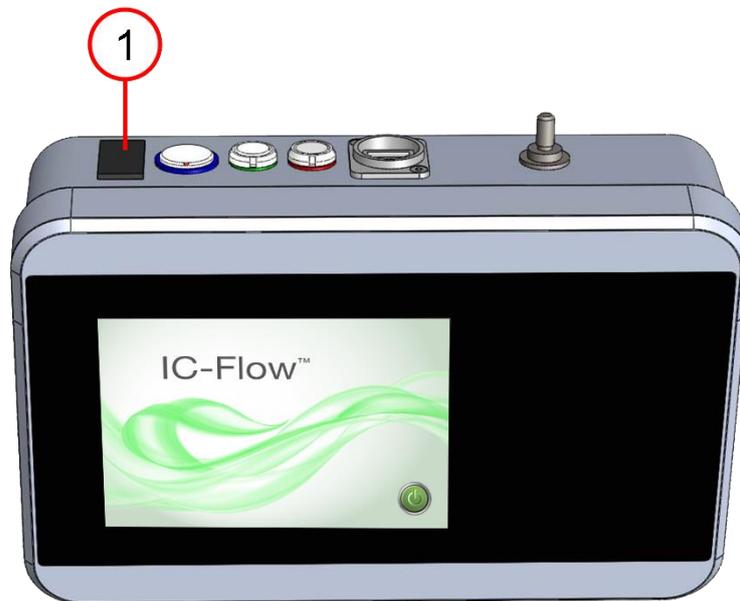
Make sure that all cables are connected (see B2.4).



**CAUTION:** Make sure that the cables have no cracks, cuts or sharp kinks.

The IC-Flow™ Camera Cable is typically subjected to mechanical stress during daily work. Check the Camera Cable before and after each use!

Switch on the IC-Flow Controller using the **Main Switch Button (1)**. An acoustical signal (beep) will follow. After booting, the standby screen will appear. (see Figure Figure ).



*Figure 15: Main Switch*

Press **Start Button (2)** on the touchscreen to start the device (see number 2, Figure ).



**NOTE:** The Start Button appears about 20-25 seconds after booting.



Figure 16: Standby

Next, the Main Menu appears on the touchscreen, and the device is operational (see Figure ).

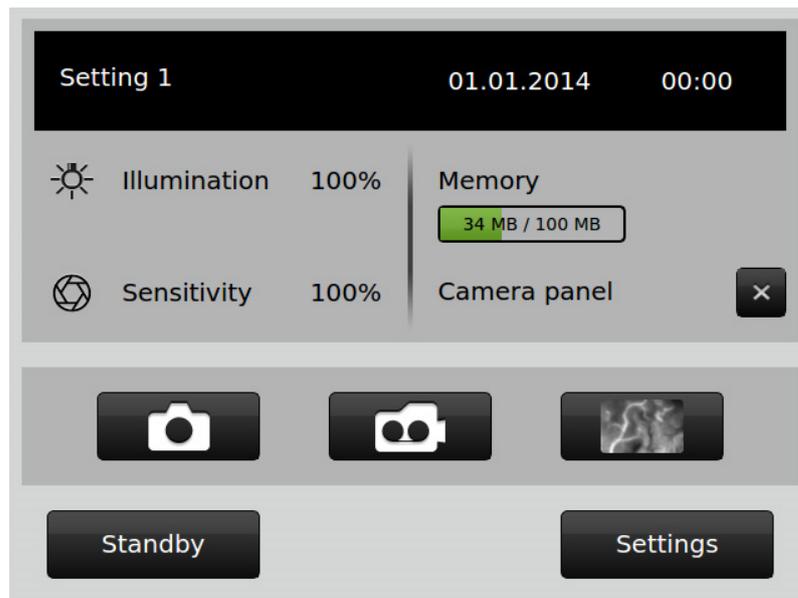


Figure 16: Main Screen

## 2. Image Configuration

Before the use of the IC-Flow please make sure that the ambient light in the room is suitably adjusted so that the body contours and fluorescence image can be visualized. If the room has windows, switch off the room lights and close the window blinds almost completely. If it is sunny outside, close the window blinds completely.



**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 visualization of fluorescence image.

In rooms without windows ensure that the ambient light is indirect. Switch off the operating lamp light and switch on the indirect room light including a near infrared light such as halogen lamps.

If the room light does not contain enough near infrared light such as LED light, the body contours might not be visible. In that case switch off the room light completely and position the switched on operating lamps away from the patient.

How to configure the image settings (sensitivity and illumination) manually is described in the following subsections.

## 2.1 Video Output on the Live screen

In order to activate video output from the IC-Flow™ Camera to the touchscreen, press the **Video Screen Button** (See number 1, Figure ) on the Main screen.

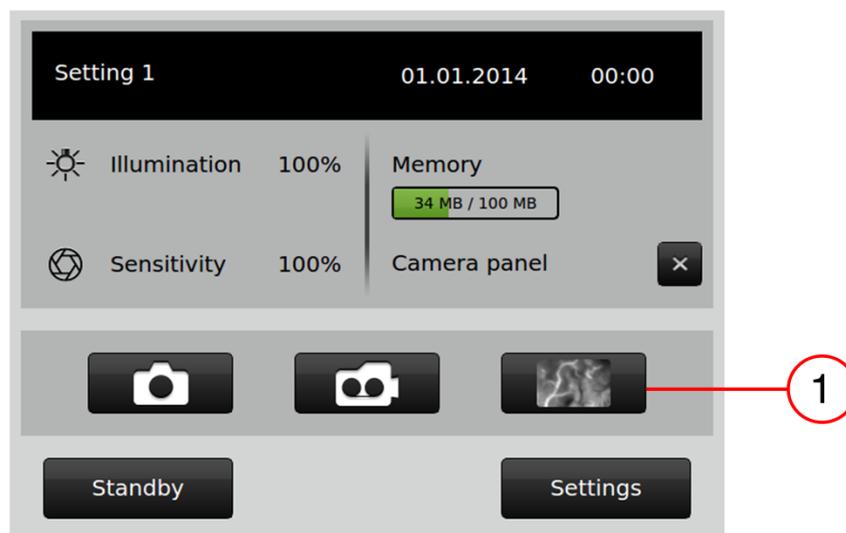


Figure 18: Video Screen Button on Main Screen



**NOTE:** If the IC-Flow is connected to a monitor, the video output from the IC-Flow Camera will be shown on the touchscreen and monitor simultaneously.

After the video output on the touchscreen has been activated, press anywhere on the touchscreen to make the Video Screen Menu appear. The Video Screen Menu will disappear within 3 seconds if no further buttons are pressed.

## 2.2 Image Configuration on the Touchscreen

Press the Settings button to get to the settings menu (see number 1, Figure ).

