



Diagnostic  
**Green**

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**ICG Diagnostic Product &  
IC-Flow™ Imaging System**  
Overview

# Company Vision and Strategy

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The Diagnostic Green company is the leading provider of trusted high quality fluorescence products for physicians worldwide.

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## Our Vision

*Diagnostic Green was established to provide high quality fluorescence imaging products to physicians worldwide. Our vision is to ensure that fluorescence imaging becomes the standard in tissue visualization worldwide, to help improve clinician outcomes, minimize procedure complications and thereby reduce overall healthcare costs.*

***We aspire to maintain our global leadership in the manufacture and distribution of ICG Diagnostic Products with guaranteed availability of high quality products – anytime, anywhere.***

# Diagnostic Green

## Core Values

The Diagnostic Green's core values serve as a foundation for the way we conduct business with our **distributors, customers** and **physicians**.



Integrity



Professionalism



Accountability



Teamwork



Excellence



Flexibility

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# Company History



**1991**

Registration of ICG  
Diagnostic Product in  
Europe



**2001**

Launch of handheld imaging  
system in major European  
territories



**2015**

Renew Group Private Ltd  
acquire both Diagnostic  
Green GmbH, and Diagnostic  
Green LLC



**2016**

IC-Flow™ Imaging System  
receives CE mark  
VERDYE, new product name  
for ICG in certain territories



**2019**

Diagnostic Green's ICG  
pharmaceutical product  
expands to new territories  
worldwide

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# ICG Diagnostic Product

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# ICG Diagnostic Product

Diagnostic Green's Indocyanine Green (ICG) is the leading fluorescence product trusted by physicians worldwide, to guide their treatment procedures, based on fluorescence.

*ICG Diagnostic Product, is well known and accepted by surgeons worldwide (over 11,000 published articles on use and applications)\**

## Key Features

- Well tolerated
- Excellent safety profile
- Half-life of 3-4 minutes
- Cleared exclusively through the liver
- Eliminated through the bile
- Not metabolized or broken down

*\*<https://www.ncbi.nlm.nih.gov/pubmed/?term=indocyanine+green>*



# Approved ICG Diagnostic Product Indications



## Cardiac, circulatory & micro-circulatory diagnostics

- Measurement of cardiac output and stroke volume
- Measurement of circulating blood volumes
- Measurement of cerebral perfusion



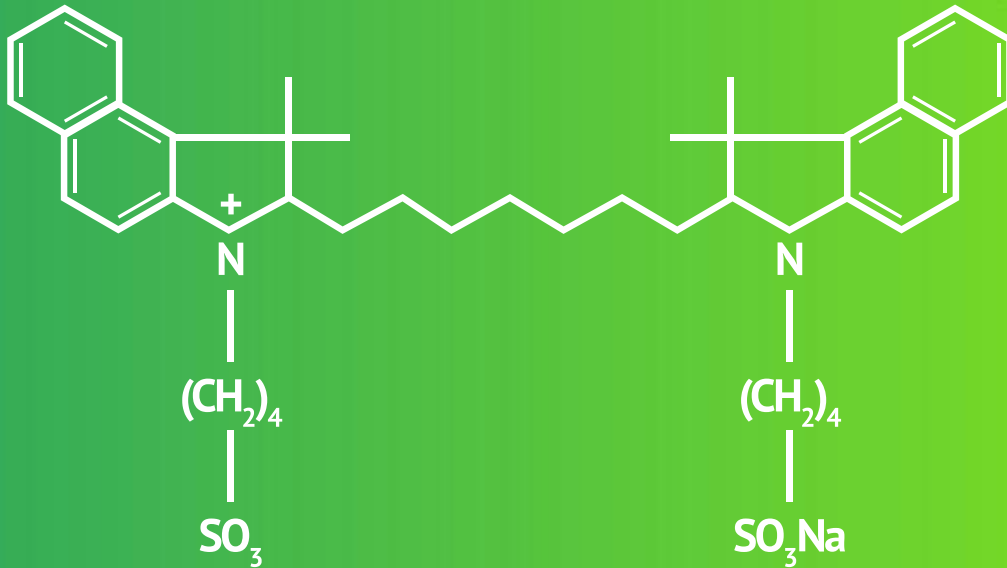
## Liver function diagnostics



## Ophthalmic Angiography Diagnostics

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# Chemical Description



- **Chemical Description:** *Tricarbocyanine Dye*
- **Appearance:** Lyophilized green powder
- **Empirical Formula:**  $C_{43}H_{47}N_2NaO_6S_2$



# ICG Diagnostic Product

Prescription only Medicine (POM/Rx Only)

