

Product Overview

Inside the human body, the tiniest changes can have an enormous impact. Within this dynamic microenvironment, Cellvizio® lets you see precisely what's occurring at the cellular level in real-time.

It is visibility on a micro level, with macro potential to transform patient management and care.



The system architecture is built with enhanced capabilities including:

- Slim profile, easy to maneuver
- Intuitive and responsive touch-screen interface
- Single-handed probe connection for quick startup
- PiP-enabled for optimized integration into procedure rooms
- Artifical intelligence
 (AI)-enabled for assisted image pattern recognition
- Platform is capable of supporting additional wavelengths and modalities such as fluorescenceguided surgery





Next-Generation Cellvizio®

REAL-TIME IN VIVO CELLULAR IMAGING PLATFORM

Technical Details



Laser Information	Confocal Laser Endomicroscopy with safe laser beam at 488 nm				
Image Capture	Real-time at 8-12 frames/sec with video recording and easy tagging				
File Export Formats	mp4, jpeg, DCM (DICOM)				
Interface	Orientable touch screen with pictograms for fast interaction				
External Display Compatibility	Picture-in-Picture enabled				
Video Outputs	DVI-D, DPP, SDI, S-video				
Recommended Display Resolution	1920(H)x1080(V) pixels (Full HD 1080p)				
DICOM/PACS Compatibility	Yes (WIFI enabled)				

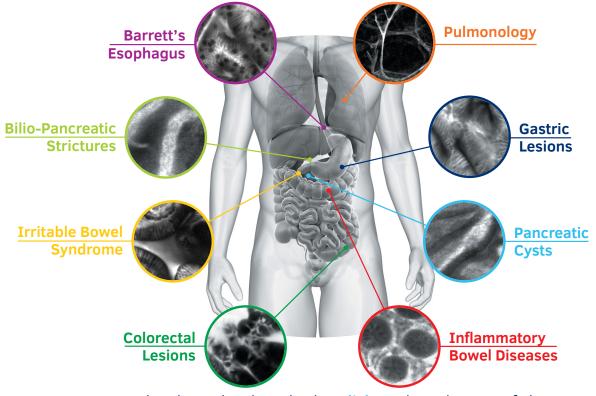




Cellvizio®

CONFOCAL MINIPROBESTM AND INDICATIONS

Cellvizio® pushes the boundaries of interventional medicine, and creates the unique opportunity to **monitor**, **assess**, **classify**, **and guide** the diagnosis and care of various diseases and cancers like never before.



For more details on the clinical value click on the indication of choice.

Indications	Confocal Miniprobes™	Compatible operating channel	Length	Maximum # of uses	Field of view	Resolution	Working Distance
	GastroFlex™ N	≥ 2.8 mm	3m	20	Ø 240 μm	1 μm	60 +/- 15 μm
	AlveoFlex™ N	≥ 1.9 mm	3m	20	Ø 600 μm	3.5 µm	>0 µm
	CholangioFlex™ N	≥ 1.0 mm	4m	10	Ø 325 μm	3.5 µm	55 +/- 15 μm
	AQ-Flex™ 19 (-,IR) N	≥ 0.91 mm	4m	10	Ø 325 µm	3.5 µm	55 +/- 15 μm
	ColoFlex™ N	≥ 2.8 mm	4m	20	Ø 240 μm	1 μm	60 +/- 15 μm

Cellvizio® I.V.E Systems with Confocal Miniprobes™ are regulated Medical Device, CE marked (CE 0459) (Class IIa - NB: G-MED) and FDA cleared. Cellvizio® is a registered trademark and Confocal Miniprobe™ is a trademark of Mauna Kea Technologies. The Cellvizio® I.V.E. is a confocal laser system with fiber optic probes that are intended to allow imaging of the internal microstructure of tissues including, but not limited to, the identification of cells and vessels and their organization or architecture. Once connected to the Cellvizio® I.V.E. system: the ColoFlex™ N and GastroFlex™ N Confocal Miniprobes™ are intended to allow imaging of anatomical tracts, i.e. gastrointestinal systems, accessed by an endoscope or endoscopic accessories, the CholangioFlex™ N Confocal Miniprobes™ are intended to allow imaging of the upper gastrointestinal tract including biliary and pancreatic ducts accessed by an endoscope or endoscopic accessories, the AlveoFlex™ N Confocal Miniprobes™ are intended to allow imaging of anatomical tracts, i.e. the respiratory system accessed by an endoscope or endoscopic accessories, the AQ-Flex™ 19 IR N Confocal Miniprobes™ are intended to provide visualisation of body cavities, organs, and canals, accessed by accessories used during interventional radiology procedures including, but not limited to catheters, endoscopic needles, coaxial needles and trocars. FDA: indications for use: Once connected to the Cellvizio® and I.V.E systems: The AQ-Flex™ 19 Confocal Miniprobes™ are intended to allow imaging of anatomical tracts, i.e., gastrointestinal and respiratory tracts, accessed by an endoscope, or endoscopic accessories (e.g. aspiration needles used during procedures including EUS-FNA, EBUS-TBNA and TBNA needles). CE marked: indications for use: Once connected to the Cellvizio® and I.V.E systems: The

AQ-Flex™ 19 Confocal Miniprobes™ are intended to allow imaging of anatomical tracts, i.e., gastrointestinal tracts and respiratory tracts accessed by an endoscope or endoscopic accessories, including through endoscopic needles. Please consult labels and instructions for use. These statements have not been reviewed, cleared, or approved by the U.S. FDA. The use of this medical device is exclusively reserved for health professionals. Product availability cannot be guaranteed in all countries. For further information, please contact your local sales representative.