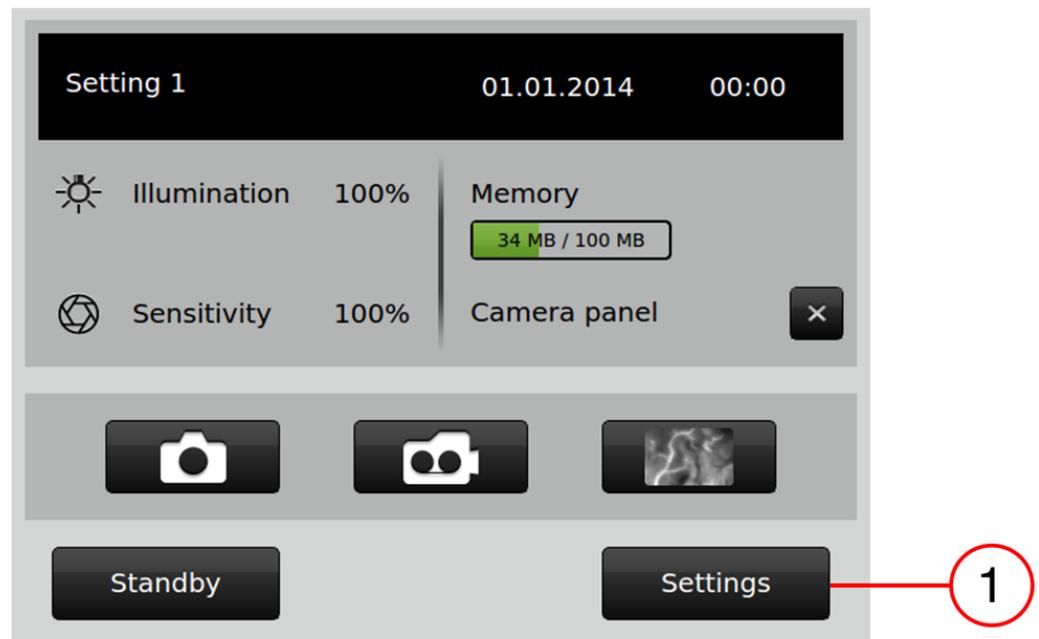


Figure 17: Change to Settings Screen from Main Screen

### 2.2.1 Setting Sensitivity

To increase image brightness - Move the sensitivity bar to the RIGHT (see number 1, yellow arrows, Figure ). To decrease image brightness - Move the sensitivity bar to the LEFT (see number 1, yellow arrows, Figure ).



**NOTE:** The settings for sensitivity and illumination can be changed in 1% steps via slider bars (see number 1 and 2, Figure ).



**NOTE:** The setting can be performed more accurately and easily by using a stylus.

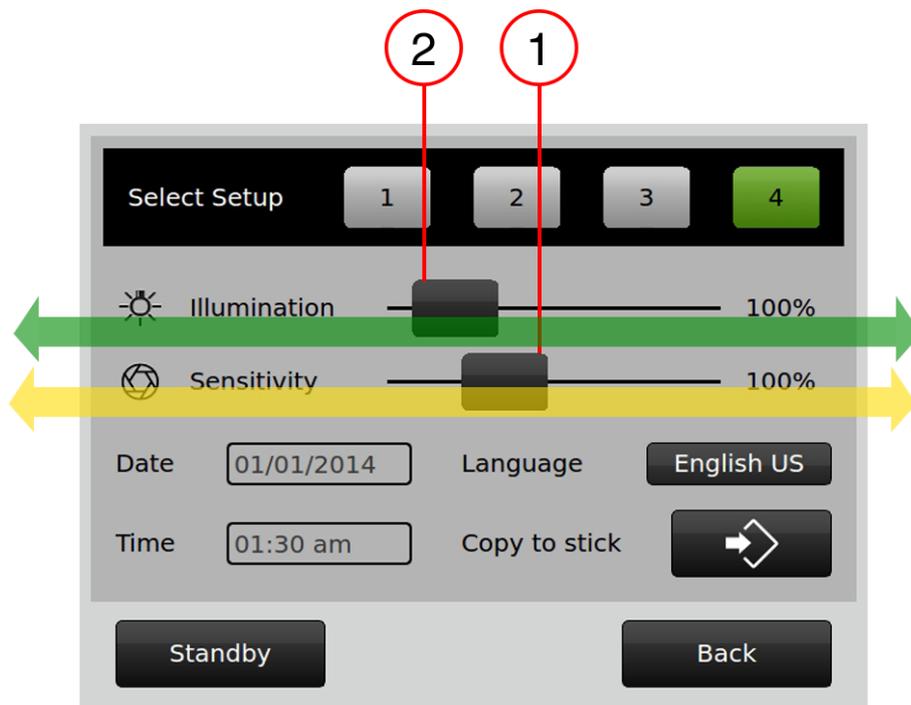


Figure 20: Image Configuration on Settings Screen

### 2.2.2 Setting Illumination of Fluorescent Image Parts

To **increase** the intensity of LED light source and the **illumination of the fluorescence in the image**, move the illumination bar to the **right** (see number 2, green arrows, Figure ). To **decrease** the intensity of LED light source and the **illumination of the fluorescence intensity** move the illumination bar to the **left** (see number 2, green arrows, Figure ).

### 2.2.3 Saving Image Configurations – Select Setup

Up to four different configurations of device settings can be saved. Via Select Setup, the different configurations from 1 to 4 can be selected (see number 1, Figure ).

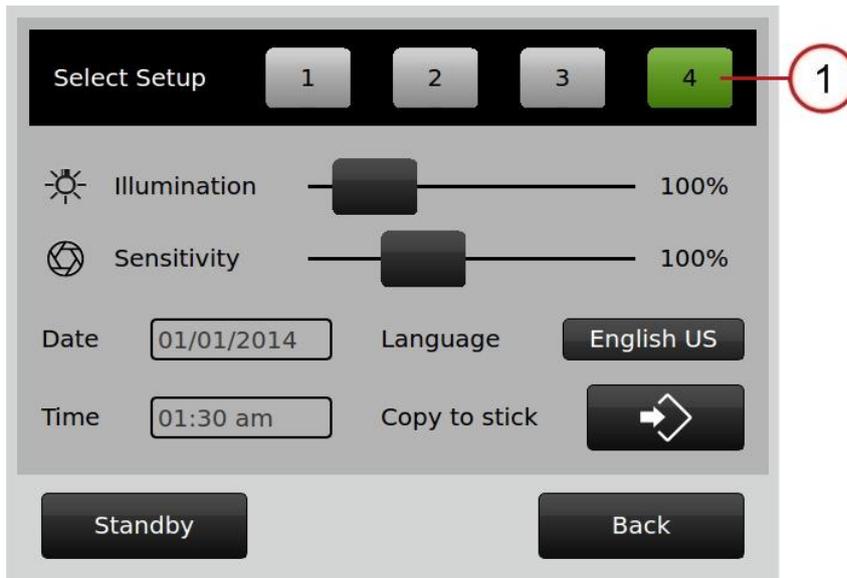


Figure 21: Select Setup

## 2.3 Image Configuration on the IC-Flow™ Camera

Alternatively, the image settings can be changed using the Camera. The operating panel of the camera must be enabled on the touchscreen to do so (see section 3.2)

### 2.3.1 Setting Sensitivity

To **decrease the image brightness**, press **button 1** (see number 1, Figure ).

