

LEAKAGE TESTER (SHA-P5)

STANDARD SET LIST

This package includes the following items:

- Leakage Tester (Main Body and Tube)
- Instructions for Use

⚠ CAUTION:

Never drop the Leakage Tester or subject it to severe impact, as this could compromise the functionality and/or safety of the unit. Should this equipment be mishandled or dropped, do not use it. Return it to an authorized PENTAX service facility for inspection or repair.

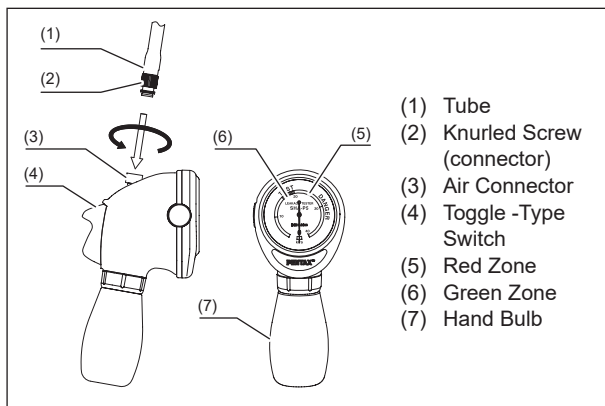
Symbols

Symbol	Description	Symbol	Description
	Date of manufacture	LOT	Batch Code
CE	The CE mark confirms the compliance to applicable European(EU) requirements.		
MD	Medical device in the EU		

Symbol	Description
	<p>*If this bar code symbol is displayed on the product, see the following explanation.</p> <p>This is a UDI (Unique Device Identification) code required by Unique Device Identification System designed to adequately identify devices through distribution and use. The following information is coded in 2D bar code (GS1 Data Matrix).</p> <ul style="list-style-type: none"> - (01) GS1 Commodity code (Global Trade Item Number) - (11) Production date - (10) Lot Number

Intended use

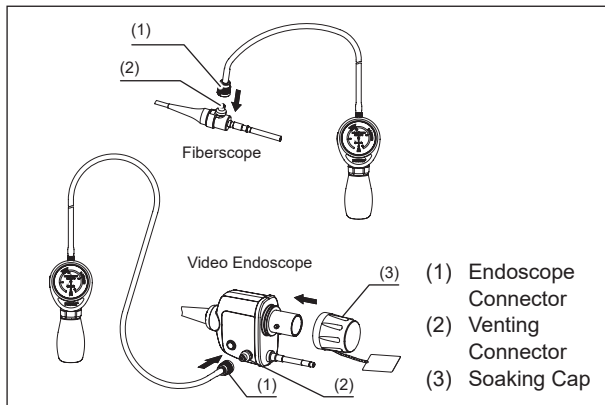
This product is intended to be used to perform leakage testing on PENTAX Medical flexible endoscopes.



• The PENTAX Leakage Tester allows for simple two-stage testing of the watertight integrity of the PENTAX Endoscopes. Air pressure is delivered by means of a hand operated bulb, eliminating the need for any electro-mechanical devices. The main body and the tube are packed separately. Before using, connect the tube to the air connector of the main body by turning the knurled screw of the tube clockwise.

STAGE I - DRY LEAKAGE TEST

BEFORE IMMERSION, PENTAX Endoscopes should be tested for any major loss of integrity in their watertight construction (example: major tear in the instrument channel). If applicable, all valves, inlet seals, distal rubber tips and other removable components should be detached from the endoscope prior to leakage test.



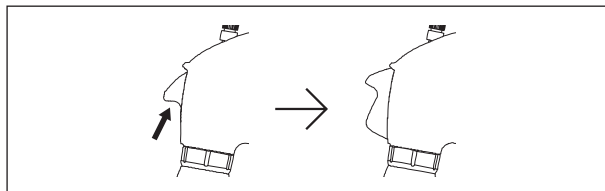
- 1) Secure the endoscope connector to the venting connector on the endoscope light guide. If applicable, the soaking cap should be securely attached to/over the electrical contacts. The endoscope connector and the venting connector on the endoscope **MUST** be dry before connecting. Proper connection will require alignment of the venting connector pin and clockwise rotation of the Leakage Tester connector.
- 2) Depress the upper half of the toggle switch to retain pressure within the endoscope.
- 3) Pressurize the endoscope by pumping the hand bulb until the indicator on the gauge is in the GREEN zone. Do NOT pressurize beyond the GREEN zone into the RED zone, as it may cause serious damage to the endoscope.

⚠ CAUTION:

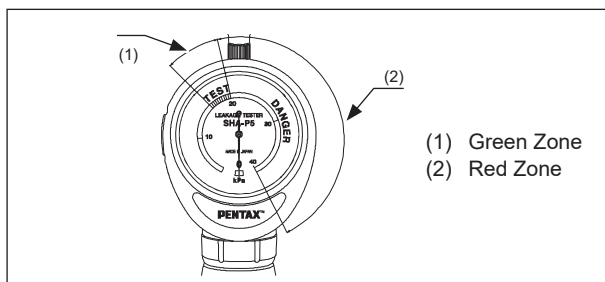
Do NOT squeeze the hand bulb too abruptly or forcefully. Doing so will cause the Leakage Tester to be pressurized to the point where the indicator enters the red zone. Be careful not to let the indicator enter into the red zone.

NOTE:

During the leakage test procedure, the insertion tube of the endoscope should be flexed in various positions, and the distal bending section should be fully angulated in all directions to confirm the absence of a leak.

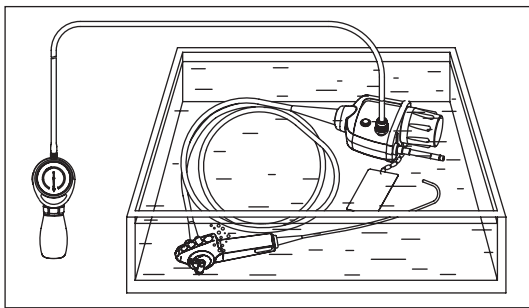


- 4) Observe the gauge pressure to determine if the indicator is standing still in the GREEN zone. If the indicator drops from the GREEN zone rapidly, a major leak may be indicated.



