Ultrasonix Medical Corporation

SonixGPS 0.55mm Needle Sensor and Nerve Block Needle Kits User Manual

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ULTRASONIX

TABLE OF CONTENTS

CHAPTER 1: SonixGPS™ NEEDLE SENSORS

1.1 SENSOR PACKAGING

Figure 1-1: Sensor with Storage Case

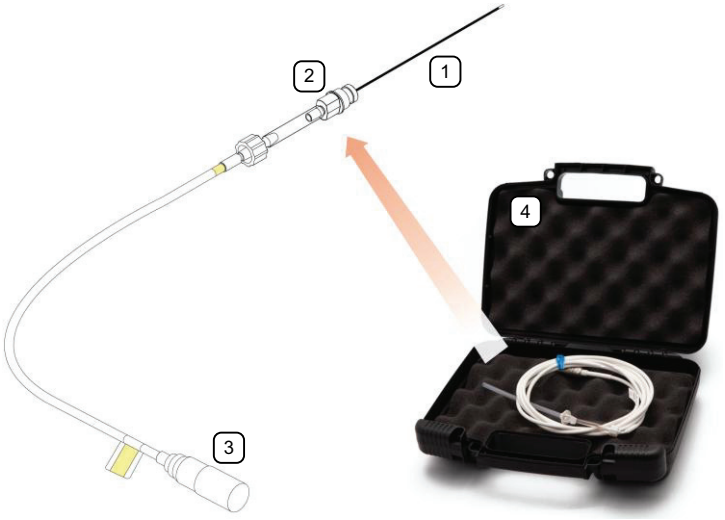


Table 1-1:

1	Sensor head
2	Accessory connector or hub
3	Drive bay connector
4	Storage case

1.2 INTENDED USE

The device is intended to provide physicians with tools for electromagnetic tracking of instruments with respect to image data. Refer to Appendix A for details on the available models.

Warnings:

Federal law restricts this device to sale by or on the order of a physician.

Prior to each use:

- *inspect needle sensor for signs of damage (e.g., nicks or cuts in cables, bent or damaged connector pins, or cracks and/or exterior damage). If damage is evident, discontinue use of needle sensor and contact Ultrasonix Technical Support*

- *test to ensure needle sensor is functioning properly. Follow all directions in Appendix A of the relevant SonixGPS User Manual*
- *ensure needle sensor is properly cleaned and disinfected after each use as it is a non-sterile, reusable device.*

Needle sensor may be subject to distortion from metal objects in the vicinity of the system. Refer to Appendix A in the relevant SonixGPS User Manual for details on determining whether metal distortion exists and how to mitigate it.

Needle sensor comes in non-sterile packaging and is reusable. To avoid possible patient contamination, ensure needle sensor is properly cleaned and disinfected before each use.

Ensure device is securely attached, failure to do so could result in inaccuracy.

SonixGPS Needle Sensor (models 0.9mm and 0.55mm) is for use with SonixGPS disposable needle kits only.

Device must be removed prior to patient defibrillation.

Refer to the relevant SonixGPS User Manual and needle package labels for complete instructions for use.

1.3 CLEANING AND DISINFECTION OF NEEDLE SENSOR

Warnings:

Users of this product have an obligation and responsibility to provide the highest degree of infection control to patients, co-workers and themselves. To avoid cross-contamination, follow infection control policies established by your facility.

Ensure needle sensor does not bend during cleaning and disinfection.

Do not gas sterilize or autoclave needle sensor.

The Ultrasonix needle sensor cleaning and disinfection protocol has been designed and evaluated to ensure efficacy and compatibility. If choosing to employ a reprocessing protocol other than those listed here, process validation must first be completed to ensure effectiveness and compatibility. Failure to comply with these cleaning/disinfecting instructions may result in damage which is not covered by the Ultrasonix warranty.

Figure 1-2: Needle Sensor Immersion Limitations

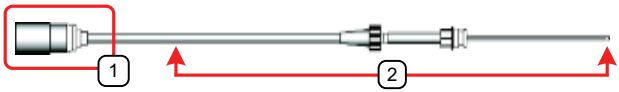


Table 1-2: Needle Sensor Immersion Limitations

1	Sensor Connector. **DO NOT IMMERSE**.
2	Immerse only this section in solution.

Warning: *After every use, clean off all visible contaminants (1.3.1) and disinfect the sensor (1.3.3).*

1.3.1 Cleaning the Sensor

To Clean the SonixGPS Sensor:

1. Remove sensor from system, discarding any single-use, disposable components (2.7.1).
2. Remove visible contaminants from the surface of sensor.
3. Soak sensor (Figure 1-2) for minimum of five (5) minutes in neutral pH, low foaming enzymatic detergent (e.g., ENZOL® Enzymatic Detergent from Johnson & Johnson). If visible contaminants cannot be easily removed, repeat soaking procedure for an additional five minutes.