To **increase the image brightness**, press **button 2** (see number 2, Figure ).

When a button is selected, the device emits a beep.

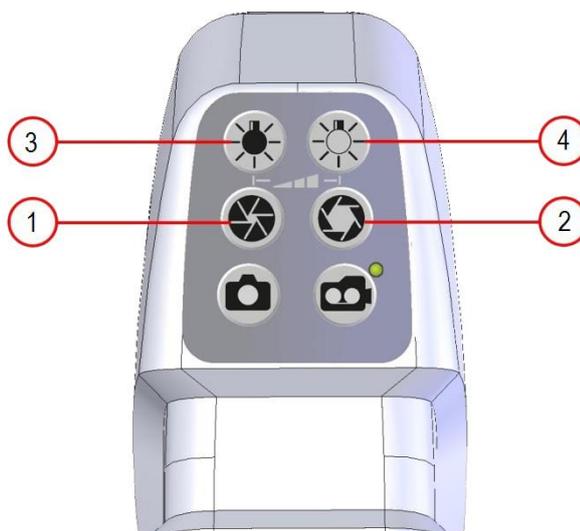


Figure 22: Image Configuration on the Camera Operating Panel



**NOTE:** The settings for sensitivity and illumination can be changed in 5% steps via camera operating panel

### 2.3.2 Setting Illumination of Fluorescent Image Parts

To **decrease** the intensity of LED light source and the **illumination of the fluorescence in the image**, press **button 3** (see number 3, Figure ).

To **increase** the intensity of LED light source and the **illumination of the fluorescence in the image**, press **button 4** (see number 4, Figure ).

When a button is selected, the device emits a beep.

## 2.4 Image Configuration on the Video Screen Menu

Press the buttons corresponding to the symbols in section 2.3, in order to configure the image on the Video Screen.

### 2.4.1 Setting Sensitivity

To **decrease** the image **Brightness**, press **button 3** (see number 3, Figure ).

To **increase** the image **Brightness**, press **button 4** (see number 4, Figure ).

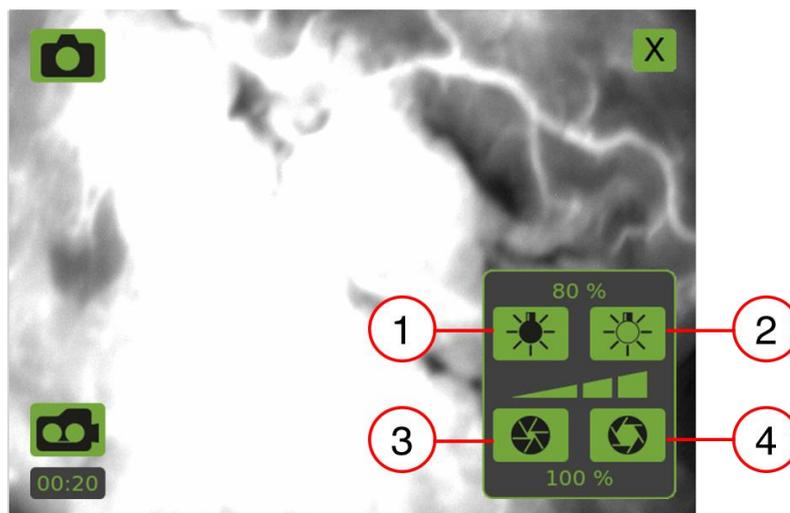


Figure 23: Video Screen Menu

## 2.4.2 Setting Illumination of Fluorescent Image Parts

To **decrease** the intensity of LED light source and the **illumination of the fluorescence in the image**, press **button 1** (see number 1, Figure ).

To **increase** the intensity of LED light source and the **illumination of the fluorescence in the image**, press **button 2** (see number 2, Figure ).

## 3. Recording

The fluorescent dye must be present in the patient in order to obtain images.



**CAUTION:** Follow the instructions in the package insert about the use of the fluorescent dye Indocyanine Green (ICG) to avoid endangering the patient's health.

Hold the IC-Flow™ Camera at a distance of approximately 18 cm (7.08 in) from the object. Note that the IC-Flow Imaging System only provides a high-contrast image, including body contours, if it is used with ambient light containing an infrared component.

There are different options for taking pictures or recording videos with the IC-Flow Imaging System.

- Using the IC-Flow Controller = see section 3.13.1 and 3.2
- Using the IC-Flow Camera = see section 3.3



**NOTE:** The recording of a video is limited to 20 minutes per file. An acoustic beep indicates that the video recording has been automatically stopped.

### 3.1 Using the Touchscreen

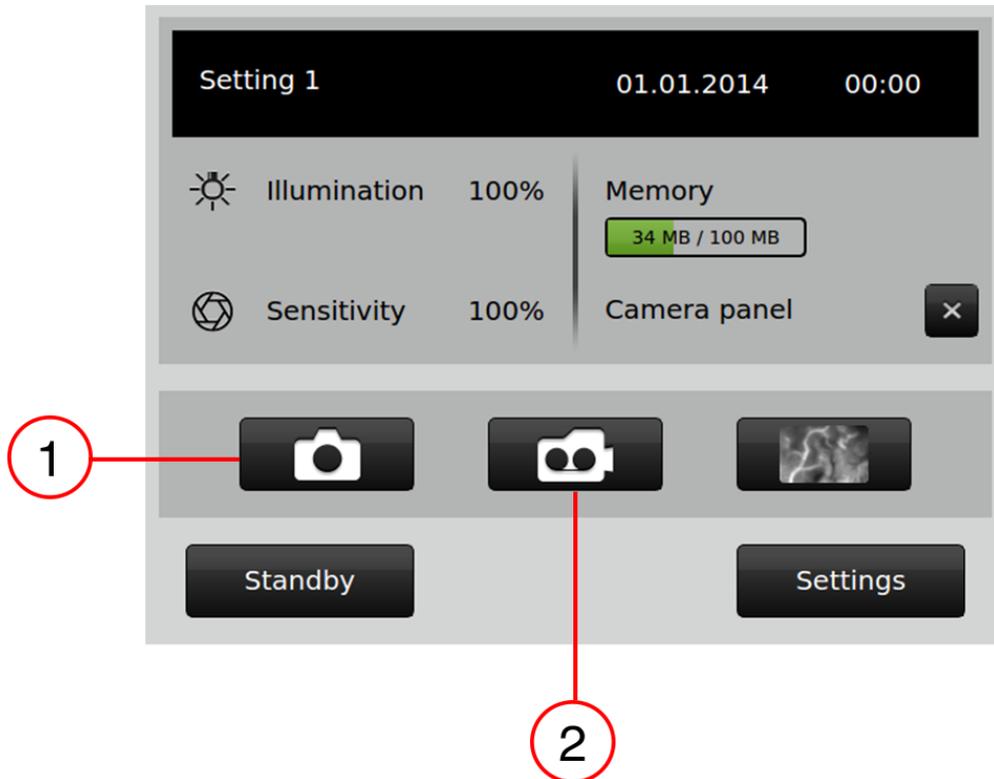


Figure 24: Triggering Pictures and Videos on Main Screen

#### 3.1.1 Taking a Picture

To take a picture, press the **camera symbol** (see number 1, Figure ). When taking a picture, an acoustical signal (a beep) sounds and the picture is frozen and highlighted by a bold green frame on the IC-Flow Monitor for a few seconds.

