
P11x Transducer

User Guide P16677-01

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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 *P11x Transducer User Guide* provides information specific to using the P11x/10-5 MHz transducer with the AxoTrack™ I Sterile Procedure Kit on the AxoTrack feature-enabled SonoSite M-Turbo ultrasound system. Contact your SonoSite representative if the AxoTrack feature is not enabled.

The user guide is for a reader familiar with ultrasound techniques. It does not provide training in sonography or clinical practices. Before using the system, you must have ultrasound training. To aid in safeguarding the patient and ensuring reliable transducer operation, SonoSite recommends users be trained in the use of the AxoTrack technology.

Refer to the *M-Turbo Ultrasound System User Guide* for instructions on system operations and connecting the transducer.

Refer to *Disinfectants for SonoSite Products* for a list of products approved for cleaning and disinfecting the P11x transducer. See www.sonosite.com.

For information on preparing the P11x transducer for use, see *AxoTrack I Sterile Procedure Kit: Instructions for Use*. The P11x transducer is designed for needle guidance procedures specifically with the AxoTrack I Sterile Procedure Kit (manufactured by Soma Access Systems, LLC).

Conventions, symbols and terms

The user guide supplement follows these conventions:

- A **WARNING** describes precautions necessary to prevent injury or loss of life.
- A **Caution** describes precautions necessary to protect the products.

- Numbered steps in procedures must be performed in order.
- Items in bulleted lists do not require a sequence.
- Single-step procedures begin with ❖.

Symbols and terms used on the system and transducer are explained in the *M-Turbo Ultrasound System User Guide*.

Customer comments

Questions and comments are encouraged. SonoSite is interested in your feedback regarding the system and the user guide. Please call SonoSite at 877-299-1783 in the U.S. Outside the U.S., call the nearest SonoSite representative.

For technical support, please contact SonoSite as follows:

SonoSite Technical Support

Phone (U.S. or Canada): 877-299-1783

Phone (Outside U.S. and Canada): 425-951-1330
Or call your local representative.

Fax: 425-951-6700

E-mail: service@sonosite.com

Web site: www.sonosite.com

Intended uses

The P11x transducer is intended for use in the identification of vascular structures and for use with the AxoTrack I Sterile Procedure Kit in the placement of needles and catheters in vascular structures.

Imaging modes

Imaging modes and exams available by transducer

Transducer, Exam Type, and Imaging Mode

Transducer	Exam Type	Imaging Mode				
		2D ¹ M Mode ¹	CPD ²	Color ²	PW Doppler	CW Doppler
P11x	Venous	✓	✓	✓	—	—
	Vascular	✓	✓	✓	—	—

1. The optimization settings for 2D are Res, Gen, and Pen.
2. The optimization settings for Color are low, medium, and high (flow sensitivity) with a range of PRF settings.

Note: A special training mode is available for use with Blue Phantom models. See “To set up training mode” on page 7.

Cleaning and disinfecting

The P11x transducer must be cleaned and disinfected before each exam. In addition to protecting the patients and employees from disease transmission, the disinfectant you choose must be safe for the transducer.

Caution: Exposing the P11x transducer to non-recommended chemical sterilants or submersion of the transducer beyond recommended levels may result in transducer degradation over time, leading to poor image quality or transducer failure. See *Disinfectants for SonoSite Products*.

For recommended cleaners and disinfectants, see the disinfectant list available on www.sonosite.com.

Preparing to use the P11x transducer

Make sure that the AxoTrack I Sterile Procedure Kit packaging has not been opened prior to use. Before using the P11x transducer with the AxoTrack I Sterile Procedure Kit, read the warnings and the instructions in *AxoTrack I Sterile Procedure Kit: Instructions for Use*.

WARNING: Before use, inspect the needle guide receiver on the P11x transducer for excessive wear. If you notice excessive wear, contact SonoSite.

WARNING: The magnet attached to the needle hub may cause electrical interference due to its proximity with other electronic equipment. The magnet must be kept at least 15 cm (6 in) away from an implanted or attached medical device. See *AxoTrack I Sterile Procedure Kit: Instructions for Use* for more information.

