



Biplane and Endfire Transducer Type 8818 for BK Medical Ultrasound Scanners

Product Data

USES

- Transrectal prostate scanning
- Transrectal puncture and biopsy
- Transperineal puncture and biopsy
- Transvaginal scanning
- Spectral and CFM Doppler examinations
- Contrast imaging with Pro Focus 2202³
- HistoScanning (tissue differentiation)*

BENEFITS

- Combines simultaneous biplane and endfire imaging in a single transducer
- Superior image quality
- Examine all parts of the prostate with excellent orientation
- Switch easily between biplane and endfire scanning using built-in control buttons
- Perform biplane and endfire biopsies without switching equipment using the unique dual biopsy guide
- Sleek design minimizes patient discomfort
- Compatible with modern sterilization methods
- Sterile-packed biopsy guides available



8818 biplane and endfire transducer assembled for transrectal puncture

General Description

The 8818 is a simultaneous biplane and endfire transducer designed for use with the Pro Focus 2202 and Flex Focus 1202 ultrasound scanners. It has two convex arrays, one for transverse scanning and one for sagittal and endfire scanning.

The convex array has a sector angle of 140°. With the Expanded Sector feature, the sector angle is widened to approximately 180° providing an even better view.

Applications

The 8818 is designed for prostate scanning. The 8818 enables both transrectal and transperineal puncture and biopsy.

Interventional Procedures

Transrectal Biopsy

Transrectal puncture and biopsy can be performed using simultaneous biplane or endfire scanning.

The advantage of simultaneous biplane scanning, where both the sagittal and transverse planes are visualized live at the same time, is that the needle is visible in both planes throughout the puncture and biopsy procedures. Use biopsy guide UA1326 or sterile-packed UA1322-S.

Endfire scanning, where scanning occurs in the lower portion of the sagittal array, is particularly good for apical biopsies of the prostate. Use biopsy guide UA1327 or sterile-packed UA1323-S.

The unique dual biopsy guide UA1328 shown in Fig. 2, houses both simultaneous biplane and endfire needle guides in a single accessory so equipment changes are not required if an exam requires both types of scanning. Biopsy guide UA1329-S is a sterile-packed dual biopsy guide.

All biopsy guides have an internal diameter of 1.6mm (17 gauge).

Transperineal Biopsy

The metal puncture attachment UA1324 is designed for transperineal puncture and biopsy. It consists of a needle guide and a mounting ring with a locking clamp.

The needle guide has nine parallel guide channels spaced 5mm apart, each with an internal diameter of 2.1mm (14 gauge). The guide channels are angled at 0° to the transducer's longitudinal axis and 90° to its transverse axis. The needle guide can be adjusted 70mm lengthwise with respect to the mounting ring, using the adjustment screw.

Multifrequency Imaging

The 8818 transmits at 6, 9 and 12 MHz. It can be used for tissue harmonic imaging and contrast imaging with the Pro Focus 2202 scanner.

Cleaning and Disinfection

The 8818 can be disinfected by immersion in the solutions listed under Specifications. The transducer is compatible with STERRAD® 50, 100S and 200 systems and STERIS SYSTEM 1®**. The puncture attachments can be disinfected by immersion and can be autoclaved. Single-use biopsy guides are also available.

Sterile transducer covers are available.

Safety

The 8818 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 BF requirements are met.

* HistoScanning has not been market cleared by the FDA for use in the USA.
** STERIS SYSTEM 1 is not market cleared in the USA.