NOTE:

Avoid depressing the lower half of the toggle switch during the leakage test, as this will cause the endoscope to deflate and the leak tester gauge needle to return to its baseline zero position. If this happens, you must repeat the leakage test. NEVER IMMERSE the entire endoscope if the gauge indicator does not remain in the GREEN zone. Instead, contact your PENTAX Service Facility.



STAGE II - WET LEAKAGE TEST

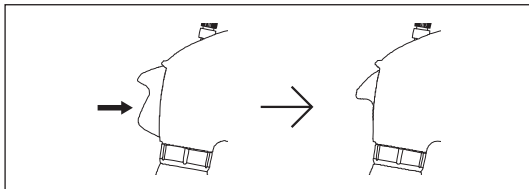
- After determining the absence of any major leak in Stage I testing, PENTAX Endoscopes should be immersed to test for loss of integrity in their watertight construction.

- With the Leakage Tester securely attached to the endoscope, the soaking cap (if applicable) securely attached to/over the endoscope, ALL valves and inlet seals removed endoscope, and the endoscope pressurized so that the gauge indicator is in the GREEN zone, immerse the entire endoscope in clean water.

NOTE:

Only the endoscope connector and the distal portion of its rubber tubing should be immersed. NEVER immerse the entire Leakage Tester.

- Observe the instrument carefully while fully angulating the distal tip of the endoscope. A few bubbles may occur initially released from recessed areas of the endoscope. This is normal. If a continuous stream of bubbles is observed from the same spot, a leak is indicated. Immediately remove the endoscope from the water. Do NOT use the endoscope. Thoroughly dry the endoscope and contact your PENTAX Service Facility.
- For a product equipped with a forceps elevator, inspect the forceps elevator while raising and lowering it to confirm if air bubbles are present. If a continuous stream of air bubbles is observed from the same spot, stop using the endoscope and send it to PENTAX Medical for repair.



- After removing the endoscope from water, release the air pressure within the endoscope by pushing the toggle switch downward. After the gauge indicates 'zero', disconnect the Leakage Tester from the endoscope.

You may proceed with cleaning and either disinfection or sterilization of the endoscope as described in the endoscope Instructions for Use (Reprocessing).

NOTE:

NEVER connect or disconnect the Leakage Tester under water. This will cause leakage of water into the endoscope and Leakage Tester.

CARE AFTER USE

- Wipe the rubber tubing with a gauze lightly dampened with a cleaning detergent (neutral pH, low foaming, mild/compatible with PENTAX products, etc.).
- Wipe the rubber tubing with a gauze lightly dampened with potable water (to remove residual detergent). Do NOT allow any fluids to enter the distal endoscope connector (green) or the tubing.
- Wipe the rubber tubing with a dry gauze or lint-free cloth to remove remaining water/fluids.
- Wipe the entire Leakage Tester with a gauze dampened with 70-90% medical grade ethyl alcohol.

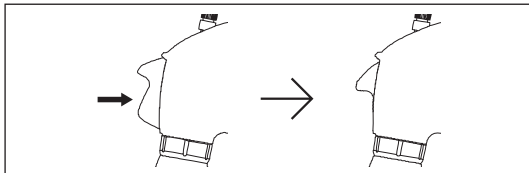
⚠ CAUTION:

Keep the entire hand-held section of the Leakage Tester (gauge, bulb, etc) from getting wet. NEVER completely immerse the entire Leakage Tester.

- After cleaning and drying as per the steps above, store the Leakage Tester in a clean, dry, and well-ventilated area. NEVER store it in an area where it could get wet or be exposed to any adverse environmental conditions such as high temperature, humidity, direct sunlight, dust, salt, etc.

⚠ WARNING:

Follow the national or local laws/guidelines to appropriately dispose of the consumables. Failure to do so may create a risk to the environment.

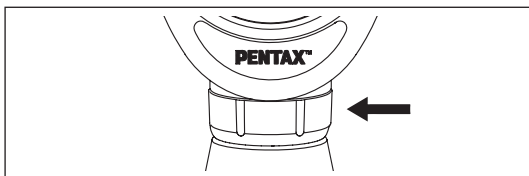


⚠ CAUTION:

When storing the Leakage Tester, raise the toggle switch. Storing the Leakage Tester with the toggle switch in the locked position for extended periods can damage the device.

⚠ CAUTION:

Never attempt to unscrew/rotate the gray ring above the hand bulb. This can damage the Leakage Tester.



NOTE:

As per the Regulation (EU) 2017/745 (EU-MDR) users should report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the Member State in which the user is established.

Manufacturer

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PENTAX™

LEAKAGE TESTER (SHA-P5) 2/2

LCPM: 02/2016/09/35102702 2020.02 6217001 Z935 R05

88228

OPTIVISTA™ EPK-i7010

Product Specifications

PENTAX
MEDICAL



Power Supply

Voltage	120V AC (NTSC) / 230 V AC (PAL); within $\pm 10\%$
Frequency	50-60 Hz

Size and Weight

Dimensions (W x H x D)	400 x 205 x 520 mm
Weight	21.5 kg

Classification (Medical Electrical Equipment)

Type of protection against electric shock	Class I equipment, 3 prong plug
Degree of protection against electric shock	Type BF (Body Floating), using insulated endoscope. Use on a heart is prohibited.
Degree of explosion proofing	Do not use in potentially flammable surroundings.

Illumination

Lamp	300W Xenon (Life: 500hrs, depending on usage)
Brightness	Brightness adjustment is possible in ± 11 steps using the button on the touchscreen.
Light exposure control	The auto light exposure control can be selected using EXPOSURE CONTROL and MODE on the touch screen. - EXPOSURE CONTROL AUTO: The light exposure is automatically adjusted. MANUAL: The light exposure is fixed in the certain level which is set on the brightness. - MODE (in AUTO mode) AVE: The light exposure is controlled based on the average level of brightness in the endoscopic image. PEAK: The light exposure is controlled to reduce halation area in the endoscopic image.