WARNING: To avoid device damage or patient injury, do not use the P11x compatible AxoTrack I Sterile Procedure Kit on patients in proximity to pacemakers or medical electronic implants. The needle includes a magnetic hub that is used to track the position of the needle when the sterile procedure kit is attached to the P11x. The magnetic field in direct proximity to the pacemaker or medical electronic implant may have an adverse effect.

WARNING: Bacterial or viral contamination can be caused by:

- Removing the sterile needle guide plug before the transducer is placed in the bottom shield
- Assembling the kit parts in the incorrect order
- Not using sterile gel

WARNING: When using the P11x transducer with the disposable kit, ensure that the disposable shield is properly attached.

Imaging with the P11x transducer

WARNING: When using the P11x transducer with the disposable kit, ensure that the sterile field is maintained throughout the disposable kit assembly procedure.

Before imaging with the P11x transducer, read these warnings and the instructions in *AxoTrack I Sterile Procedure Kit: Instructions for Use*.

WARNING: Failure to make contact between the magnet and the surface of the sterile shield may lead to inaccurate needle tracking and loss of the needle graphic on the ultrasound system.

WARNING: Applying too much force with the needle clamp engaged may lead to needle bending, needle breakage, inaccurate needle tracking, or loss of the needle graphic on the ultrasound system.

- WARNING:** Twisting the syringe to disengage from the needle hub can cause the needle to spin in the clamp, resulting in misorientation of the needle bevel. This misorientation can direct the guide wire into the vessel wall, leading to procedure delay, patient discomfort, or patient injury.
- WARNING:** Needle bending due to torquing to reposition the needle in tissue may lead to procedure delay from feed wire difficulties or an inability to aspirate.
- WARNING:** Application of too much needle force with the needle clamp engaged, or attempting to reposition the needle in tissue, may lead to needle breakage, and, subsequently, procedure delay, patient discomfort, or patient injury.
- WARNING:** Failure to orient the needle bevel correctly can lead to difficulty advancing the guide wire, procedure delay, patient discomfort, or patient injury.
- WARNING:** Virtual needle position error due to transducer, kit, or ultrasound system failure can lead to procedure delay, patient discomfort, or patient injury.
Stop the procedure and contact SonoSite if the system displays warnings or if you notice atypical virtual needle behavior, such as needle image misalignment to the ultrasound image, flashing, or disappearing.
- WARNING:** Attempting to reorient the transducer with the needle inserted can lead to procedural delay, patient discomfort, or patient injury.
- WARNING:** Partial engagement of the needle clamp or failure to fully set the needle clamp can lead to procedure delay, patient discomfort, or patient injury.
- WARNING:** Inserting the needle at too steep of an angle may lead to procedure delay due to difficulty feeding a guide wire or having to restart the procedure.

To turn on the guideline

Before imaging with the P11x transducer, consider using a standard transducer to visualize the anatomy that includes the intended target. For more information, see the *M-Turbo Ultrasound System User Guide*.

Do not rely solely on the visibility of the needle tip on the system display. Use other tactile or visual indicators to confirm you are at or in the vessel. (Example: indentation of anterior wall, decreased resistance as the needle enters the vessel lumen, or blood return in the needle.)

- 1 Choose an Exam Type: Press the EXAM key, and select from the menu.
- 2 Press **Guide**. A dotted guideline appears on the display.