Specifications 8818

<p>SAFETY: Complies with Type BF requirements of EN60601-1 (IEC 60601-1)</p> <p>FREQUENCY RANGE: 4-12MHz (depending on scanner)</p> <p>OPERATIONAL FACILITIES: Two built-in control buttons</p> <p>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 temperatures: Max. +40°C (+104°F) Watertight immersion time: Max. 15 hours per 24 hours Resistance to chemicals during</p>	<p>disinfection: Immersion for less than 10 minutes in each hour in: ■ Chlorhexidine gluconate (5-20%)</p> <p>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) ■ Korsolex® ■ Tristel® ■ PeraSafe® ■ Cidex OPA®</p> <p>■ Wiping with: Ethanol (70% in water)</p> <p>■ Transducer 8818 is compatible with STERRAD® 50, 100S and 200 systems and STERIS SYSTEM 1®*.</p> <p>POWER SUPPLY: Internally from scanner</p>	<p>CABLE LENGTH: 2.3m (7.5ft)</p> <p>TRADEMARKS ■ Korsolex is a registered trademark of Bode Chemie GmbH. ■ Tristel is a registered trademark of Tristel Pharmaceutical. ■ PeraSafe is a registered trademark of Antec International. ■ STERRAD and Cidex OPA are registered trademarks of Advanced Sterilization Products (ASP), a Johnson & Johnson Company. ■ STERIS and STERIS SYSTEM 1 are registered trademarks of STERIS Corporation.</p> <p>* STERIS SYSTEM 1 is not market cleared in the USA</p>
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	Units	Pro Focus 2202			Flex Focus 1202		
Scanning planes		Transverse, sagittal and endfire			Transverse, sagittal and endfire		
Center frequency	MHz	6	9	12	6	9	12
Doppler frequency	MHz	5	6	7.5	5	6	7.5
Tissue Harmonic frequency	MHz	8	10	12	8	10	12
Contrast frequency	MHz	4 and 4.3			-		
Number of elements		128+192					
Radius of curvature	mm	10					
Transverse plane aperture	mm	5.5					
Transverse focal length (typical)	mm	40					
Image plane aperture	mm	23					
Image plane focal length	mm	variable					
Axial resolution*	mm	0.3(T), 0.4(S), 0.3(E)	0.3(T), 0.3(S), 0.3(E)	0.2(T), 0.3(S), 0.2(E)	0.4(T), 0.3(S), 0.3(E)	0.4(T), 0.3(S), 0.4(E)	0.4(T), 0.3(S), 0.4(E)
Lateral resolution*	mm	1.5(T), 1.9(S), 2(E)	1.2(T), 1.7(S), 1.8(E)	1.3(T), 1.7(S), 1.2(E)	0.9(T), 1.8(S), 1.8(E)	0.8(T), 1.4(S), 1.5(E)	0.8(T), 1.7(S), 1.5(E)
Image field		140°					
B-mode image field including expanded sector		180°					
Basic scanning modes		B, M, CFM, Doppler, Tissue Harmonic imaging, Contrast imaging**			B, M, CFM, Doppler, Tissue Harmonic imaging		
Penetration depth*	mm	90(T), 91(S), 88(E)***	81(T), 80(S), 77(E)	67(T), 67(S), 62(E)	91(T), 97(S), 92(E)	75(T), 79(S), 76(E)	70(T), 72(S), 73(E)
Focal range	mm	3-60					
Frame rate (max)	Hz	60					
Contact surface (acoustic)	mm	34.4 x 5.5					
Total dimensions	mm	36 x 39 x 323					
Size of handle	mm	36 x 39 x 146					
Weight (approximate)		230					
Applications (typical)		Transrectal, Transvaginal					

* Measurements according to IEC/TS 61390 and JIS T 1501. Penetration depth is measured at 0.7dB/cm/MHz and recalculated corresponding to a realistic tissue attenuation of 0.5 dB/cm/MHz. Axial resolution (measured at 26 mm for endfire and sagittal, 45 mm for transverse)

** In the USA, contrast-enhanced ultrasound has not been market cleared by the FDA, with the exception of only select cardiac imaging applications.

*** Penetration depth limited by the scanner

For definitions of terms, refer to Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, AIUM/NEMA, 2004.