Air flow function

Pump	Diaphragm type pump / Air flow can be selected from 5 different levels.
Air pressure	45-70 kPa (6.5-10.2 PSI)

Observation

HD signal output	Digital: 1080i (1920 x 1080) thru DVI and HD-SDI / Analog: SXGA (1280 x 1024) thru DVI
Analog SD signal output	RGB, S-Video, Composite Video
White balance adjustment	White balance adjustment is possible using the white balance button on the touchscreen.
Color balance adjustment	The following color balance adjustments are possible using the touch screen interface: Red adjustment: ± 11 steps, Blue adjustment: ± 11 steps.
Contrast	Image contrast can be adjusted in 3 settings (illumination, Mode 1 and Mode 2).

Observation

D-Range Expansion	D-Range Expansion can improve far field illumination.
Image enhancement setting	Post-processing image enhancement / i-SCAN (Mode 1, Mode 2, and Mode 3) OE Optical image Enhancement (Mode 1, Mode 2)
TwinMode	TwinMode shows white light image and images with image enhancement side by side on the monitor.
Digital zoom	Digital zoom is available. Magnification ratio: OFF, 1.2, 1.5, 2.0.
Image size selection	The size of the endoscopic image can be changed in 2 modes (Full, Med).
Freeze	The still image can be shown when activating Freeze mode.
Freeze Scan	Freeze Scan is a software function that selects the sharpest image from a series of images temporarily stored in the video processor.

System settings

Customizable buttons	There are 4 customizable buttons in the touchscreen and functions on the video processor can be assigned to these buttons.
PinP	External composite video signal can be the input into the video processor and shown on the monitor.
Endoscope's remote button function	The video processor's functions can be set on the remote buttons of the endoscope by using the touchscreen.
Remote control	The following peripheral devices can be controlled by the remote control. (LAN, RS-232C, USB, Remote terminal) / Video Printer, Video recorder, Filing system.

Documentation

Patient data	The following data can be displayed on the monitor: Patient ID, Patient name, Sex, Age, Facility, Comments.
Displaying the recorded state	The recording state of the following peripheral devices can be displayed on the monitor. External storage media, Filing system, Video printer.
Displaying the image information	The following data is displayed on the monitor. Enhancement level, image enhancement (i-SCAN modes and OE modes), Zoom Level, Color balance, Brightness.
Advance registration of patient data	Up to 50 patients' data can be registered.
HD video recording	Integrated HD video recorder (20 mins with high quality to 40 mins with standard quality) the video file is stored into the external storage media.

External storage

Media	USB port is equipped on the front panel and the rear panel. USB memory stick, USB HDD drive.
Recording format	Still image: JPEG, BMP / Video: TS format.

Memory Backup

User settings	Up to 20 user settings can be registered.
Memorization of selected settings	Following settings can be individually set for users: - SE, CE - Enhancement - Ave / Peak - Noise reduction - Sub screen position - Manual brightness level - Auto brightness level
Lithium battery	Lithium battery is equipped in the processor for a real time clock.

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Legal Manufacturer

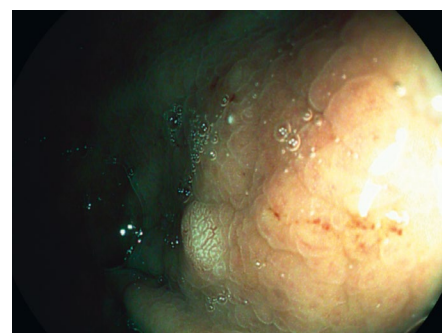
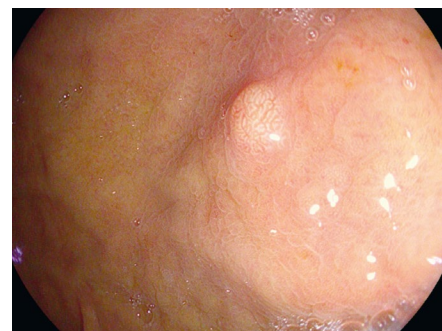
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PENTAX
MEDICAL

OPTIVISTA plus⁺

*A unique combination of optical and digital enhancements,
for improved in vivo diagnosis*

PENTAX
MEDICAL



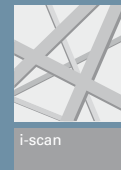
Courtesy of Dr. Federico Buffoli,
Cremona Hospital, Italy



A leap forward for *in vivo* histology with i-scan and i-scan OE, a unique combination of digital and optical enhancements

1

Enhanced detection



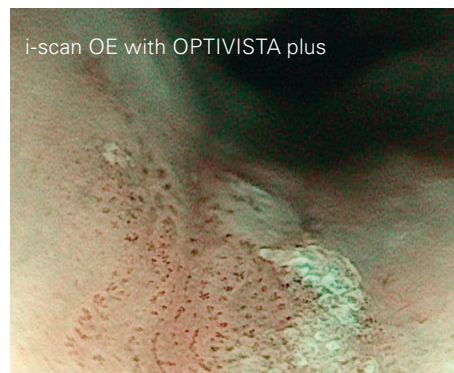
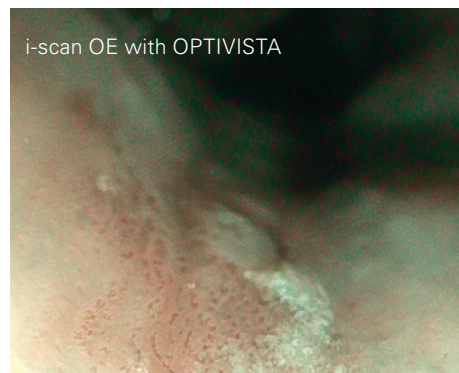
Sharp High-Definition image, combined with **i-scan imaging** and **excellent illumination** for a more detailed view of the mucosa and enhanced detection.