**Active substance:** *Indocyanine Green (lyophilized powder)*

**Purpose of use:** *perfusion diagnostic (fluorescence)*



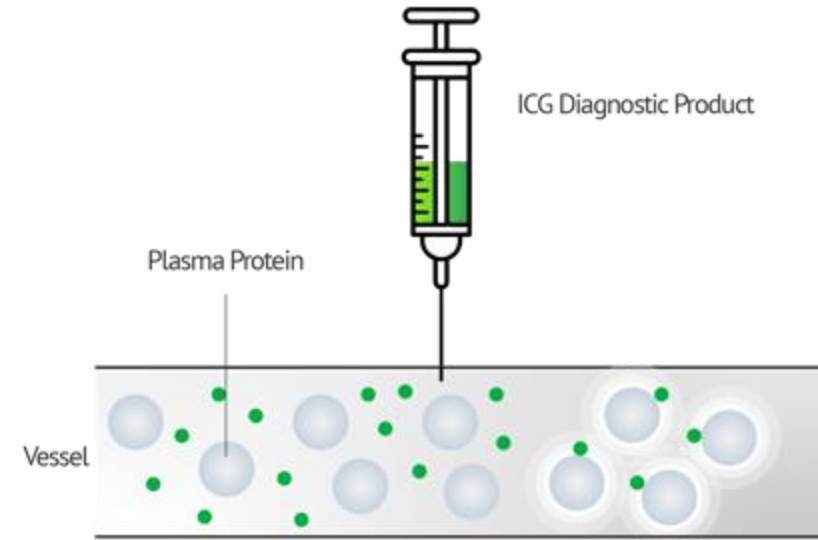
## Conditions of Use:

- Dissolve in water for injection and inject intravenously
- Keep away from light after it is reconstituted
- Sterile product, intended for a single patient use only
- Dosage depends on the indication and weight of the patient

# ICG Diagnostic Product

## Features:

- After injection the ICG binds rapidly to the blood plasma proteins (98%) and remains within the blood vessels
- It is cleared exclusively through the liver, not reabsorbed in the intestines and eliminated through the bile
- Intravenous indication: half-life is 3-4 min
- The substance is not metabolized or broken down



## Excellent safety profile:

- Well-tolerated
- Contains up to 5 % of the salt sodium iodide and so is used with caution in patients who have a history of allergy to iodides

# Verdye

(ICG Pharmaceutical Product)



Excellent  
Safety Profile



Cleared exclusively  
through the liver



Secreted entirely  
into the bile



Proud  
Supporter





# ICG Worldwide

## Registration & Distribution

### Currently registered for distribution

- USA
- Germany
- Austria
- Belgium
- Netherlands
- Italy
- Sweden
- Canada
- Portugal
- UK
- Israel
- Chile
- Spain
- Malta

### Supplied under exemption

- Australia
- Baltic States
- Czech Republic
- Croatia
- Denmark
- South Africa
- Luxembourg
- Belarus
- Bosnia
- Slovenia
- Finland
- Greece
- Hungary
- Iceland
- Norway
- Poland
- Switzerland
- Thailand

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# IC-Flow™ Imaging System

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# IC-Flow™ Imaging System

IC-Flow™ Imaging System is a compact and easy to use handheld device that visualizes and records tissue fluorescence.



## EG-Konformitätserklärung (gemäß EG-Richtlinie 93/42/EWG, Anhang VII vom Juni 1993) Declaration of Conformity (according to MDD 93/42/EEC, Annex VII dated June 1993)

Diagnostic Green GmbH  
Otto-Hahn-Straße 20  
85609 Aschheim-Dornach  
Germany

erklärt in alleiniger Verantwortung, dass das Produkt  
declares under its sole responsibility that the product

### PC6200 IC-Flow Imaging System Seriennummer/Serial number SN00001-SN00999

auf das sich diese Erklärung bezieht, mit folgender Richtlinie übereinstimmt:  
to which this declaration relates in conformity with the following directive:

Bewertungsverfahren nach EG-Richtlinie für Medizinprodukte 93/42/EWG, Anhang VII  
Evaluation procedure according to MDD 93/42/EEC, Annex VII

Klassifizierung nach Richtlinie 93/42/EWG, Anhang IX:  
Classification according to MDD 93/42/EEC, Annex IX:

**Aktives Medizinprodukt der Klasse I**  
**Active medical device class I**

Gemäß §9 Medizinproduktegesetz wurde dieses Produkt aufgrund der Erfüllung der Grundlegenden Anforderungen nach Richtlinie 93/42/EWG, Anhang I mit der CE-Kennzeichnung versehen.  
Corresponding to §9 German medical devices law (MPG) this product has been CE-marked due to the fulfilment of the essential requirements according to MDD 93/42/EEC, Annex I.



