Diagnostic Green

IC-Flow™ Imaging System

INSTRUCTIONS FOR USE (IFU)

Instructions for Use

Intended Purpose

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.

1.1 Intended Use:

The IC-Flow Imaging System is used by surgeons or trained health care professionals within a doctor's office environment and in hospital settings.

1.2 Claims

Applications which shall be possible with IC-Flow Imaging System are:

- Sentinel Lymph Node (SLN) detection and navigation
- Lymphedema evaluation
- Burn diagnostics and assessment of perfusion of wounds
- Plastic, reconstructive and abdominal surgery
- Diabetic foot evaluation

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 in the patient's body. It has a light source (excitation light) and camera for creating and viewing the ICG 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 alternative external memory device.

3. Safety Instructions

CAUTION: Read the quick start and online user manual carefully before working with the IC-Flow Imaging System. Failure to read these 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 when 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. 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 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 **Error! Reference source not found.** of the User Manual 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 /Verdye Package Insert:**

  Carefully read the ICG package insert for information regarding indications, contraindications and side effects.
- **Stored Pictures and Videos**

  The stored pictures and videos found on the IC-Flow 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).
- **Connecting IC-Flow Monitor**
  - The Monitor must comply with the EN 60601-1 standard.
  - Anyone connecting other devices to the video signal input or output of this device is configuring a system used for medical purposes and is therefore responsible for compliance with the requirements of the system standard for medical products.
- **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**
  - Store at ambient conditions and protect the IC-Flow Imaging System from sunlight and heat. Do not cover any part of the device or fan.
  - 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**
  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 as outlined in the User Manual, this device cannot be sterilized.
- **Repairs and Service**
  The IC-Flow Imaging System is a maintenance and calibration free device, as there are no user serviceable components in the device. Merely inspect visually on a regular basis. In the event of an error, refer to the online user manual and try to solve the problem. Alternatively, contact your Diagnostic Green distributor or Diagnostic Green directly.

Please visit https://diagnosticgreen.com/row/ic-flow-imaging-system-lp/resources to access the detailed online user manual and troubleshooting guide.

4. Malfunctions

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

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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.

All information in this Instruction for Use is subject to change without notice.