   Caution: *Do not immerse the entire needle sensor. Refer to Figure 1-2 to confirm needle sensor immersion limitations.*

4. Remove sensor from cleaning solution and remove any remaining residue with dry wipe.

   Caution: *Always consult the cleaning solution manufacturer's instructions to ensure both correct and safe usage.*

1.3.2 Cleaning the Sensor Connector

Apply a small amount of one of the following recommended cleaning solutions to a soft, non-abrasive cloth and wipe the sensor connector:

- water
- mild detergent (PH level at or near 7) and water solution.

1.3.3 Disinfecting the Sensor

Always clean the sensor prior to disinfection (**1.3.1**).

Table 1-3: Recommended Disinfectants

Low Level Disinfectants	High Level Disinfectants
• Super Sani-Cloth®	• Cidex® OPA Solution
• T-Spray™	

To Disinfect the SonixGPS Needle Sensor:

1. Remove sensor from system, discarding any single-use, disposable components.
2. Remove visible contaminants from the surface of sensor (**1.3.1 Cleaning the Sensor**).
3. Using one of the recommended disinfectants (**Table 1-3**), disinfect the needle sensor.

   Caution: *Do not immerse the entire needle sensor. Refer to* **Figure 1-2** *to confirm needle sensor immersion limitations.*

4. After disinfecting the needle sensor, inspect for signs of damage.

   Caution: *If damage is detected, discontinue use and contact Ultrasonix Technical Support.*

CHAPTER 2: INSTRUCTIONS FOR USE: NERVE BLOCK NEEDLE KIT

2.1 INDICATIONS FOR USE

The device is intended for use by a trained physician to puncture the tissue in order to gain entry and locally inject anesthetics to induce regional anesthesia.

Figure 2-1: Nerve Block Needle Kit (for use with 0.55 Needle Sensor)

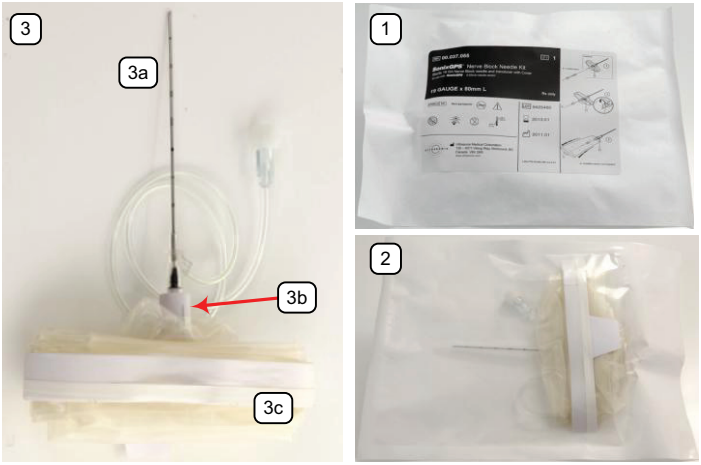


Table 2-1: Nerve Block Needle Kit (for use with 0.55 Needle Sensor)

	Nerve Block needle kit package (front)
1	***Warning:*** *Refer to* **Appendix A**, **Table A-1** *for details on package symbols.*
2	Nerve Block needle kit package (back)
3	Nerve Block needle kit parts
	3a Nerve Block needle
	3b Needle sensor Introducer
	3c Cover

2.2 PRODUCT SPECIFICATION/COMPATIBILITY

SonixGPS Nerve Block needle kit:

- pre-assembled Ga 19 x 80mm Nerve Block needle, Sensor introducer and cover
- compatible with SonixGPS 0.55 needle sensor.

Warnings:

Federal law restricts device sale or use by or on order of a physician.

Prior to use inspect components for signs of damage.

Do not use the Nerve Block needle without the sensor introducer when performing patient insertions.

Do not apply excessive bending force during procedure.

While cannula is being introduced, the cannula tip may be damaged by the application of excessive force upon coming into contact with the bone.

Disposable components are packaged sterile and are single-use only. Do not use if integrity of packaging is violated or if expiration date has passed.

Disposable products may not, under any circumstances, be re-sterilized or reprocessed in any other way. They are to be safely and properly discarded immediately after use.

Follow your institution's procedures for the disposal of all infectious/bio-hazardous materials.

Due to the risk of coming into contact with pathogens which are transferred by blood, the medical staff must apply general precautions as a routine measure for handling of blood and of body fluids with regard to the use and disposal of such products.

Only physicians trained and experienced with vessel cannulation should use this device.

Patient and procedure selection is the responsibility of the physician.

Do not modify the device in any way.