Diagnostic Green  
Diagnostic Green GmbH

*Ramona Segner*  
Authorized Person

Feb 24, 2016 Singapore  
Date Location

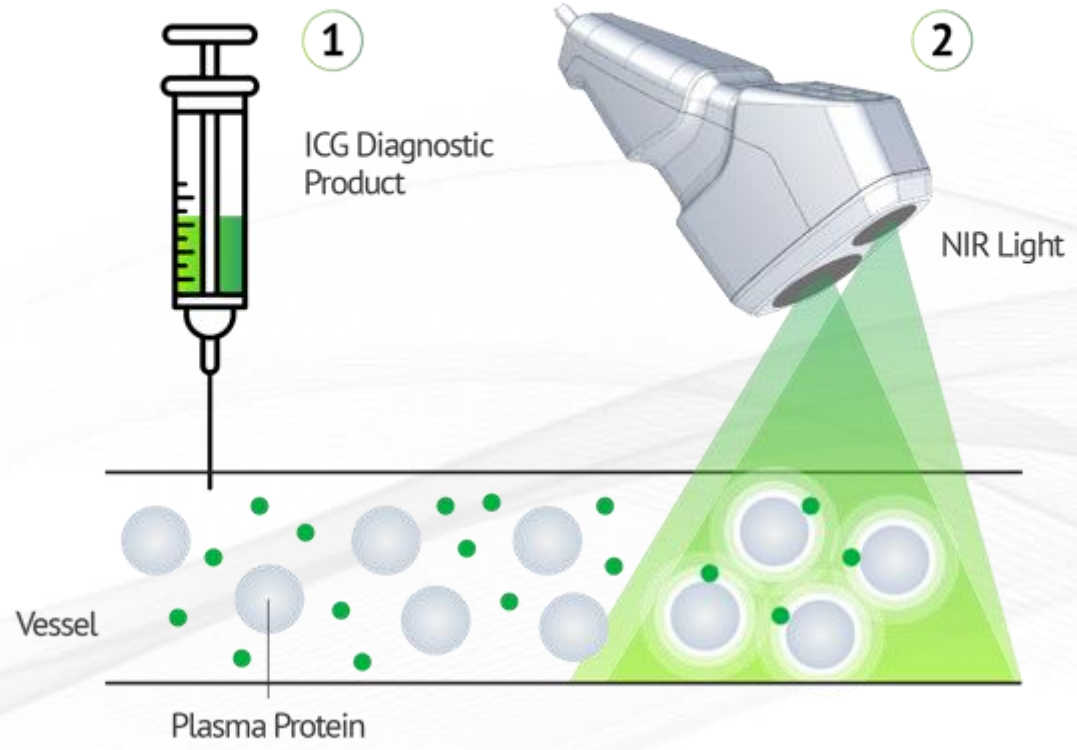


1

Injection

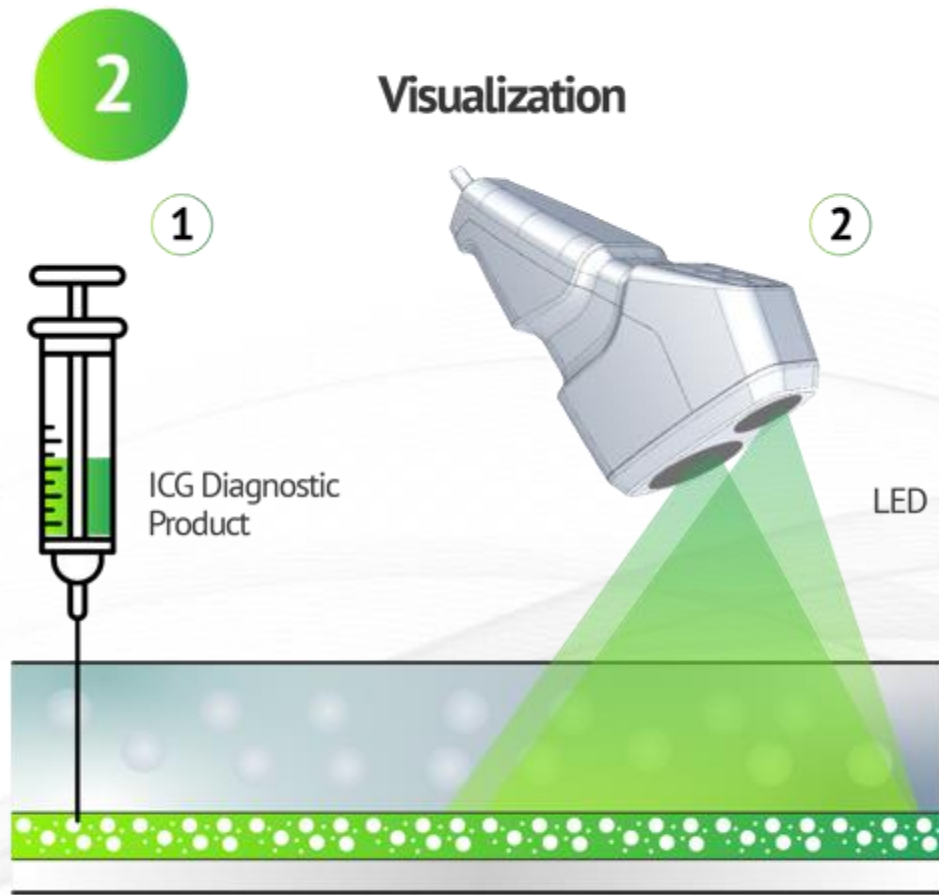
# IC-Flow™ Imaging System

## How it Works



- ICG diagnostic product is reconstituted and injected

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# IC-Flow™ Imaging System

## How it Works

- Through the use of a camera system, such as IC-Flow™ Imaging System, a near-infrared light is exhibited
- The light source excites the ICG diagnostic product molecules in the patient
- The ICG diagnostic product emits fluorescence
