

for BK Medical Ultrasound Scanners

Product Data

USES

- Investigating the anal sphincter
- Investigating the rectal wall
- Preoperative evaluation for treatment planning
- Transurethral capabilities for the urethra and bladder

BENEFITS

- One transducer suitable for all transrectal and transurethral examinations
- Provides a full 360° transverse image
- Superb imaging technique for the anal sphincter – sphincter defects are clearly seen
- Increased post-operative control possible to detect small recurrences at an early stage, and can increase the chances of curative surgery.

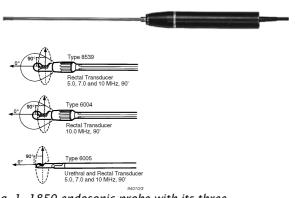


Fig. 1 1850 endosonic probe with its three transducer heads: 8539, 6004 and 6005. (Note the scanning planes for each of the transducer heads)

General Description

Endosonic Probe Type 1850 is a mechanical sector transducer designed for use with ultrasound scanners from BK Medical.

Applications

1850 is designed for anorectal and transurethral examinations. It has a rotating shaft to give a full 360-degree transverse scan image without the operator having to move the handle. Three interchangeable transducer heads (Fig. 1) are available that can be mounted on the 1850 probe handle and can scan through 360°:

- 6005 urethral and rectal transducer head is used for scanning the bladder, rectum and anal canal. It has a frequency range of 5 to 10MHz.
- 8539 head is used for scanning the anal canal. It has a frequency range from 5 to 10MHz.
- 6004 is designed to scan the anal canal and rectal wall. It has a frequency of 10MHz.

The EA4006 RASHA applicator is intended for use with 1850 when it is set up for rectal scanning. The applicator is designed as an aid for inserting High Dose Rate (HDR) radioactive seeds into a low rectal tumor.

The single-use rectosigmoidoscope, obturator and grip (UA0681), is a sterile kit, designed to be used with 1850 to examine the rectum. A light source cable adaptor can be attached to the rectosigmoidoscope and grip.

Interventional Procedures

During interventional procedures, the ultrasound scanner superimposes a puncture line on the scan image to help you guide the needle to its target. 1850 uses the puncture attachment UA0650 (optional) with a bore diameter of 2.1 mm.

Cleaning and Disinfection

1850 and its puncture attachment UA0650 can be disinfected by immersion in the solutions listed under Specifications. The puncture attachment can also be autoclaved.

Safety

1850 is designed and tested in accordance with EN60601-1 (IEC60601-1), "Medical Electrical Equipment, General Requirements for Safety." When used with BK Medical's ultrasound scanners, Type B requirements are met.

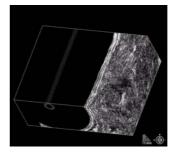


Fig. 2 3D image of the rectal wall in 80Y male, taken with transducer 1850

Specifications 1850

SAFETY:

When used with BK Medical's ultrasound scanners, this transducer complies with Safety Standard EN60601-1 (IEC60601-1) Type B

FREQUENCY RANGE: 6004: 10MHz 6005 and 8539: 5-10MHz.

OPERATIONAL FACILITIES:

Built-in control button Three interchangeable transducer heads

ENVIRONMENTAL: Operating pressure: 700-1060hPa (normal atmospheric pressure)

Operating temperature: +10 to +40°C (+50 to +104°F)

Storage temperature -25 to +70°C (-13 to +158°F) Watertight immersion time Max 15 hours per 24 hours

Watertight immersion temperature Max +40°C (+104°F)

Resistance to chemicals during disinfection Immersion for less than 10 minutes in each hour in: Chlorhexidine gluconate (5-20%)

Immersion in the following solutions, following manufacturer's instructions (but not exceeding maximum watertight immersion time specified for this transducer):

- Glutaraldehyde (2-3.4% in water) Ethanol 70%
- Wiping with Ethanol (70% in water)

The following disinfectants can also be used:

- Korsolex[®] Basic
- Korsolex[®] Extra
- Cidex[®] OPA
- PeraSafe*/ PeraSafe LG

OVERLOAD

Torque-controlled motor shutdown

POWER SUPPLY: Internally from scanner

CABLE LENGTH: 2.3 m (7.5 ft)

OVERALL DIMENSIONS Length: 514 mm excluding transducer head

WEIGHT 0.6kg (1.3lb.)