SonixGPS Nerve Block needle kit is for use with SonixGPS 0.55 needle sensor only.

SonixGPS Nerve Block needle kit is an Ultrasonix-approved accessory and shall only be used on an Ultrasonix system licensed with the SonixGPS option.

Special Observance: *Read the following information and application notes carefully.*

The product may only be used by experienced medical staff in accordance with these instructions. Ultrasonix does not make any recommendations regarding a method of treatment. The treating medical specialist staff is responsible for the manner of application and patient selection.

Non-observance or contravention of the instructions will void the guarantee and jeopardize patient safety.

If used in combination with other products, the instructions for use and the compatibility statements of those products must always to be taken into account. Check the product for missing parts or defective packaging before application.

If there is cause for doubt regarding missing parts or defective packaging, do not use the product.

2.3 PRODUCT LINE

Table 2-2: SonixGPS Nerve Block Needle with Bevel-tip

Size	Part Number
19 G x 80mm L (3.15 in)	00.037.055

2.4 PROCEDURE INSTRUCTIONS

Warnings:

Prior to clinical use, employ proper sterile techniques to ensure needle kit needle is securely attached to the needle kit sensor introducer. Inspect needle kit cover to ensure it has no holes or tears and is sealed to needle kit.

Needle sensor may be subject to distortion from metal objects in the vicinity of the system. Refer to Appendix A in the relevant SonixGPS User Manual for details on determining whether metal distortion exists and how to mitigate it.

Note: *The following component is sold separately: SonixGPS Needle Kit including needle, sensor introducer and cover.*

Figure 2-2: Sample Needle Sensor and Kit: Assembled Components

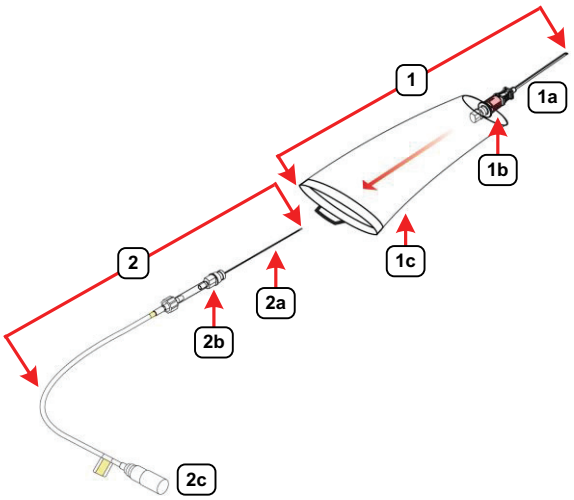


Table 2-3: Sample Needle Sensor and Kit: Assembled Components

1	Disposable Needle Kit
1a	Needle
1b	Sensor introducer
1c	Cover
2	Reusable Needle Sensor
2a	Needle sensor
2b	Accessory connector or hub
2c	Drive bay connector

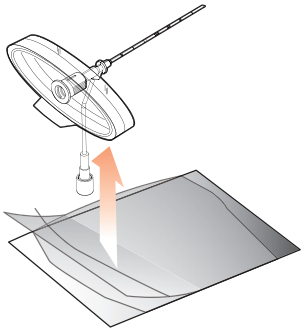
2.5 NEEDLE SYSTEM ASSEMBLY

To Assemble the Nerve Block Needle System:

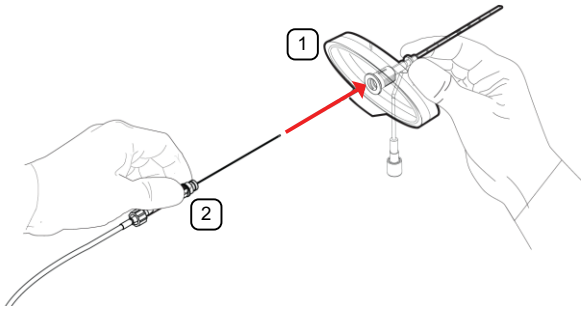
1. Remove the needle sensor from the storage case.

Warning: *Always ensure the needle sensor has been properly cleaned and disinfected (***1.3 Cleaning and Disinfection of Needle Sensor***).*

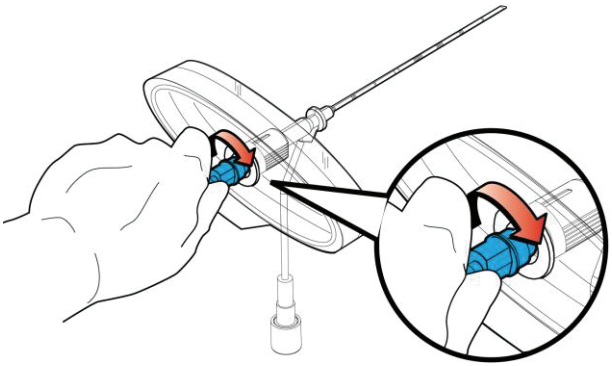
2. Using proper sterile technique, remove Nerve Block needle kit from its package.