Made for you: the OPTIVISTA plus⁺

Further improved *in vivo* diagnosis for therapeutic guidance

PENTAX Medical is proud to introduce the new OPTIVISTA plus, the next generation processor that enhances the OPTIVISTA's already superb image quality and other capabilities.

- OPTIVISTA plus supports the best clinical outcome by providing sharper, brighter image quality thanks to i-scan and i-scan OE.
- It supports diagnosis and case documentation, and guides treatment and therapeutic decisions through easier image capture and sharper than ever frozen images.
- It is an effective cross-segment investment due to its proven clinical characterization capabilities being expanded into pulmonology and ENT.



Courtesy of Dr. Fujishiro, The University of Tokyo Hospital, Japan

2

Improved *in vivo* diagnosis



A unique combination of **digital enhancement** (i-scan) and **optical enhancement** (i-scan OE) provides extra information for a more accurate *in vivo* diagnosis through improved vessel and mucosal pattern characterization.

3

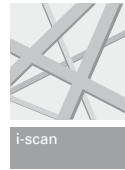
Powerful educational platform



The **TwinMode** is perfectly designed to demonstrate the appropriate interpretation of image enhancement endoscopy by providing simultaneous comparison of side by side endoscopic images.



The **integrated audio and HD+ video recorder** enables to collect and share the latest scientific findings from the endoscopy room with fellows and peers.

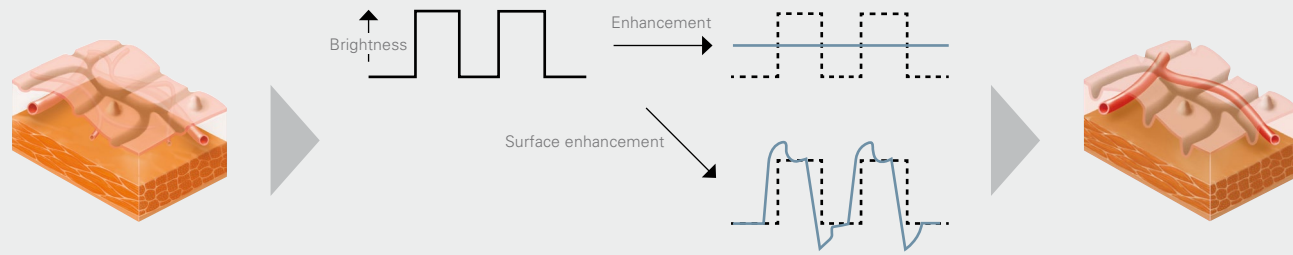


i-scan for enhanced detection and characterization

i-scan technology is a digital, image enhanced endoscopy (IEE) technology by PENTAX Medical. As a virtual chromo-endoscopy tool, i-scan provides an enhanced view of the mucosal structures and vascular patterns, supporting early detection, demarcation and characterization.

i-scan 1 (SE) for detection

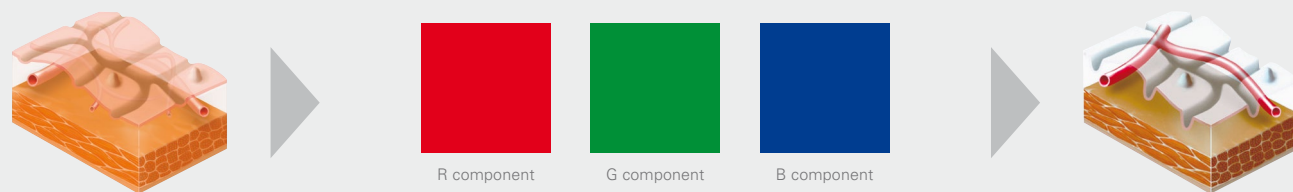
By enhancing the mucosal structure in a natural color tone, SE (Surface Enhancement) supports detection, especially of flat lesions by highlighting abnormalities.



With SE, the difference in luminance intensity between the pixels concerned and the surrounding pixels is analyzed and the edge components are enhanced. SE adjustment of the noise erasure function allows more evident enhancement of the edges, which corresponds to minor changes in structure.¹

i-scan 2 (TE) for pattern characterization

TE (Tone Enhancement) enhances the changes of vascular and mucosal structure with a color tone change, supporting pattern characterization.



The RGB components of an ordinary endoscope image are disintegrated into each component (R, G and B), and each component thus isolated is converted independently along the tone curve, followed by a reconstruction of the three components in one single image.¹

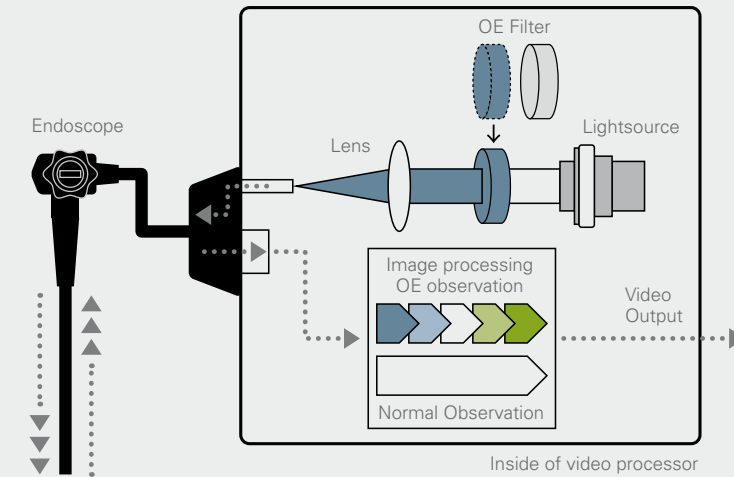
¹Kodashima et al: Novel image-enhanced endoscopy with i-scan technology. World J Gastroenterol 2010