#### 3.1.2 Recording a Video

To record a video, press the **video symbol** (see number 2, Figure ). When recording a video, a beep sounds and the video recording time is shown in green on the IC-Flow Monitor for the duration of the recording.

When the video symbol is pressed again and the beep sounds, recording has ended. The green frame of the symbol and the recording time disappear.

## 3.2 Using the Video Screen



Figure 25: Using the Video Screen Menu

### 3.2.1 Taking a Picture

To take a picture press the camera symbol (see number 1, Figure ). When taking a picture, an acoustical signal (a beep) sounds and the picture is frozen and highlighted by a bold green frame for a few seconds.

### 3.2.2 Recording a Video

To record a video press the video button (see number 2, Figure ). When recording a video, a beep sounds and the video recording time is shown in green for the duration of the recording on the Video Screen. If a monitor is connected, the video recording time is also shown in green for the duration of the recording on the monitor.

When the video symbol is pressed again and the beep sounds, the recording has ended. The video recording time disappears.

### 3.3 Using the Camera Unit

The camera's operating panel can be enabled and disabled on the touchscreen's main menu (see number 1,

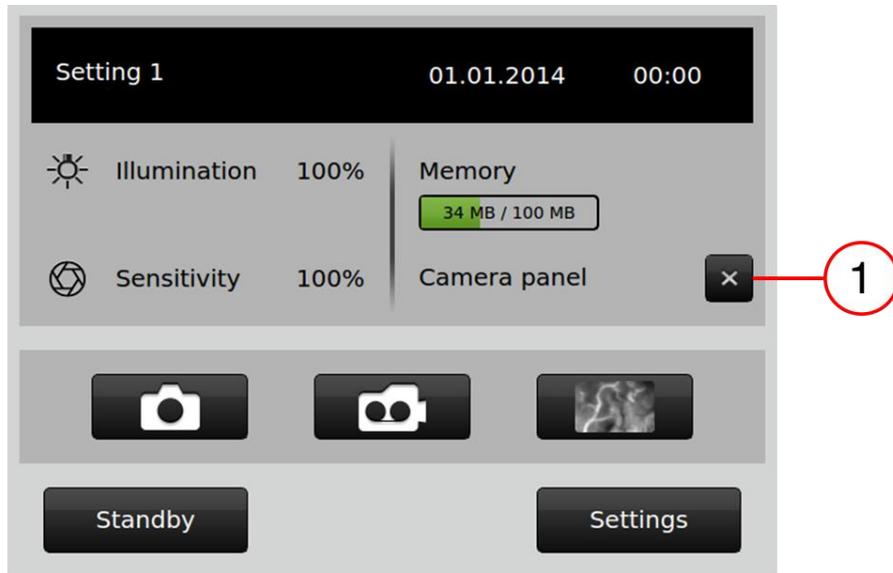


Figure )

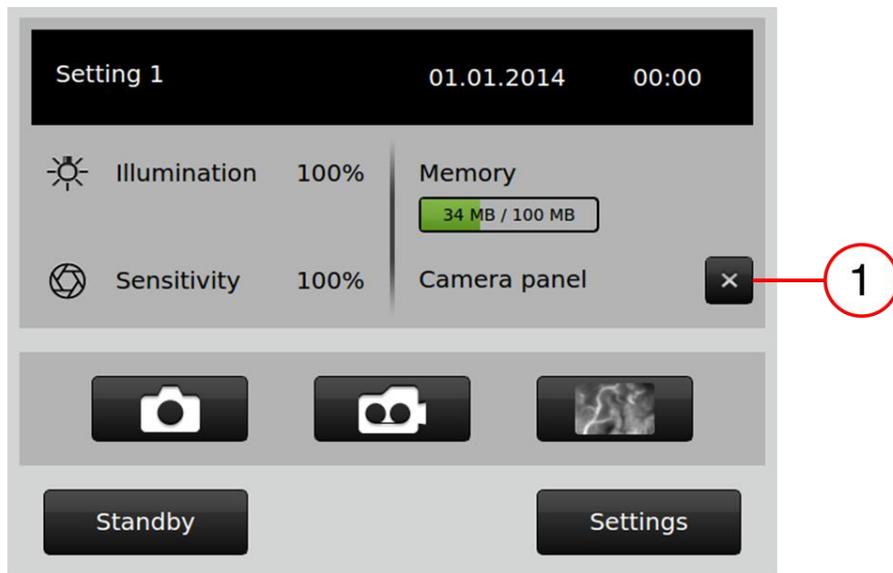


Figure ).

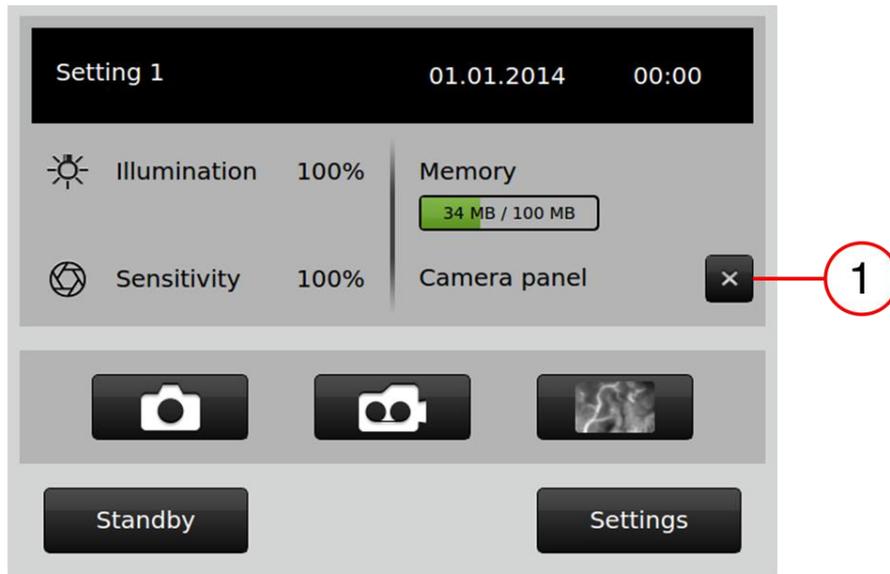


Figure 27: Activating the Camera Operating Panel

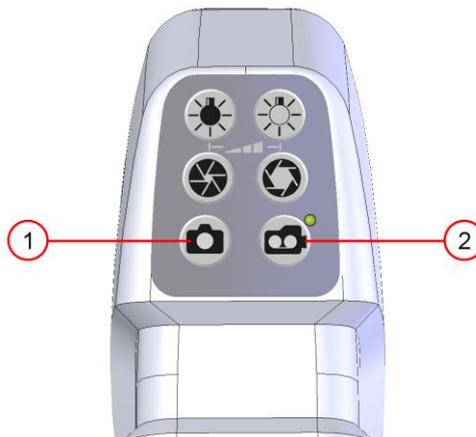


Figure 28: Triggering Pictures and Videos on the Camera Head

### 3.3.1 Taking a Picture

To take a picture press the camera symbol (see number 1, Figure ). When taking a picture, an acoustical signal (a beep) sounds and the picture is frozen and highlighted by a bold green frame for a few seconds.