- Fluorescent light of ICG diagnostic product is detected by the camera filters
- Images are displayed on camera system monitor

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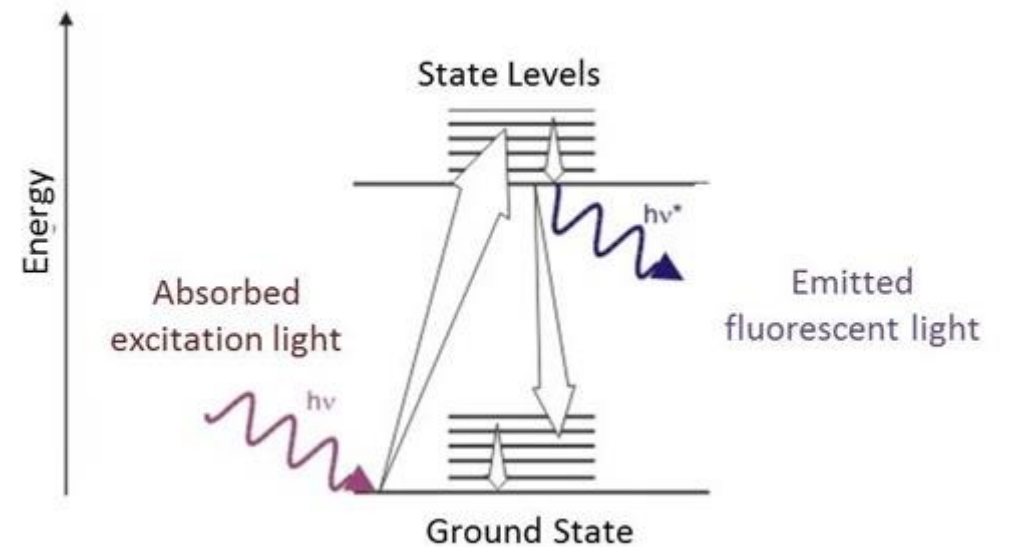
# IC-Flow™ Imaging System

## Fluorescence Principle

### Features

- Fluorescence: substance which releases light when it is illuminated (at a certain wavelength)
- Chemical reaction: the electrons of the ICG molecules absorb the illuminating light (excitation light) and are pushed into a higher energy level
- The electrons fall immediately back to their original energy level. The released energy appears in the form of fluorescent light (emission light)