TRADEMARKS

- Korsolex is a registered trademark of Bode Chemie Gmbh.
- PeraSafe is a registered trademark of Antec International.
- Cidex OPA is a registered trademark of Advanced Sterilization Products (ASP), a Johnson & Johnson Company.

	Units	Transducers for 1850 Endosonic Probe						
	onits	6004 6005			8539			
Number of elements		One	One			One		
Center frequency	MHz	10	5	7.5	10	5	7.5	10
Crystal diameter	mm	6	5 6					
Focal length (typical)*	mm	17	15 20					
Focal range (typical)*	mm	15-40	5-30			10-40		
Focal area*	mm²	1	1.3	1	1	1.8	1.8	1.6
Focal beam width*	mm	1	1.2	1.1	1.1	1.5	1.5	1.4
Axial resolution (measured at 25 mm)**	mm	0.3	0.5	0.4	0.4	0.4	0.3	0.3
Axial resolution on Flex Focus 1202 (measured at 45 mm)**	mm	0.5	0.7	0.6	0.6	1	1	0.9
Lateral resolution**	mm	1.4	1.9	2.2	1.6	1.8	1.9	1.8
Lateral resolution on flex Focus 1202**	mm	0.9	1.5	1.2	0.7	1.6	1.8	1.6
Absolute max ultrasonic power*	mW	10	10 15 15		10			
Basic scanning modes	-	В	В В					
Sector angle	_	360°	360°		360°			
Penetration depth**	mm	47	65	65	65	65	65	65
Beam angle to rotating axis	•	90	90 90					
Length	mm	53	40 53					
Diameter	Mm	13	6.9 13					
Weight (approximate)	g	15	5 15					
Applications (typical)	-	Transrectal (anal canal and rectum)	Intraoperative (urethra, bladder) Transrectal (rectum) Transrectal					
Scanner types supported		2202 and 1202						

Values measured in water Measurements according to IEC/TS 61390 and JIS T 1501. Penetration depth limited by max image depth. For definition of terms, refer to Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, AIUM/NEMA 2004

Ordering Information 1850

ACCESS	ORIES AVAILABLE	6004 trar	
UA0650	Perineal Puncture Attachment	6004:	Rectal transducer, 10MHz,90°
	for transrectal and endoanal		
	applications (bore diameter	Accessor	ies for 8539 and 6004
	2.1 mm)	UA0878:	17mm rectal tube (including
6005 transducer			QS0011 lubricant and UA0799
6005:	Urethral and rectal transducer,		rubber sheaths)
	5, 7.5 and 10MHz, 90°		Hood for UA0878
			Plastic hood for UA0878
Accessor	ies for 6005	UA0799:	Water stand-off rubber sheaths
UA0652:	Storz adaptor		(pack of 100)
WQ0410:	Storz sheath	YJ0621:	O-rings for WA0543/EA4020
WA0500:	10mm tube (including WA0499	YA0514:	Inner cylindrical ring for
	and WA0597 hoods and		UA0878
	QS0011 lubricant)	YM1615:	···· ·· · · · · · · · · · · · · · · ·
WA0499:	Convex hood for WA0500		UA0878
WA0597:	Slim hood for WA0500	UA0681:	
WS3416:	Hood for WA0637		rectosigmoidoscope kit
		UA0682:	Light cable adaptor for UA0681
			(reusable)
8539 trar	isducer		
8539:	Rectal transducer, 5, 7.5 and		ies for 3D scanning*
	10MHz,90°	UA0553:	Variable friction support arm

MISCELLANEOUS						
EA4006:	RASHA applicator					
YJ0632:	O-ring for sealing between					
	1850 and rectal tubes					
YJ0619:	O-ring for crystals					
QS0011:	Lubricant					

TRANSDUCER COVERS UA0799: Water-standoff SI

UA0799:	Water-standoff Sheaths (pack of 100)
UA0069:	Sterile, latex covers (24 pcs).

* For 3D options, contact your local BK Medical representative

1850 Technical Drawings

