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Sonosite Edge II

P21x Transducer User Guide Supplement

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Caution United States federal law restricts this device to sale by or on the order of a physician.

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Introduction

This user guide supplement provides information on the P21x transducer, compatible with the Sonosite Edge II ultrasound system.

The Sonosite Edge II ultrasound system is a general purpose ultrasound system. It is intended for use by qualified physicians and healthcare professionals for evaluation by ultrasound imaging or fluid flow analysis of the human body.

FUJIFILM Sonosite is adding an existing transducer, the P21x, to the Sonosite Edge II ultrasound system in compliance with USFDA Guidance Marketing Clearance of Diagnostic Ultrasound Systems and Transducers issued June 27, 2019. The P21x transducer is already marketed for use on Sonosite M-Turbo ultrasound system. This supplement adds the transducer with limited exam types to the Sonosite Edge II ultrasound systems, which are cardiac, abdomen and lung.

The clinical indication for the Sonosite Edge II does not change from previous clearance.

In accordance with the Enforcement Policy for Imaging Systems Used During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency, FUJIFILM Sonosite reminds users that imaging devices are not intended for the diagnosis of COVID-19. In vitro diagnostic testing is currently the only definitive method to diagnose COVID-19.

Document conventions

The document follows these conventions:

- A **WARNING** describes precautions necessary to prevent injury or loss of life.
- A **Caution** describes precautions necessary to protect the products.
- A **Note** provides supplemental information.
- Numbered and lettered steps must be performed in a specific order.
- Bulleted lists present information in list format but do not imply a sequence.

For a description of labeling symbols that appear on the product, see "Labeling symbols" in the ultrasound system user guide.

Getting Help

For technical support, please contact FUJIFILM Sonosite as follows:

Phone (U.S. or Canada)	+1-877-657-8118
Phone (outside U.S. or Canada)	+1-425-951-1330, or call your local representative
Fax	+1-425-951-6700
Email	ffss-service@fujifilm.com
Web	www.sonosite.com
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Imaging modes

Table 1: Available exam types and imaging modes

Transducer	Exam type	Imaging mode			
		2D M Mode	Color[a]	PW Doppler[b]	CW Doppler
P21x	Abdomen	✓	CVD, CPD	✓	—
	Cardiac	✓	CVD, Var	✓	✓
	Lung	✓	CVD, CPD	✓	—

[a]Var = Color Doppler Variance, which is available in the cardiac exam only. CPD = Color Power Doppler, which is available in all exams except the cardiac exam type. CVD = Color Velocity Doppler.

[b]For the cardiac exam type, PW TDI is also available.

Cleaning and disinfecting

Table 2: Approved cleaners

Product	Compatible transducer	Minimum wet contact time[a]
SaniCloth AF3[b]	P21x	3 minutes
PI-Spray II	P21x	10 minutes

[a] For maximum effectiveness, the component being cleaned must remain wet with disinfectant for a minimum period of time.

[b] Qualified for use as an intermediate-level disinfectant for mycobacteria.

Refer to the cleaners and disinfection document available at **www.sonosite.com** for a complete list of the most current cleaners and disinfectants.

Table 3: Approved high-level compatible disinfectants

Disinfectant[a]	Compatible transducer	Temperature	Disinfectant soak duration
Cidex	P21x	25°C, 77°F	45 minutes

[a]Refer to the cleaners and disinfection document available at **www.sonosite.com** for a complete list of the most current cleaners and disinfectants.

Table 3: Approved high-level compatible disinfectants

Disinfectant[a]	Compatible transducer	Temperature	Disinfectant soak duration
Cidex OPA	P21x	20°C, 68°F	12 minutes

[a]Refer to the cleaners and disinfection document available at **www.sonosite.com** for a complete list of the most current cleaners and disinfectants.