i-scan OE for vessel characterization

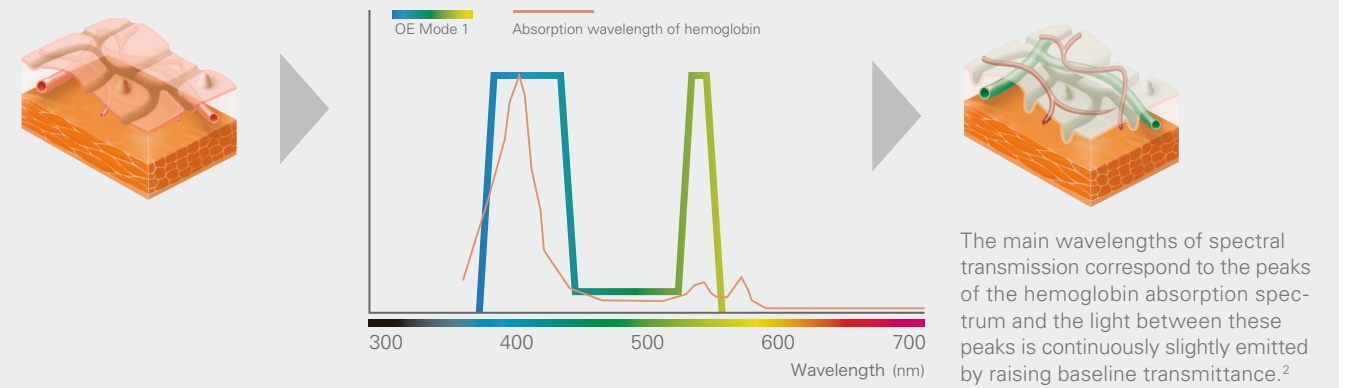
PENTAX Medical has recently developed the i-scan OE (Optical Enhancement), an optical filter that produces bandwidth-limiting light. When combined with image enhancement processing technology it clearly displays the surface structures of blood vessels, glandular ducts and mucosal membranes in higher contrasts than white light.

i-scan OE technology



i-scan 3 (OE) for vessel characterization

i-scan OE displays the surface structures of the blood vessels, glandular ducts and mucosal membranes in a color tone **and supporting vessel's characterization.**

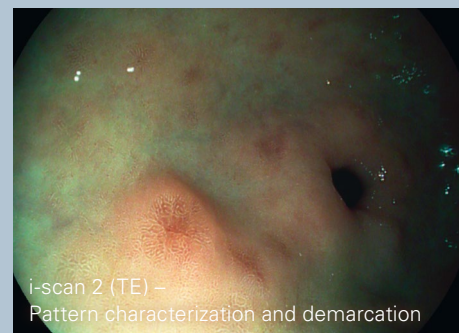


The main wavelengths of spectral transmission correspond to the peaks of the hemoglobin absorption spectrum and the light between these peaks is continuously slightly emitted by raising baseline transmittance.²

²K Mönkemüller et al.: Present and future perspectives of virtual chromoendoscopy with i-scan and optical enhancement technology. Digestive Endoscopy 2013; 26.



i-scan 1 (SE) - Detection



i-scan 2 (TE) - Pattern characterization and demarcation



i-scan 3 (OE) - Vessel characterization

Improved *in vivo* diagnosis
A unique combination of digital and optical enhancements

OPTIVISTA, a powerful educational platform

The OPTIVISTA EPK-i7010 video processor is a state-of-the-art educational tool with customizable functions operated easily by the touch screen, or via the endoscope buttons.

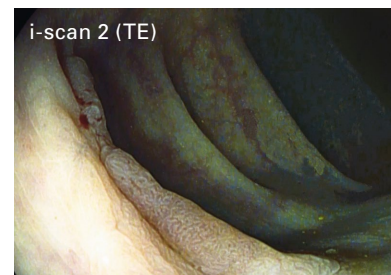


Teach and assess with the unique TwinMode

- TwinMode is useful in teaching the appropriate interpretation of image enhanced endoscopy, providing simultaneous comparison of side by side endoscopic images.
- Among experts, TwinMode is appreciated as an educational tool for non-experts
- in “building the bridge” between HD+ white light images and the different i-scan modes and findings.
- The simultaneous comparison of enhanced clinical images is useful in teaching the appropriate characterization of lesions.



Colon adenoma



Collect and share with the unique integrated video and audio recording

- The video recording function enables capture of HD+ video files through a USB storage device, for fast and easy sharing of findings with peers. Audio recording for video is captured through external microphone.
- Contributes to cost savings in the endo-scopy room by avoiding unnecessary external HD recording devices.
- For best image collection, the OPTIVISTA also incorporates freeze scan technology which automatically selects the sharpest picture.



Exchange and expand your knowledge of i-scan by visiting the i-scan website

www.i-scanimaging.com



OPTIVISTA plus A multifunctional platform across segments



1. VNL-J10

The new VNL-J10 series will provide support to both diagnostic as well as therapeutic procedures. The VNL product range can be used in a wide variety of applications in ENT such as FEES examinations and functional video stroboscopy examinations.

2. J10 - Pulmonology

The Video Bronchoscope EB-J10 product range offers sharp and clear High-Definition image quality, with unmatched ergonomic design and flexibility to ease operation in daily use.

3. GI i10

Slim caliber, bigger working channel and Close Focus, all combined in an i10 HD+ endoscope, the high performance endoscopes series, for the day-to-day advanced endoscopy practice.

4. 90i

With the 90i endoscope series, you can experience HD+ images combined with exceptional illumination, during routine examinations.

EC	REP
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PENTAX Medical
CO₂ Insufflator and Irrigation Pump



PENTAX Medical is committed to improving the quality of patient care and productivity of healthcare delivery around the globe by providing the best endoscopic products and services, with a focus on clinically relevant innovation, simplicity, and quality.

The CO₂ Solution for GI Endoscopy

The PENTAX Medical CO₂ Insufflator is a versatile system that connects to either a wall or tank CO₂ source. Combined with the full line of the disposable PENTAX Medical DispoCap CO₂, the PENTAX Medical CO₂ Insufflator allows clinicians to offer the optimal procedure for the patient.

The PENTAX Medical CO₂ Insufflator offers a complete range of CO₂ solutions to suit individual facility needs for PENTAX Medical GI endoscopes. With direct connection to sterile water and any CO₂ tank or wall source – PENTAX Medical CO₂ Insufflator has the comprehensive solution for your facility and patients.