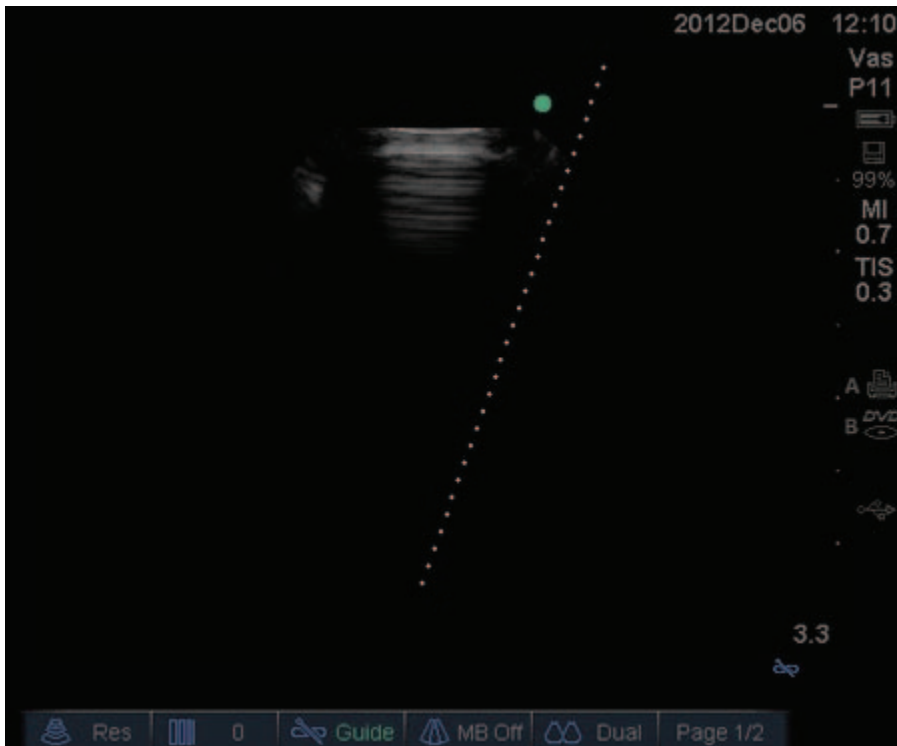


Figure 1 Guideline

- 3** Image with the P11x transducer until the guideline on the display is aligned with the intended target.

Note: Follow the instructions in the AxoTrack I Sterile Procedure Kit: Instructions for Use for holding the probe properly. Failure to do so can lead to unstable positioning on the patient's skin and unintended lateral movement of the needle.

- 4** Insert the needle. The virtual needle image appears superimposed on the guideline. The system displays the virtual depth in centimeters in the lower-right corner of the display.

Note: When inserting the needle in Color Mode, the initial entry of the needle may be obscured by the color bars.

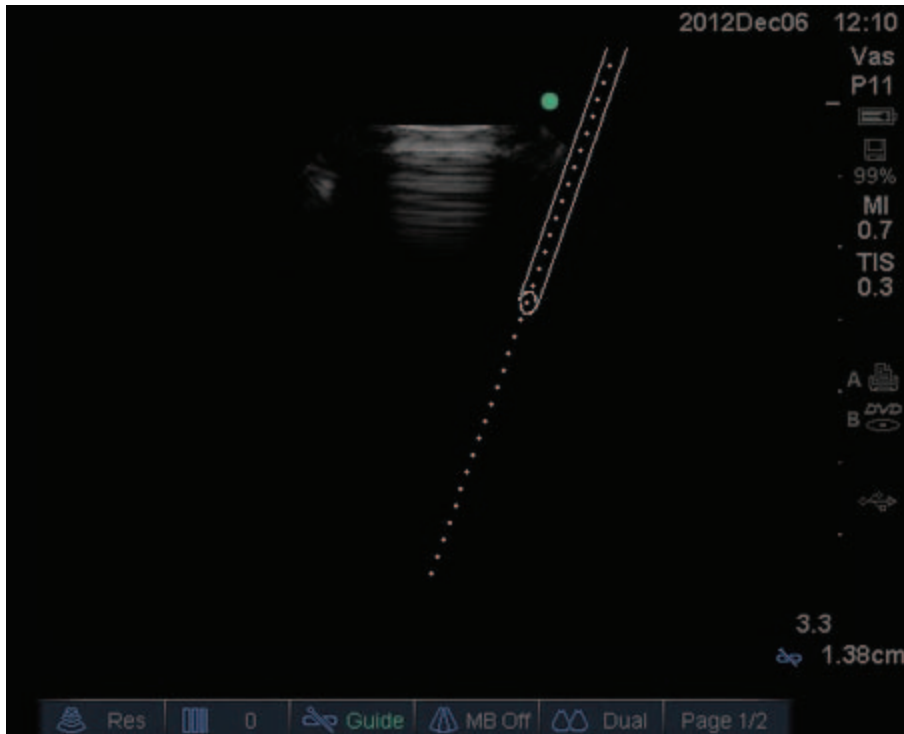


Figure 2 Virtual needle image and depth (lower-right corner of the display)

- 5 Follow the instructions in the *AxoTrack I Sterile Procedure Kit: Instructions for Use* to insert the needle to the desired target and complete the procedure.