### 3.3.2 Recording a Video

To record a video press the video button (see number 2, Figure ). When recording a video, a beep sounds and the light next to the video button on the camera unit turns green. For the duration of recording the frame of the video button on the touchscreen turns green and the recording time is shown in green on the monitor.

When the video symbol is pressed again and the beep sounds, the recording has ended. The video recording time disappears.

#### 4. Saving Records

To store pictures and videos on an external data storage device, connect a USB stick to the IC-Flow™ Controller.



**NOTE:** Consider the technical data on the USB stick in Appendix E2 Technical Data.



*Figure 29: Connecting the USB stick to the IC-Flow Controller*

The size of the used and available data of the device unit is shown in the main menu (see number 2, Figure ).

**Recordings** can be transferred by directly touching the Memory Bar on the Main Screen (see number 1, Figure ) or by activating the “Copy to Stick” button on the **Settings Screen** (see button 2, Figure and button 1, Figure31).

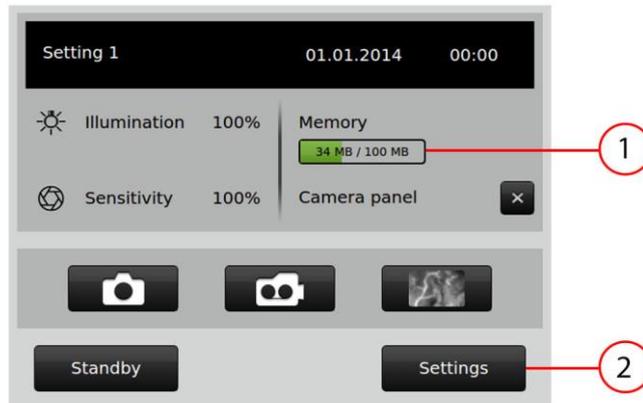


Figure 30: Copy to Stick by Touching the Memory Bar

**USB transfer** is performed by activating the “Copy to Stick” button in the **settings menu** (see button 2, Figure31).



Figure31: USB Transfer

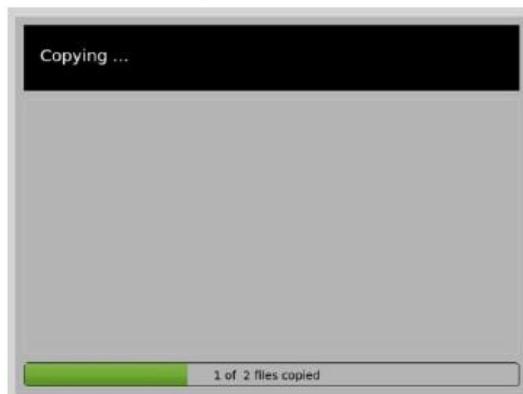


Figure 32: Data Transfer

**Copy Progress** is shown during the entire transfer (see Figure ).

After **successful transfer**, the device automatically goes back to the **settings menu**. The data files are automatically deleted from the IC-Flow Controller after being transferred to the USB stick.

#### 4.1 Error Messages Related to Data Transfer

Error messages might possibly appear during transfer.

| Error Message                                  | Measure   |
|--|---|
| Memory full!                                   | Replace the USB stick. Close the message and start the copying process again. |
| The device was unable to access the USB stick! | Connect another USB stick and start the copying process again.                |
| Connect the USB stick!                         | Check the connection of the USB stick.  |



**NOTE:** Read the technical data on the USB stick in Appendix E2 Technical Data. Consider the error descriptions in section D3.2

## 5. Other Settings

### 5.1 Language Settings

Select the desired language using the **Language button** in the **Settings menu** (see number 1, Figure33 and number 2, Figure ).



Figure33: Language Selection

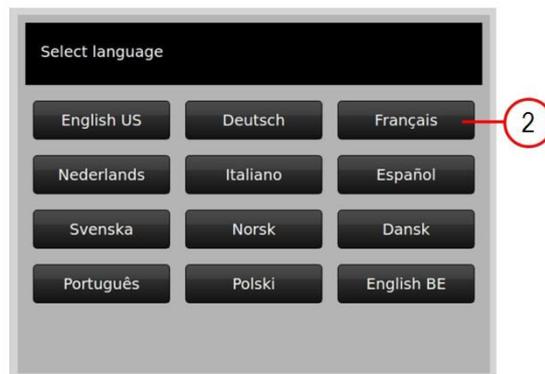


Figure 34: Languages

## 5.2 Set Date

Touch the screen where the date is shown.

A number-input field automatically opens for configuration.

After setting the current date, confirm your input with the enter key and the number-input field closes automatically.

## 5.3 Set Time

Touch the screen where the time is shown.

A number-input field automatically opens for configuration.

After setting the current time, confirm your input with the enter key and the number-input field closes automatically.

## 6. Standby

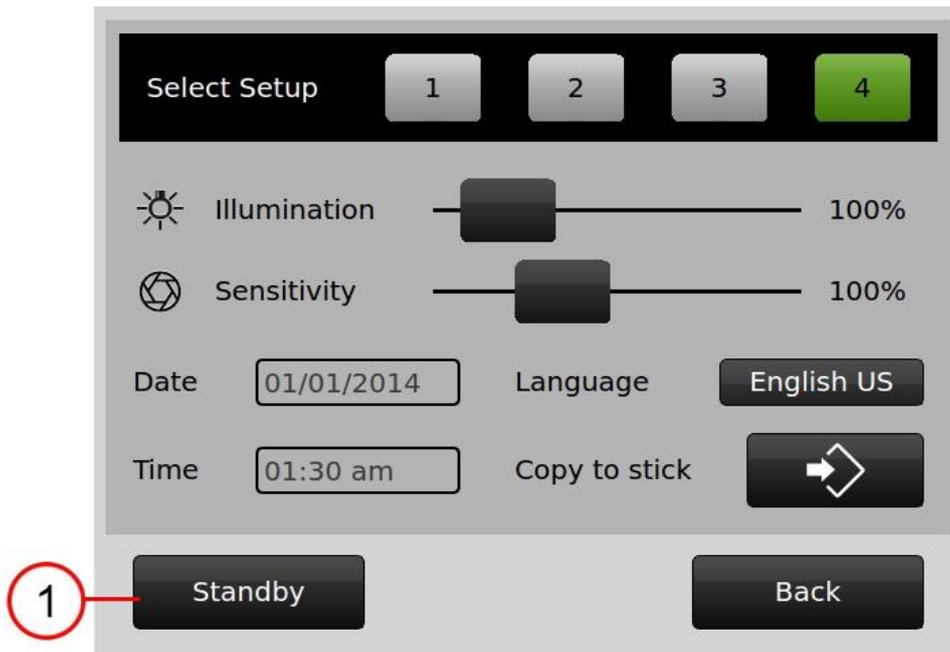


Figure 35: Standby Selection

If the device is not expected to be used for a short time, standby mode can be activated. To do so, press the **Standby button** (see number 1, Figure ).