Benefits of Using CO₂

- CO₂ is easier on the patient both during and after the procedure due to rapid absorption by surrounding tissue.¹
- Minimises patient discomfort associated with bloating and cramping from room air.¹
- Less sedation required during the procedure.²
- Reduces the number of patients that need to be seen by the physician in recovery.²



Daily Use PENTAX Medical DispoCap CO₂ Full disposable system minimises infection control risks.

Warm Water Technology

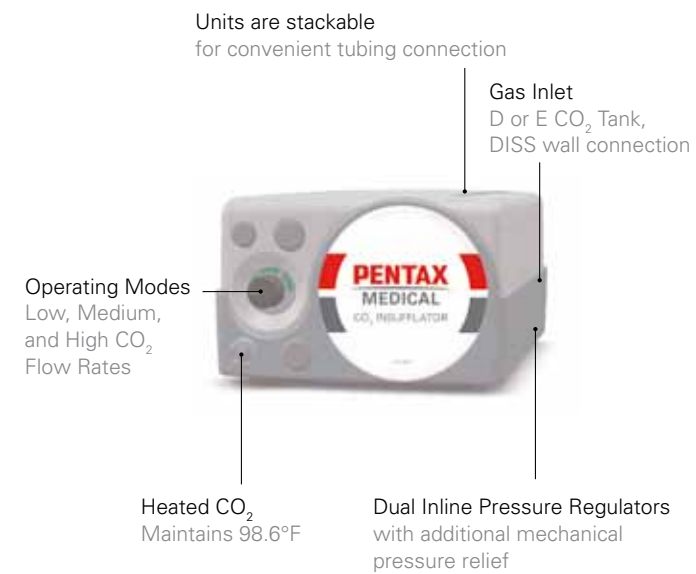
Deliver irrigation for GI endoscopy procedures with a warm water option by utilising the PENTAX Medical Irrigation Pump. Combine the pump with PENTAX Medical GI endoscopes and irrigate through the auxiliary water jet or biopsy channel to improve procedural visibility.

- Greater visibility for improved diagnosis and polyp detection
- Auxiliary water jet or biopsy channel irrigation capability
- Warm water technology
- Compatible with PENTAX Medical Irrigation Tubing and Connectors
- Easy to use water bottle cradle
- Automatic prime button provides instant irrigation upon foot pedal depression

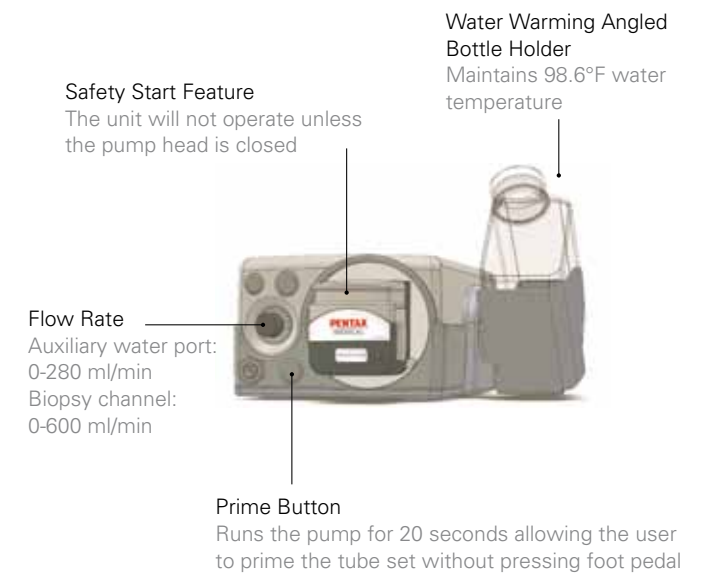


Auxiliary Water Jet Connection

CO₂ Insufflator Features



Irrigation Pump Features



Specifications

PENTAX Medical CO₂ Insufflation

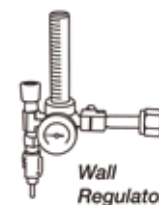
REF#	EGA-501P
Dimensions [mm]	197x 121x 349
Weight [Kg]	4.8
Power Requirements [V]	100-240

PENTAX Medical Irrigation Pump

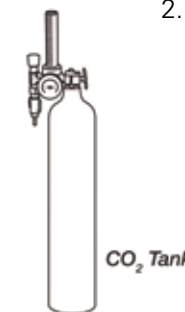
REF#	EGA-500P
Dimensions [mm]	197x 121x 349
Weight [Kg]	4.8
Power Requirements [V]	100-240
Max Flow Rate:	
Auxiliary Water Channel [ml/min]	0-300
Biopsy Channel [ml/min]	0-600

Easy Set Up and Installation

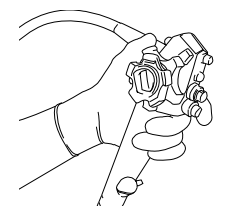
1. Choose a CO₂ Source



2. Connect Hose and Tubing to Insufflator



3. Ready for Procedure



Compatible Accessories

Tubing

REF# 100150CO2P	PENTAX Medical DispoCap CO ₂
REF # 100160P	PENTAX Medical DispoCap Air
REF# 100130P	PENTAX Medical Irrigation Tubing for EGA-500P
REF# 100551P	PENTAX Medical CO ₂ Source Tubing

Connectors

REF# 100116P	PENTAX Medical 24hr Use Waterjet Connector
REF# 100242P	PENTAX Medical Single Use Waterjet Connector

Source: 1. Dellon, E.S. (2009). The use of carbon dioxide for insufflation during GI endoscopy: a systematic review. *Gastrointestinal Endoscopy*, 69(4), 843-849.
2. Author: Miroslaw Szura, MD PhD, Rafal Solecki, MD PhD, Krzysztof Bucki, MD, Andrzej Matyja, MD PhD. MEDICINA Specialist Diagnostic & Therapeutic Centre
Title: Helpfulness of Carbon Dioxide Insufflation During Colonoscopy - SAGES 2011 Program Number P211

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RADIANCE® ULTRA 32"

Premium Endoscopy Visualization



- Optimized for endoscopy applications
- Advanced imaging capabilities
- Medi-Match™ color calibrated
- Cleanable splash-proof design
- 10-year scratch-resistant-glass guarantee
- ZeroWire® embedded receiver optional

The Radiance® Ultra series leads the industry as a revolutionary display with the aim to transform advanced visualization technology capabilities and features into a clinical solution that supports the drive to improve patient outcomes, improve workflow efficiency, and lower operating costs.