If the image quality is not adequate, review the instructions in *AxoTrack I Sterile Procedure Kit: Instructions for Use* to confirm the correct assembly and alignment of the kit components.

Note: Maintain the magnet in contact with the magnet rail. Movement of the magnet away from the rail will cause the virtual needle to disappear from the display.

Training mode

To set up training mode

- 1 Press the PATIENT key.
- 2 Select New/End.
- 3 Type @AXOTRACK in the Last Name field.
- 4 Leave all other fields blank.
- 5 Select Done. The guideline is blue when training mode is active.

To exit training mode

- 1 Press the PATIENT key.
- 2 Select New/End.
- 3 Type any name other than @AXOTRACK in the last Name field.
- 4 Select Done.

Measurements and calculations

The distance between the tip of the graphic overlay (center of needle graphic ellipse) and the sonographic tip is within 2 mm plus 1% of the depth of the needle tip. Only calculations related to 2D, M Mode, and Color apply to the P11x transducer.

Measurement accuracy

The measurements provided by the system are verified on a static bench model and do not account for acoustic anomalies of the body. The 2D linear distance measurement results are displayed in centimeters with two places past the decimal point. The linear distance measurement components for the P11x transducer have the accuracy of +/- 0.4 cm.

Safety

Electrostatic discharge

WARNING: Unless following ESD precautionary procedures, all users and staff must be instructed not to connect to or to touch (with body or hand-held tools) pins of connectors that have the ESD Sensitive Devices symbol:



If the symbol is on a border surrounding multiple connectors, the symbol pertains to all connectors within the border.

ESD precautionary procedures include the following:

- Receive training about ESD, including the following at a minimum: an introduction to the physics of electrostatic charge, the voltage levels that can occur in normal practice, and the damage that can occur to electronic components if equipment is touched by an individual who is electrostatically charged.
- Prevent the buildup of electrostatic charge. For example, use humidification, conductive floor coverings, nonsynthetic clothing, ionizers, and minimizing insulating materials.
- Discharge your body to earth.
- Use a wrist strap to bond yourself to the ultrasound system or to earth.

Guidelines for reducing MI and TI

MI

Transducer	Depth
P11x	↑

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

TI (TIS, TIC, TIB)

Transducer	CPD Settings					
	Box Width	Box Height	Box Depth	PRF	Depth	Optimize
P11x				↓	↓	

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

Output display

TI or MI ≥ 1.0

Transducer Model	Index	2D/ M Mode	CPD/ Color	PW Doppler	CW Doppler
P11x	MI	No	Yes	—	—
	TIC, TIB, or TIS	No	No	—	—

Transducer Surface Temperature Rise, Internal Use (°C)

Test	AxoTrack
Still air	17.0
Simulated use	8.9

Acoustic output tables

Table 1: Transducer Model: P11x

Operating Mode: *Color*

Index Label			M.I.	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.2	(a)	—	—	(b)	
Associated Acoustic Parameter	$p_{r,3}$	(MPa)	2.64					
	W_0	(mW)		#	—		#	
	min of [$W_3(z_1), I_{TA,3}(z_1)$]		(mW)			—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	2.0				—	
	$d_{eq}(z_{sp})$	(cm)					—	
	f_c	(MHz)	4.76	#	—	—	—	#
	Dim of A_{aprt}	X (cm)		#	—	—	—	#
Y (cm)			#	—	—	—	#	
Other Information	PD	(μ sec)	0.675					
	PRF	(Hz)	1425					
	$p_r@PII_{max}$	(MPa)	3.64					
	$d_{eq}@PII_{max}$	(cm)					—	
	Focal Length	FL_x (cm)		#	—	—		#
		FL_y (cm)		#	—	—		#
$I_{PA,3}@MI_{max}$	(W/cm ²)	417						
Operating Control Conditions	Control 1: Exam Type		Ven					
	Control 2: Mode		Color/CPD					
	Control 3: 2D Optimization/Depth		Any/3.3cm					
	Control 4: Color Optimization/PRF		Low/434Hz					
	Control 5: Color Box Position/Size		Any/Tall					

(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 is reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference Global Maximum Index Value line.)

— Data is not applicable for this transducer/mode.



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