### Fluorescence Process



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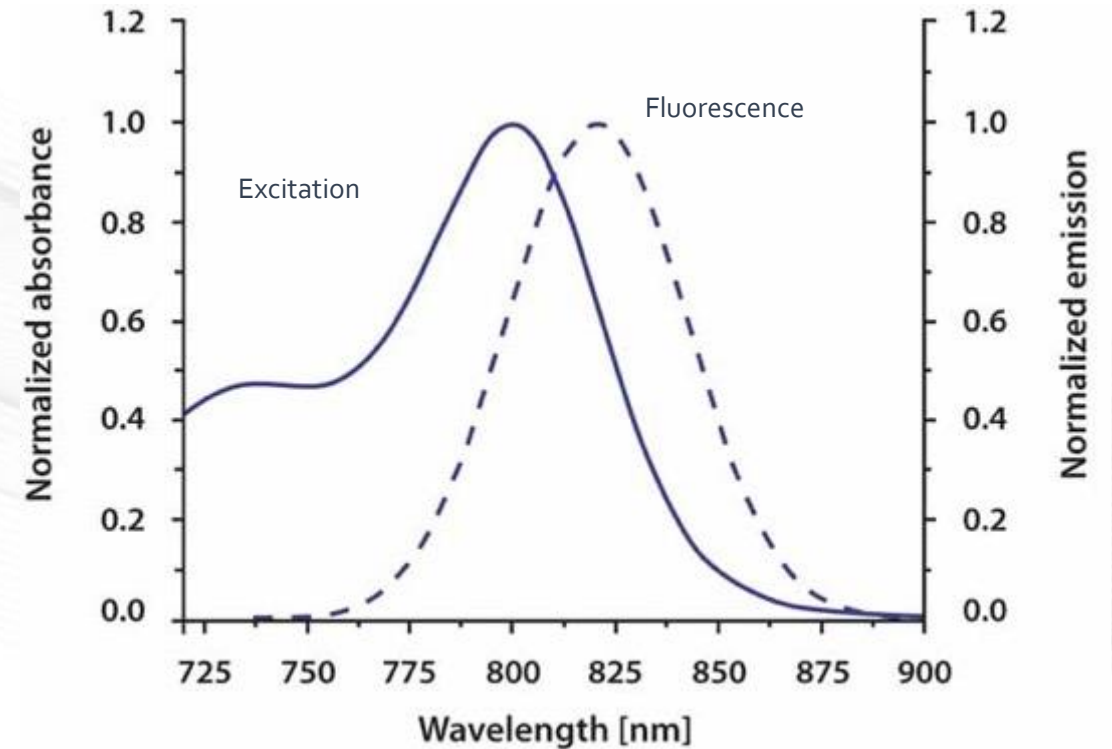


# IC-Flow™ Imaging System

## Fluorescence Principle

### ICG Wavelength

- Both absorption and fluorescence maximum of ICG are within the near-infrared spectral range
- Therefore, to detect the fluorescence light the camera requires special filters



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# IC-Flow™ Imaging System



## Handheld System

- Compact and easily portable
- Integrated display
- Easy to use
- Data transfer to USB stick
- No additional equipment required



## Operating Room System

- Portable cart system
- Integrated system with monitor
- External USB for official recording of patient data
- Display of fluorescence image on both touchscreen

# IC-Flow™ Imaging System

## Technical Features

<b>Images/ Display</b>	Display of fluorescence image on monitor and touchscreen
<b>Internal memory</b>	Internal memory of 800 MB (100 min videos/ 1000 images) Transfer to USB stick
<b>Video format</b>	MPEG1
<b>Picture format</b>	JPEG
<b>Field size of view</b>	640 x 480 pixel
<b>Focus/ zoom Work distance</b>	Manual/No Approx. 15-20 cm
<b>Light source</b>	LED
<b>Functions:</b>	Video & image recording Data transfer to USB stick







# IC-Flow<sup>TM</sup> Imaging System Procedure Steps

1. Set up the device
2. Pre-adjust the camera settings
3. Prepare ICG injection
4. Adjust the ambient light
5. Adjust the camera settings
6. Administer the ICG injection
7. Undertake the fluorescence procedure
8. Transfer data to USB stick

# IC-Flow™ Imaging System

## Registration & Distribution

IC-Flow™ Imaging System is currently available in all territories where the CE approval mark is accepted and include:



- Austria
  - Belgium
  - Bulgaria
  - Czech Republic
  - Cyprus
  - Denmark
  - Estonia
  - Finland
  - France
  - Germany
  - Greece
  - Hungary
  - Iceland
  - Ireland
  - Italy
  - Latvia
  - Liechtenstein
  - Lithuania
  - Luxembourg
  - Malta
  - Netherlands
  - Norway
  - Poland
  - Portugal
  - Romania
  - Slovakia
  - Slovenia
  - Spain
  - Sweden
  - United Kingdom
- Also available in Chile*

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# IC-Flow™ Imaging System

March 2016 IC-Flow™ Imaging System  
received CE mark as Medical Device Class I



## 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 and visualization of primary liver tumors and/or hepatic metastases. The IC-Flow Imaging System is used as an adjunctive method for visual assessment.*



Diagnostic  
Green

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## Contact Us

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