Enhanced endoscopic visualization is accomplished with an LED backlight technology that produces bright and vivid color video images even during deep abdominal procedures. Medi-Match™ color calibration assures consistent image quality and accurate color reproduction. The result is outstanding endoscopic video image performance.

With a focus to improve workflow efficiency and workplace safety, the Radiance Ultra series is available with an optional built-in ZeroWire receiver. When paired with the ZeroWire *Mobile* battery-powered stand, the combination becomes the world's first and only truly cordless and wireless mobile endoscopic solution (patent pending). To eliminate display scratches caused by IV poles or surgical light heads, the Radiance Ultra series uses scratch-resistant, splash-proof edge-to-edge glass that includes an industry-exclusive 10-year scratch-resistance guarantee.

RADIANCE® ULTRA 32"

Premium Endoscopy Visualization



A Novanta Company

SPECIFICATIONS

Screen Size	32" diagonal	
Image Size	27" x 15"/698 x 393 mm (WxH)	
Resolution	1920 x 1080	
Aspect Ratio	16:9	
View Angle	178°	
Luminance	400 cd/m ² typical	
Contrast Ratio	1,000:1 (nominal)	
Numbers of Colors	16.7 Million (8-bit)	
Backlight Stabilization	NDS Intelli-Guard™	
Color Calibration	NDS Medi-Match™	
Color Gamut	BT.709 or SMPTE-C	
Response Time	10ms	
Latency	18ms	
Video Board Configurations	Primary Board – Digital & Analog	DVI-I and 3G-SDI Input/Output (supports VGA/RGB/SoG)
	Secondary Board – Digital	2nd DVI-D and 3G-SDI Inputs/Outputs, Analog Component/VGA
	Secondary Board – Analog	2nd DVI-D Input/Output, Analog Component/VGA, S-Video, Composite
Embedded Wireless Receiver	Optional ZeroWire Embedded Receiver	
Sealed Glass	Bezel Protected, Edge-to-Edge, Chemically Strengthened	
Glass Anti-Scratch Warranty	10-Year Scratch-Resistant Guarantee	
Warranty	3 Years	
Dimensions	30.7" x 20" x 3.4"/780mm x 509mm x 87mm (WxHxD)	
Weight	24 lbs/10.9 kg (primary board only)	
Shipping Weight**	40 lbs/18.2 kg	
Shipping Dimensions	36" x 9" x 29"/92 x 23 x 74 cm	
Green Compliance	REACH, RoHS-2, WEEE	
Regulatory Compliance	ANSI/AAMI ES60601-1, CAN/CSA C22.2 No. 60601-1, Conflict Minerals, FCC Class B, EN60601-1, EN60601-1-2, CE, MDR 2017/745, Class I Medical Device, Designed to meet IPX6, CCC	
Regulatory Compliance with ZeroWire Embedded	ANSI/AAMI ES60601-1, CAN/CSA C22.2 No. 60601-1, FCC Class B, CAN ICES-3(B) / NMB-3(B); EN60601-1, EN60601-1-2, MDR 2017/745, EU Class I Medical Device, (RE-D) Directive 2014/53/EU, this device contains RF module: SII-SK63101, EN 302-567 V2.0.24, CE, US Class II Medical Device, FDA cleared, FCC ID: UK2-SII-SK63101, IC ID: 6705A-SIISK63101, Designed to meet IPX6, 007AA106	
Supplied Accessories	Power Supply, 100-240 VAC, 50-60 Hz to 24 VDC, 6.25 A AC power cord, region appropriate	

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NDS Quality System

ISO 13485
 FDA Registration #2954921

ORDER INFORMATION

Radiance Ultra 32"

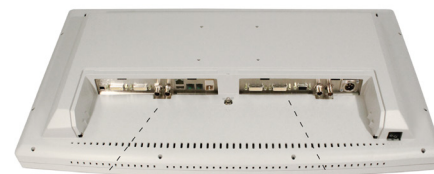
90R0108	RU 32" with Primary Board
90R0106	RU 32" with Primary and Secondary Digital Board
90R0107	RU 32" with Primary and Secondary Analog Board
90R0110	RU 32" with Primary Board and ZeroWire Embedded Receiver

OPTIONAL ACCESSORIES

90Z0221	Fiber Converter 5 VDC Power Cable
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*Must be installed at factory; not field upgradable.
 **Shipping weights are approximate.

CONFIGURATION



Primary Board
 90R0108: Primary Board Only

Secondary Board* (optional)
 90R0106: Primary + Digital Board
 90R0107: Primary + Analog Board

Reusable Biopsy Forceps with Window and Spike



Model Name	Compatible Endoscopes		Note	
	Instrument Channel Diameter [mm]	Working Length [mm]		
KH2411S	2.8	1100	Autoclavable	
KH2415S	2.8	1500		
KH2418CS	2.8	1800		for ERCP scopes
KH2422S	2.8	2200		
KH2430S	2.8	3000		

Reusable Biopsy Forceps with Mini Cups



Model Name	Compatible Endoscopes		Note
	Instrument Channel Diameter [mm]	Working Length [mm]	
KS1011CS	1.2	1100	Autoclavable
KS1022CS	1.2	2200	

Reusable Biopsy Forceps with Window and Extra Large Cups



Model Name	Compatible Endoscopes		Note
	Instrument Channel Diameter [mm]	Working Length [mm]	
KW3111S	3.2	1100	Autoclavable
KW3115S	3.2	1500	
KW3122S	3.2	2200	

Reusable Biopsy Forceps with Round Cups



Model Name	Compatible Endoscopes		Note
	Instrument Channel Diameter [mm]	Working Length [mm]	
KW2411R	2.8	1100	Autoclavable
KW2415R	2.8	1500	
KW2418R	2.8	1800	
KW2422R	2.8	2200	
KW2430R	2.8	3000	

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Product availability cannot be guaranteed in all countries. For further information please contact your local sales representative.