The camera is switched off during standby. The standby image appears on the touchscreen (see Figure ).

To exit standby and return to operation mode, press the **Start button** (see button 2, Figure ).



Figure 36: Standby Screen

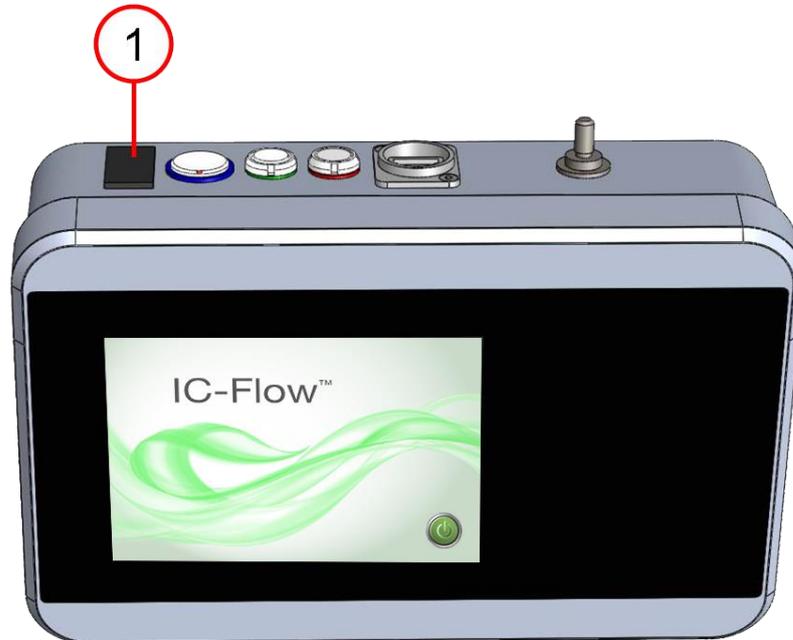


**NOTE:** This device switches to standby mode after a period of 20 minutes of inactivity.

## 7. Switching Off

Switch off the device using the **Main Switch** (see button 1, Figure 18).

The touchscreen display on the IC-Flow Controller will turn off, along with the Camera.



*Figure 18: Main Switch*

## D Maintenance & Service



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

### 1. Cleaning and Disinfecting

Only use the recommended and tested cleaning and disinfecting agents. Neither the device, nor its accessories can be sterilized.

Turn the device off and disconnect the cable connectors!

Prevent the inside of the device from getting wet!



**NOTE:** The camera front glass is made of perspex and is sensitive to chemical cleaning agents (ethanol, acetone, methanol, etc).

#### 1.1 Cleaning Agents

Use soft, non-scratching disposable cloths for cleaning the device. In particular, clean the camera front glass and touchscreen carefully to avoid scratches. It is best to use soft cloth material with a non-aggressive (caustic, corrosive, or abrasive cleaning agents) soap solution for the sensitive components (e.g. camera front glass, touchscreen).

#### 1.2 Disinfectants

Use soft, non-scratching disposable cloths for disinfecting the device. 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 usable for the materials used on the device. In case of unknown combinations, ask the manufacturer or your local distributor about using the correct disinfection agent.

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

### 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 Imaging System! Check the camera front glass for scratches and irregularities. Check all labels attached to the device for legibility. Replace them if necessary. Contact your Diagnostic Green distribution partner for new labels.

### 3. Troubleshooting

#### 3.1 Common Errors and Measures

| Error                      | Cause   | Solution   |
|----------------------------|---|--|
| Device does not react      | Cable incorrectly connected                           | Turn off the device. Check and re-connect all cables (see section B2.4).             |
|                            | Damaged cables  | Contact your Diagnostic Green distribution partner.                                  |
|                            | Device not switched on                                | Turn the device on (see section C1).   |
|                            | Software crash  | Turn the device off and restart it (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 off the device. Check and re-connect all cables (see section B2.4).             |
|                            | Damaged cables  | Contact your Diagnostic Green distribution partner.                                  |
| Picture too dark           | Sensitivity set too low                               | Increase sensitivity (see section C2) 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 C2) and/or decrease illumination intensity.        |
|                            | Ambient lighting too strong                           | Decrease ambient lighting.   |
| Fluorescent image too dark | Intensity too low                                     | Increase illumination intensity (see section C2) and/or increase sensitivity.        |
|                            | Device's light source damaged                         | Contact Diagnostic Green or your distribution partner authorized by Diagnostic Green |

|                                       |                                    |   |
|---------------------------------------|------------------------------------|---|
| Fluorescent image too bright          | Intensity too high                 | Decrease illumination intensity (see section C2) and/or decrease sensitivity. |
|                                       | Device's light source damaged      | Contact your Diagnostic Green distribution partner                            |
|                                       |                                    |   |
| Operation of camera unit not possible | Camera operating panel is disabled | Enable the camera unit operating panel (see section C3.3).                    |
|                                       | Cables incorrectly connected       | Turn the device off. Check and re-connect all cables (see section B2.4).      |

### 3.2 Error Messages

| Message   | Solution  |
|---|---|
| <i>Copy failed!</i>                                   | Check or replace the USB stick if necessary and repeat copying process.                                 |
| <i>The device was unable to access the USB stick!</i> | Check the USB stick's connection to the device unit, formatting and transfer format (see section B2.6). |
| <i>Connect USB stick</i>                              | Connect a USB stick to the device.  |
| <i>Memory full!</i>                                   | Replace the full USB stick.   |
|   |   |
| <i>Plug in camera and restart!</i>                    | Turn the device off. Connect the camera to the controller and restart the device.                       |

### 3.3 Other Malfunctions

For irregularities during operation, state condition during which error occurred. Contact your Diagnostic Green distribution partner with the details or contact Diagnostic Green directly:

Diagnostic Green GmbH  
 Otto-Hahn-Straße 20  
 85609 Aschheim-Dornach, Germany  
 Telephone: +49 (0) 89 1241 477 20  
 Fax: +49 (0) 89 1241 477 29  
 E-Mail: [info@diagnosticgreen.com](mailto:info@diagnosticgreen.com)

### **3.4 Repairs and Return Shipments**

Should you notice any irregularities, attempt to troubleshoot (see section 3) whether there is actually a defect. 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 here, contact your Diagnostic Green distribution partner or Diagnostic Green directly. Please have product information, serial number, and a detailed description of the problem ready at hand. As soon as we have identified the problem as a defect, we will decide whether to have the device returned to us for repairs.