Ordering Information 8818

ACCESSORIES INCLUDED:

UA1325 Dummy channel bracket

ACCESSORIES AVAILABLE:

KE 4300 Carrying case
QZ0040 Cleaning brush
UA1404 Leakage Testing Kit
UA0513 Magnetic wheel mover for 3D scanning
UA0512 Mover adaptor ring for UA0513

Endfire biopsy guides*

UA1327 Reusable (bore diameter 1.6 mm; angle of insertion 0° to the long axis of the transducer)
UA1323-S Single use, sterile-packed. Pack of 18

Simultaneous biplane biopsy guides*

UA1326 Reusable (bore diameter 1.6 mm; angle of insertion 19° to the long axis of the transducer)
UA1322-S Single use, sterile-packed. Pack of 18

Dual biopsy guides*

UA1328 Reusable (bore diameter 1.6 mm; angle of insertion 0° and 19° to the long axis of the transducer)
UA1329-S Single use, sterile-packed. Pack of 18
UA1329-S1: Dual biopsy guide sample. For demo purposes only.

Perineal puncture guide

UA1324 Perineal puncture attachment (bore diameter 2.1 mm; angle of insertion 0° to the long axis of the transducer)

TRANSDUCER COVERS

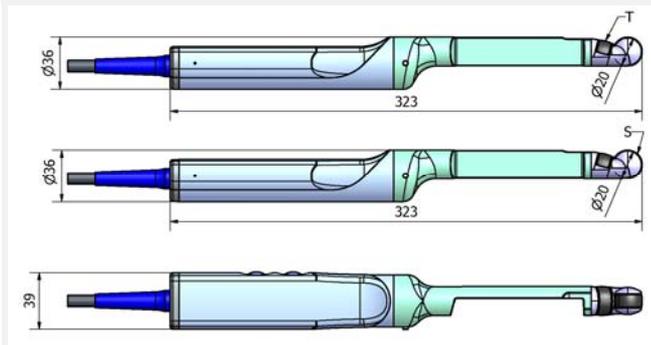
UA0008 CIV-Flex™, sterile, latex-free transducer cover (pack of 24)
UA0032 Transducer cover (pack of 24) Latex
UA0069 Latex covers, sterile (pack of 24)

CIV-Flex is a trademark of CIVCO Medical Instruments Co., Inc.

*All biopsy guides include needle guides

Technical Drawings

All measurements are in mm.



Perineal Puncture Guide UA1324

- Weight: 125g
- Dimensions: 101 x 95 x 50mm
- Material: stainless steel AISI303



Dual Biopsy Guide UA1329-S

- Weight: 21g
- Dimensions: 180 x 45 x 28mm
- Material: ABS (Terlux), Stainless steel AISI304 and XCR12Ni17.7



Endfire Biopsy Guide UA1327

- Weight: 18g
- Dimensions: 150 x 28 x 28mm
- Material: PEI (Ultem), stainless steel AISI304 and XCR12Ni17.7



Simultaneous Biplane Biopsy Guide UA1326

- Weight: 21g
- Dimensions: 116 x 42 x 28mm
- Material: PEI (Ultem), stainless steel AISI304 and XCR12Ni17.7



Endfire Biopsy Guide UA1323-S

- Weight: 14g
- Dimensions: 150 x 28 x 28mm
- Material: ABS (Terlux), Stainless steel AISI304 and XCR12Ni17.7



Simultaneous Biplane Biopsy Guide UA1322-S

- Weight: 14g
- Dimensions: 120 x 45 x 28mm
- Material: ABS (Terlux), stainless steel AISI304, AISI303 and XCR12Ni17.7



Dual Biopsy Guide UA1328

- Weight: 30g
- Dimensions: 180 x 42 x 28mm
- Material: PEI (Ultem), stainless steel AISI304 and XCR12Ni17.7



Dummy Channel Bracket UA1325

- Weight: 11g
- Dimensions: 110 x 24 x 28mm
- Material: PEI (Ultem) and stainless steel XCR12Ni17.7