Therapeutic Accessories – The Choice
 for Quality and Efficiency in Endoscopy.

Available to ensure highest standards.



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PENTAX Medical

State-of-the-art accessories product line for diagnosis and treatment in endoscopy.



Our commitment to quality

Safe and successful endoscopy depends upon the use of a finely tuned endoscopic system of components. This is the underlying principle behind PENTAX Medical's commitment to a product line of therapeutic accessories with the highest possible level of quality. We invite you to examine our carefully selected and meticulously crafted therapeutic accessories for state-of-the-art diagnostic and treatment applications. All PENTAX Medical accessories have been tested in conjunction with PENTAX Medical endoscopes for function and compatibility.

How to select the correct accessories.

Before you select new accessories, please consider the following:

- The compatibility of your endoscope with the desired diagnostic/treatment application.
- The diameter of the instrument channel and working length of your endoscope.
- Use only accessories that are compatible with your endoscope to ensure the highest standards of endoscopic therapy.

PENTAX Medical

Single Use Accessories

Single Use Biopsy Forceps



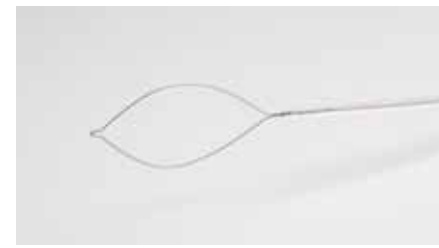
Description	Model Name	Compatible Endoscopes	
		Instrument Channel Diameter [mm]	Working Length [mm]
with Windows	KW-D1810	2.0	1000
	KW-D1816	2.0	1600
	KW-D2416T	2.8	1600
	KW-D2423T	2.8	2300
with Windows/ Spike	KH-D2416T	2.8	1600
	KH-D2423T	2.8	2300
Crocodile	KA-D2416T	2.8	1600
	KA-D2423T	2.8	2300
Crocodile with Spike	KB-D2416T	2.8	1600
	KB-D2423T	2.8	2300

Single Use Retrieval Basket



Model Name	Compatible Endoscopes		Width of Basket [mm]
	Instrument Channel Diameter [mm]	Working Length [mm]	
GB-D1807L015	2.0	700	15
GB-D1810L020	2.0	1000	20
GB-D1819L020	2.0	1900	20
GB-D2415L030	2.8	1500	30
GB-D2419L020	2.8	1900	20
GB-D2423L035	2.8	2300	35

Single Use Polypectomy Snare



Description	Model Name	Compatible Endoscopes		Width of Snare Wire [mm]
		Instrument Channel Diameter [mm]	Working Length [mm]	
Oval	DO-D2416-15	2.8	1650	15
	DO-D2423-15	2.8	2300	15
	DO-D2416-20	2.8	1650	20
	DO-D2423-20	2.8	2300	20
	DO-D2416-25	2.8	1650	25
	DO-D2423-25	2.8	2300	25
Hexagonal	DH-D2416-15	2.8	1650	15
	DH-D2423-15	2.8	2300	15
	DH-D2423-20	2.8	2300	20
	DH-D2416-25	2.8	1650	25
	DH-D2423-25	2.8	2300	25

Single Use Injection Needle



Needle Size	Model Name	Compatible Endoscopes		Needle Length [mm]
		Instrument Channel Diameter [mm]	Working Length [mm]	
23G	NI-D1816-T2304	2.0	1650	4
	NI-D1816-T2305	2.0	1650	5
	NI-D1816-T2306	2.0	1650	6
	NI-D1816-T2308	2.0	1650	8
	NI-D2416-T2304	2.8	1650	4
	NI-D2416-T2306	2.8	1650	6
	NI-D2423-T2304	2.8	2300	4
	NI-D2423-T2305	2.8	2300	5
	NI-D2423-T2306	2.8	2300	6
	25G	NI-D1816-T2504	2.0	1650
NI-D1816-T2505		2.0	1650	5
NI-D2416-T2504		2.8	1650	4
NI-D2416-T2505		2.8	1650	5
NI-D2416-T2506		2.8	1650	6
NI-D2423-T2504		2.8	2300	4
NI-D2423-T2505		2.8	2300	5
NI-D2423-T2506		2.8	2300	6

Single Use Sprayer



Model Name	Compatible Endoscopes	
	Instrument Channel Diameter [mm]	Working Length [mm]
TJ-D2418PB	2.8	1800
TJ-D2423PB	2.8	2300

PENTAX Medical

Reusable Accessories (Autoclavable)

Reusable Crocodile Biopsy Forceps



Model Name	Compatible Endoscopes		Note
	Instrument Channel Diameter [mm]	Working Length [mm]	
KA1806S	1.8	600	Autoclavable
KA1811S	2.0	1100	
KA1815S	2.0	1500	
KA2411S	2.8	1100	
KA2415S	2.8	1500	
KA2422S	2.8	2200	

Reusable Biopsy Forceps with Window



Model Name	Compatible Endoscopes		Note	
	Instrument Channel Diameter [mm]	Working Length [mm]		
KW1511S	2.0	1100	Autoclavable	
KW1806S	2.0	600		
KW1811S	2.0	1100		
KW1815S	2.0	1500		
KW1818S	2.0	1800		
KW1818CS	2.0	1800		for ERCP scopes
KW2211S	2.4	1100		
KW2215S	2.4	1500		
KW2218CS	2.4	1800		for ERCP scopes
KW2411S	2.8	1100		
KW2415S	2.8	1500		
KW2418S	2.8	1800		
KW2422S	2.8	2200		
KW2430S	2.8	3000		