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

Always switch off the device before cleaning or inspection measures.

### **3.5 Guarantee**

In observance of the described purposes and indications, and in compliance with the guidelines of the User Manual, Diagnostic Green guarantees the proper functioning of the IC-Flow™ Imaging System for the duration of the legal warranty period from the date of purchase. If the IC-Flow Imaging System is not used in accordance with the requirements 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 employees or persons authorized by Diagnostic Green.

Disposable products, accessories or components used with the IC-Flow™ Imaging System are not part of this warranty. Diagnostic Green is not obliged to repair or replace a damaged or defective IC-Flow Imaging System within the framework of this warranty if the damage or malfunction is caused by the operator when using products, accessories, or components that are not authorized by Diagnostic Green.

No further explicit or implicit warranties exist, for example, with regards to the marketability or suitability of the IC-Flow Imaging System for a specific purpose.

### **Disclaimer**

Diagnostic Green does not assume any liability if the device 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. Disposal



**NOTE:** The owner of this device is responsible for the safe and environmentally conforming disposal of the system after its service.

The IC-Flow™ Imaging System 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 device 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.

As an extra safety precaution, we recommend contacting your local waste collection service or competent authorities in order to be properly informed about the disposal of this device.

Alternatively, the disposal of this device can be arranged by Diagnostic Green upon request. If disposing of this device yourself, please ensure environmental compliance.

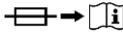
Please make sure this device is disinfected according to the hygiene guidance of your practice/hospital and national hospital guidelines.

### **Disposal of consumables/accessories/waste:**

Please follow your practice's/hospital's guidelines regarding hygiene and the national guidelines regarding the disposal of contaminated consumables and waste.

# E Appendix

## 1. Symbols

| Symbol  | Description   |
|---|---|
|    | Part number   |
|    | Name and address of the manufacturer  |
|    | Date manufactured (year/month)  |
|    | Serial number   |
|    | CE mark   |
|    | Do not dispose of in household garbage. Separate disposal of old electrical devices |
|    | direct current  |
|  | Refer to the user manual  |
|  | Refer to the user manual  |
|  | Potential equalization  |
| Type:   | Characterization of the component   |
|  | Fuse specifications: Refer to the user manual                                       |
| STILL   | Connecting point for image transfer   |
| MOTION  | Connecting point for video transfer   |
|  | Authorized Representative in the European community                                 |
|  | Humidity limitation   |
|  | Pressure limitation   |

| Symbol  | Description  |
|---|--|
|    | Temperature limitation                                     |
|    | Caution symbol   |
|    | Warning symbol   |
|    | Note symbol  |
|    | Keep dry   |
|    | Keep away from sunlight                                    |
|   | Do not use if sterile package is damage                    |
| <b>STERILE</b>   <b>EO</b>  | Sterilized Using Ethylene Oxide                            |
|  | Do Not Re-Use  |
|  | Transportation is only allowed with folded and locked arm. |

## 2. Technical Data

| Classifications in accordance with IEC 60601-1 |                                   |
|--|-----------------------------------|
| Electrical protection class                    | II                                |
| IP   | 20                                |
| Sterility                                      | non-sterile, cannot be sterilized |
| Use in oxygen-rich environment                 | not usable                        |
| Operating mode                                 | Continuous operation              |

|                                |  |
|--------------------------------|--|
| Essential Performance          | The device is used as a fluorescence visualization device, and has no essential performance.                               |
| <b>Electrical Connection</b>   |  |
| 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              | 63-94 VA   |
| Electric fuses                 | FUSE T 5A, L 125V  |
| <b>Operation and Display</b>   |  |
| Touchpad on device unit        | 5.7", color  |
| Membrane keypad on camera unit | Can be wiped clean with the cleaning agents mentioned.   |
| Monitor output on device unit  | HDMI 2.3   |
| Working distance               | 15-20cm, optimum at 18cm (highest sharpness)   |
| Image field of view            | About 80 x 105 mm (at 200mm distance)  |
| <b>Memory</b>                  |  |
| Internal image memory          | Approximately 800 MB   |
| USB stick                      | USB 2.0, FAT32 file system<br>Socket on the right side of the Controller   |
| <b>Image Data</b>              |  |
| Formats                        | Pictures: JPEG<br>Videos: MPEG1  |
| Image size for pictures        | 640 x 480 pixels   |
| Image size for videos          | 640 x 480 pixels   |
| <b>Operating Conditions</b>    |  |
| Operating temperature          | +10°C to +30°C (+50°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<br>LED lighting without a component of IR light is not suitable. |
| <b>Storage Conditions</b>      |  |
| Storage temperature            | 5°C to +40°C (+41°F to +104°F)   |
| Storage humidity               | 20 % to 70 % (non-condensing)  |
| Storage air pressure           | 700 hPa to 1060 hPA (2.248 psi to 15.374 psi)  |

| <b>Transportation Conditions</b>                                  |   |
|---|---|
| Transportation temperature  | -20°C to +50°C (-4°F to +122°F)   |
| Transportation humidity   | 20 % to 70 % (non-condensing)   |
| Transportation air pressure                                       | 700 hPa to 1060 hPa (2.248 psi to 15.374 psi)   |
| <b>Dimensions and Weight</b>                                      |   |
| Camera unit   | Metal housing<br>54 mm x 164 mm x 134 mm (2.126 in x 6.457 in x 5.276 in) (width x depth x height)<br>Weight: 0.66 kg (1 lb 7.3 oz) (without cable)<br>Cable length: about 5 m (5.5 yd) |
| Device unit   | Metal housing<br>Touchscreen<br>240 mm x 161 mm x 75 mm (9.45 in x 6.3 in x 2.95 in) (width x depth x height)<br>Weight: 2 kg (4 lb 6 oz) (without cable or accessories)                |
| <b>Optics</b>   |   |
| Radiation class<br>in accordance with IEC 62471 and<br>2006/25/EU | Continuous wave lamp (CW)<br>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  |

### 3. Applied Standards

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

### 4. Electromagnetic Compatibility

Table 201 – Guidance and manufacturer’s declaration – electromagnetic emissions  
(EN 60601-1-2; 6.8.3.201 a, 3)

### Guidance and manufacturer's declaration – electromagnetic emissions

The IC-Flow System PC6200 is intended for use in the electromagnetic environment specified below. The customer or the user of the IC-Flow System PC6200 should assure that it is used in such an environment.

