

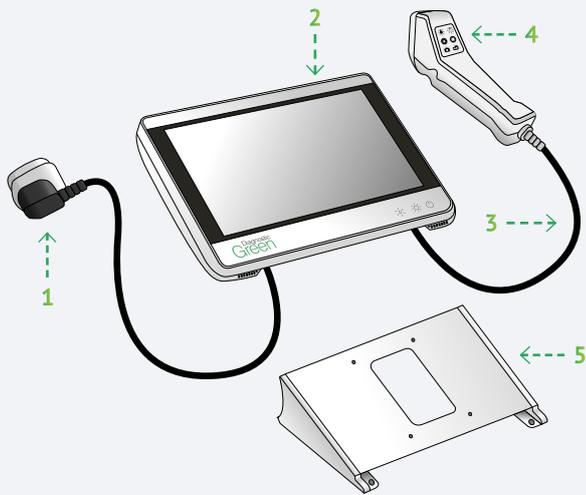
Diagnostic
Green

IC-Flow™ Imaging System: Quick Reference Guide



www.diagnosticgreen.com

Key Device Components



IC-Flow Controller

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

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

A. SWITCH ON

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



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

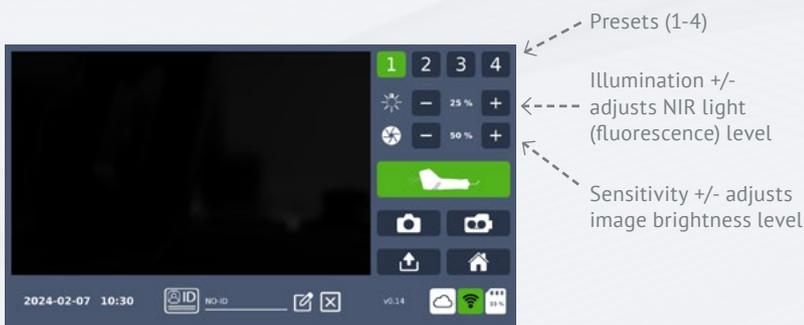
Select start on the Standby Screen to enter the Home Screen.



The Camera is ready for use (highlighted green) in the Home Screen.

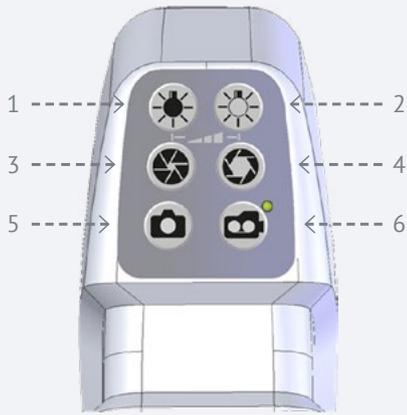


B. VIEW/ADJUST PRESETS



Select Preset buttons to view associated illumination and sensitivity settings.

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



Alternatively, settings can be adjusted on Camera.

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

C. ADMINISTER ICG (VERDYE)

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

D. CAPTURE IMAGE/RECORD VIDEO

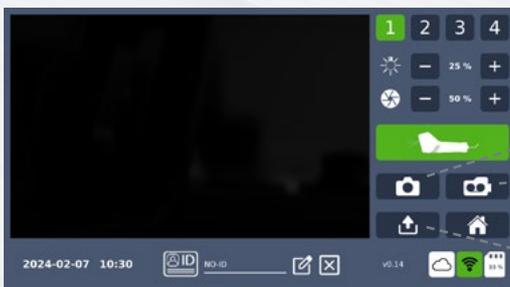
Hold the Camera between 15-20 cm above tissue/organ of interest.



Adjust settings to ensure high contrast image capture.



E. CAPTURE IMAGES/VIDEOS



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

View 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

Filter data

Icon	Display	Action
<p>Multiple data view</p>		<p>Arranges multiple recorded images/videos by Patient ID</p>
<p>Individual data view</p>		<p>Permits individual Patient ID view of images/videos*</p>

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

F. TRANSFER DATA

Transfer data (USB)

- Insert USB (Controller port located underneath).
Note: Ensure USB is formatted FAT32
- Select Transfer or turn Camera off.
- Press and hold image/video for two seconds (green outline appears).
Note: All images can be transferred by selecting the checkbox beside the photo or video icon.

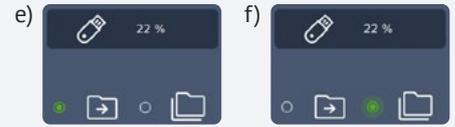


- Select JPEG/MPEG or DICOM button.



Options:

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



- Select the USB button.



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

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

patient id_YYYYMMDD_HHMMSS.

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

Transfer data (Cloud)

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.
- Choose Cloud Drive provider.
- Use keyboard to create User ID, select accept.
Note: User ID required when there are multiple device users. This ensures each users captured data is protected.



- Sign in to selected drive.

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



- Create password for User's account

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



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



- Close screen to return to Home or Transfer Screens.



- Cloud and Wi-Fi icons change to green.

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



- Select Transfer Screen or turn Camera off.



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

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



- Select JPEG/MPEG/DICOM.



Options:

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



OR

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



- Select IC-Flow user ID Cloud button.



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

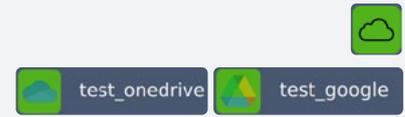
Images/videos are saved in an IC-Flow folder on the Cloud Drive.

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

patient id_YYYYMMDD_HHMMSS.

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

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



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



G. DELETE DATA

- Select Transfer Screen or turn Camera off.



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



- Select Delete, repeat to confirm deletion.



H. SWITCH OFF

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



IC-FLOW™ IMAGING SYSTEM REGISTRATION & DISTRIBUTION

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



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

IC-Flow™ Imaging System Intended Use

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

IC-Flow Imaging System is indicated to visualise 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: visualisation of the blood flow; visualisation of the lymphatic flow; visualisation of the bile ducts during hepatobiliary surgery; visualisation of primary liver tumors and/or hepatic metastases.

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