Safety

WARNING To avoid device damage or patient injury, do not use the P21x needle-guide bracket on patients with pacemakers or medical electronic implants. The needle-guide bracket for P21x contains a magnet that is used to ensure that the bracket is correctly oriented on the transducer. The magnetic field in direct proximity to the pacemaker or medical electronic implant may have an adverse effect.

Compatible accessories and peripherals

Table 4: Accessories and peripherals

Description	Maximum Cable Length
P21x transducer[a]	6.0 ft /1.8 m

[a]For transducers, maximum cable length is measured between the strain reliefs. The stated lengths do not include the lengths of cable in the following locations: underneath the strain reliefs, inside the transducer enclosure, or inside the transducer connector.

Labeling symbols

Table 5: Standards labeling symbols

Symbol	Title	Standards development organization (SDO)	Reference number	Description
MD	Medical Device	EU MDR	EU MDR Annex I, 23.2 (q)	Indicates the item the label is adhered to is categorized as a medical device per the MDR, Annex 1, 23.2, q.

This is in addition to the labeling symbols listed in the Sonosite Edge II ultrasound system user guide.

Acoustic output

Guidelines for reducing MI and TI

Table 6: Guidelines for reducing mechanical index (MI)

Transducer	Depth
P21x	↑

↓Decrease or lower setting of parameter to reduce MI.
↑Increase or raise setting of parameter to reduce MI.

Table 7: Guidelines for reducing thermal index (TI)

Transducer	CPD Settings						PW Settings
	Box Width	Box Height	Box Depth	PRF	Depth	Optimize	
P21x		↓		↓	↑		↓ (PRF)

↓Decrease or lower setting of parameter to reduce TI.
↑Increase or raise setting of parameter to reduce TI.

Output display

Table 8: TI or MI ≥1.0

Transducer	Index	2D/ M Mode	CPD/ Color	PW Doppler	CW Doppler
P21x	MI	Yes	Yes	Yes	No
	TIC, TIB, or TIS	Yes	Yes	Yes	Yes

Transducer surface temperature rise

Table 9: Transducer Surface Temperature Rise, External Use (°C)

Test	P21x
Still air	17.2
Simulated use	8.5

Acoustic output tables

Table 10: Transducer model: P21x Operating mode: 2D

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		1.4	(a)		(a)		2.3
Index component value			#	#	#	#	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	1.92					
	P (mW)		#		#		171.7
	P_{1x1} (mW)		#		#		
	z_s (cm)			—			
	z_b (cm)					—	
	z_{MI} (cm)	3.65					
	$z_{pii,\alpha}$ (cm)	3.65					
	f_{awf} (MHz)	1.93	#		#		1.94
Other information	*prr* (Hz)	4444					
	srr (Hz)	34.7					
	n_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	192					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	31.5					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	41.9					
	p_r at z_{pii} (MPa)	2.44					
Operating controls	Exam type	Crd					Crd
	Optimization	Res					Pen
	Depth (cm)	4.7					27
	MB/THI	On					Off
	Sector Width	Any					Narrow

(a) This index is not required for this operating mode; value is <1.
(b) This transducer is not intended for transcranial or neonatal cephalic uses.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference global maximum index value line.)
— Not applicable for this transducer/mode.

Table 11: Transducer model: P21x Operating mode: M Mode

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		1.4	(a)		1.4		1.1
Index component value			#	#	0.3	1.4	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	1.94					
	P (mW)		#		79.5		79.7
	P_{1x1} (mW)		#		32.2		
	z_s (cm)			#			
	z_b (cm)					3.50	
	z_{MI} (cm)	5.1					
	$z_{pii,\alpha}$ (cm)	5.1					
	f_{awf} (MHz)	1.93	#		1.93		1.94
Other information	*prr* (Hz)	800					
	srr (Hz)	—					
	n_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	295					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	197.8					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	396.2					
	p_r at z_{pii} (MPa)	2.72					
Operating controls	Exam type	Abd			Crd		Abd
	Optimization	Res			Pen		Pen
	Depth (cm)	10.2			30		32
	THI	On			Off		Off

(a) This index is not required for this operating mode; value is <1.
(b) This transducer is not intended for transcranial or neonatal cephalic uses.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference global maximum index value line.)
— Not applicable for this transducer/mode.