| Emissions test  | Compliance         | Electromagnetic environment – guidance  |
|---|--------------------|---|
| RF emissions<br>CISPR 11                                | Group 1<br>Class A | The IC-Flow System PC6200 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<br>CISPR 11                                | Group 1<br>Class A | The IC-Flow System PC6200 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions<br>IEC 61000-3-2                     | Class A            |   |
| Voltage fluctuations/flicker emissions<br>IEC 61000-3-3 | Complies           |   |



**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 PC6200 or shielding the location.

Table 202 – Guidance and manufacturer’s declaration – electromagnetic immunity  
(EN 60601-1-2; 6.8.3.201 a, 6)

| <b>Guidance and manufacturer’s declaration – electromagnetic immunity</b>  |  |  |  |
|--|--|--|--|
| The IC-Flow System PC6200 is intended for use in the electromagnetic environment specified below. The customer or the user of the IC-Flow Imaging System should assure that it is used in such an environment. |  |  |  |
| <b>Immunity test</b>   | <b>IEC 60601 test level</b>                                    | <b>Compliance level</b>  | <b>Electromagnetic environment – guidance</b>  |
| Electrostatic discharge (ESD)<br>IEC 61000-4-2   | ± 8 kV contact discharge<br>± 15 kV air discharge              | ± 8 kV contact discharge<br>± 15 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<br>IEC 61000-4-4   | ± 2 kV for power supply lines<br>± 1 kV for input/output lines | ± 2 kV for power supply lines<br>± 1 kV for input/output lines | Mains power quality should be that of a typical commercial or hospital environment.  |
| Surge<br>IEC 61000-4-5   | ± 1 kV differential mode voltage<br>± 2 kV common mode voltage | ± 1 kV differential mode voltage<br>± 2 kV common mode voltage | Mains power quality should be that of a typical commercial or hospital environment.  |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br>IEC 61000-4-11   | < 5% $U_T$<br>(>95 % dip in $U_T$ ) for 0,5 cycle              | < 5% $U_T$<br>(>95 % dip in $U_T$ ) for 0,5 cycle              | Mains power quality should be that of a typical commercial or hospital environment. If the user of the IC-Flow Imaging System requires continued Operation during power mains interruptions, it is recommended that the IC-Flow Imaging System be powered from an uninterruptible power supply or a battery. |
|  | 40% $U_T$<br>(60 % dip in $U_T$ ) for 5 cycles                 | 40% $U_T$<br>(60 % dip in $U_T$ ) for 5 cycles                 |  |
|  | 70% $U_T$<br>(30 % dip in $U_T$ ) for 25 cycles                | 70% $U_T$<br>(30 % dip in $U_T$ ) for 25 cycles                |  |
|  | < 5% $U_T$<br>(> 95% dip in $U_T$ ) for 5 s                    | < 5% $U_T$<br>(> 95% dip in $U_T$ ) for 5 s                    |  |
| Power frequency (50/60 Hz) magnetic field<br>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:**  $U_T$  is the A.C. mains voltage prior to application of the test level.

Table 204 – Guidance and manufacturer’s declaration – electromagnetic immunity (EN 60601-1-2; 6.8.3.201, b)

| <b>Guidance and manufacturer’s declaration – electromagnetic immunity</b>   |  |   |  |
|---|--|---|--|
| <p>The IC-Flow™ Imaging System is intended for use in the electromagnetic environment specified below. The customer or the user of the IC-Flow Imaging System should assure that it is used in such an environment.</p> |  |   |  |
| Immunity test   | IEC 60601 test level                           | Compliance level  | Electromagnetic environment – guidance   |
| <p>Conducted RF<br/>IEC 61000-4-6</p>   | <p>3 V<sub>eff</sub><br/>150 kHz to 80 MHz</p> | <p>3 V<sub>eff</sub></p>  | <p>Portable and mobile RF communications equipment should be used no closer to any part of IC-Flow Imaging System PC6200, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p><b>Recommended separation distance:</b><br/> <math>d = 1.17 1/V * \sqrt{P}</math><br/> <math>d = 1.17 m/V * \sqrt{P}</math> for 80 MHz to 800 MHz</p> <hr/> <p><math>d = 2,33 m/V * \sqrt{P}</math> for 800 MHz to 2,5 GHz where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in meters (m).</p> <p>Field strength from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range <sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>  |
| <p>Radiated RF<br/>IEC 61000-4-3</p>  | <p>3 V/m<br/>80 MHz to 2.5 GHz</p>             | <p>3 V/m</p>  |  |
| <p>a</p>  |  | <p>Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the</p> |  |

measured field strength in the location in which the IC-Flow System PC6200 is used exceeds the applicable RF compliance level above, the IC-Flow System PC6200 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 PC6200.

B Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.



**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.

Table 206 – Recommended separation distances between portable and mobile RF communications equipment and the IC-Flow™ Imaging System (EN 60601-1-2; 6.8.3.201 b)

**Recommended separation distances between portable and mobile RF communications equipment and the IC-Flow System PC6200**

The IC-Flow System PC6200 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 PC6200 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the IC-Flow System PC6200 as recommended below, according to the maximum output power of the communications equipment.

| Rated maximum output power of transmitter<br>W | Separation distance according to frequency of transmitter<br>m |  |   |
|--|--|--|---|
|  | 150 kHz to 80 MHz<br>$d = 1.17 \text{ 1/V} * \sqrt{P}$         | 80 MHz to 800 MHz<br>$d = 1.17 \text{ m/V} * \sqrt{P}$ | 800 MHz to 2.5 GHz<br>$d = 2.33 \text{ m/V} * \sqrt{P}$ |
| 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 higher frequency range applies.

**NOTE 2:** 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 Imaging System is subject to specific precautions concerning EMC (Electromagnetic compatibility) and is only allowed to be installed and used according to the EMC advice contained in this User Manual.

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

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

## 5. Declaration of Conformity

- Declaration of Conformity for devices in accordance with the Medical Device Directive 93/42/EEG
- 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

## 6. List of System Components | Non-Disposable

| PRODUCT              | REFERENCE No. | DESCRIPTION   |
|----------------------|---------------|---|
| IC-Flow Controller   | PC6201        | Unit comprised of touchscreen monitor, storage for data collection, and controls for settings adjustments |
| IC-Flow Power Unit   | PC6203        | Approved power supply unit for connection to the IC-Flow Imaging System. See section B2.5                 |
| IC-Flow Camera       | PC6202        | Comprised of a LED light source and camera for viewing Indocyanine Green (ICG)                            |
| IC-Flow Camera Cable | PC6204        | Cable that connects the Camera to the Controller Unit. See section B2.4                                   |

|                       |        |   |
|-----------------------|--------|---|
| IC-Flow Monitor       | PC6224 | Medical grade monitor. See section B2.4                     |
| IC-Flow Monitor Cable | PC6205 | Cable that connects Controller Unit to Monitor.<br>See B2.4 |



## Manufacturer

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