Table 12: Transducer model: P21x Operating mode: CPD/Color

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		1.4	1.3		1.3		2.4
Index component value			1.3	1.3	1.3	1.3	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	1.94					
	P (mW)		135.6		135.6		134.4
	P_{1x1} (mW)		121.7		121.7		
	z_s (cm)			—			
	z_b (cm)					—	
	z_{MI} (cm)	5.1					
	$z_{pii,\alpha}$ (cm)	5.1					
	f_{awf} (MHz)	1.93	2.16		2.16		2.16
Other information	*prr* (Hz)	881					
	srr (Hz)	13.8					
	n_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	295					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	9.6					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	13.2					
	p_r at z_{pii} (MPa)	2.72					
Operating controls	Mode	CVD	CVD		CVD		CVD
	Exam type	Abd	Lung		Lung		Lung
	2D Optimization/Depth (cm)	Pen/7.5	Pen/4.7		Pen/4.7		Pen/4.7
	Color Optimization/PRF	Med/Any	Med/2500 Hz		Med/2500 Hz		Med/ 1524 Hz
	THI	On	N/A		N/A		N/A
	Color box size	Any	Small		Small		Small

(a) This index is not required for this operating mode; value is <1.
(b) This transducer is not intended for transcranial or neonatal cephalic uses.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference global maximum index value line.)
— Not applicable for this transducer/mode.

Table 13: Transducer model: P21x Operating mode: CW Doppler

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		(a)	1.0		3.6		3.1
Index component value			1.0	0.9	1.0	3.6	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	#					
	P (mW)		108.8		108.8		108.8
	P_{1x1} (mW)		108.8		108.8		
	z_s (cm)			1.2			
	z_b (cm)					1.2	
	z_{MI} (cm)	#					
	$z_{pii,\alpha}$ (cm)	#					
	f_{awf} (MHz)	#	2.0		2.0		2.0
Other information	prr (Hz)	#					
	srr (Hz)	#					
	n_{pps}	#					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	#					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	#					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	#					
	p_r at z_{pii} (MPa)	#					
Operating controls	Exam type		Crd		Crd		Crd
	Sample volume position		Zone 0		Zone 0		Zone 0

(a) This index is not required for this operating mode; value is <1.
(b) This transducer is not intended for transcranial or neonatal cephalic uses.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference global maximum index value line.)
— Not applicable for this transducer/mode.

Table 14: Transducer model: P2 1x Operating mode: PW Doppler

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		1.2	1.3		3.7		2.8
Index component value			0.8	1.3	1.0	3.7	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	1.73					
	P (mW)		200.3		93.8		201.2
	P_{1x1} (mW)		78.4		93.8		
	z_s (cm)			3.1			
	z_b (cm)					0.60	
	z_{MI} (cm)	5.0					
	$z_{pii,\alpha}$ (cm)	5.0					
	f_{awf} (MHz)	2.15	2.22		2.17		2.12
Other information	*prr* (Hz)	1562					
	srr (Hz)	—					
	n_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	216					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	400.8					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	830.4					
	p_r at z_{pii} (MPa)	2.5					
Operating controls	Exam type	Crd	Crd		Crd		Crd
	Sample volume size (mm)	1	3		1		1
	PRF (Hz)	1563	3906		15625		3906
	Sample volume position	Zone 2	Zone 4		Zone 0		Zone 5

(a) This index is not required for this operating mode; value is <1.
(b) This transducer is not intended for transcranial or neonatal cephalic uses.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference global maximum index value line.)
— Not applicable for this transducer/mode.

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