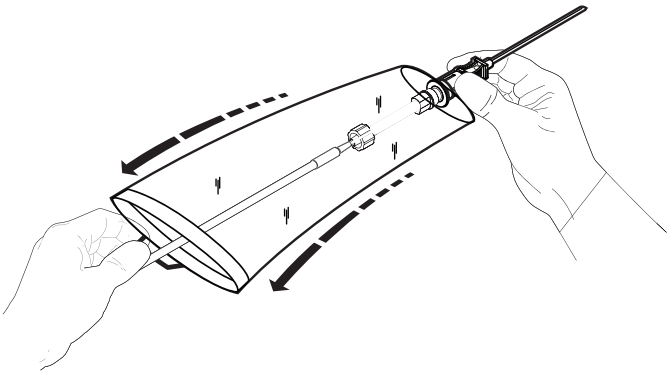
3. Using proper sterile technique, insert SonixGPS 0.55 needle sensor (**2**) through opening in Nerve Block needle kit cover (**1**), taking care to minimize bending of needle sensor.



4. Rotate hub clockwise to lock SonixGPS 0.55 needle sensor into Nerve Block needle kit.



5. Extend needle kit cover over SonixGPS 0.55 needle sensor assembly and along needle sensor cable.



6. Inspect cover to ensure there are no holes or tears.

2.6 NERVE BLOCK APPLICATION

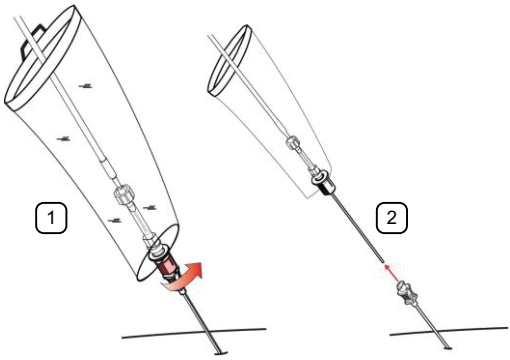
With the Nerve Block needle in place, it is the responsibility of an experienced medical team to ensure proper completion of the anesthesia procedure.

2.7 NEEDLE SYSTEM REMOVAL AND DISPOSAL

2.7.1 Needle System Removal

To Remove the Nerve Block Needle System:

1. Once target is reached, rotate needle sensor hub (with sensor introducer) counter-clockwise (**1**), then carefully lift needle sensor (with sensor introducer and cover) out of the way (**2**).

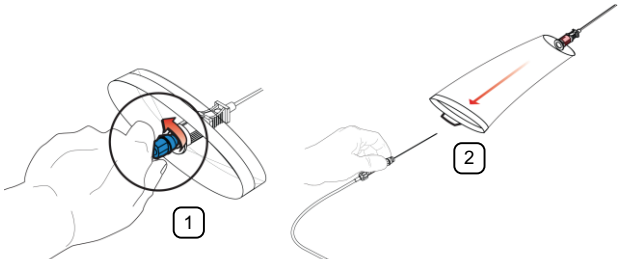


2. Treatment is ready to begin.

2.7.2 Needle System Disposal

To Dispose of the Nerve Block Needle:

1. Rotate needle sensor hub counter-clockwise (**1**), then remove needle sensor from disposable needle (**2**).



2. Dispose of single-use components as infectious waste.
3. Clean and disinfect reusable components after each use (**1.3**).

APPENDIX A: SYMBOLS AND ACCESSORIES

A.1 PACKAGING SYMBOL DEFINITIONS

Table A-1: Packaging Symbols

	**Caution, consult accompanying documents.**
	**Sterilized using Ethylene Oxide.**
	**Batch code/Lot number.**
	**Date of manufacture.**
	**Temperature limitation.**
	**Do not use if package damaged.**
	**Non-Latex.**
	**Catalog/Part number.**
	**Single use disposable.**
	**Use by.**
	**Keep away from sunlight.**
	**Non-sterile.**
	**Manufacturer.**
	**Quantity.**

A.2 SYSTEM ACCESSORIES

Note: *Ultrasonix Medical Corporation reserves the right to alter the available accessories at any time.*

Table A-2: System Specifications

	TCH	MDP	SP	OP
ULTRASONIX ACCESSORIES				
SonixGPS Needle Kits and Accessories:				
SonixGPS Vascular Access Starter Kit (contains 1x 00.037.047 and 1x 00.037.041) (UXID 00.037.050)	♦	♦	♦	♦
SonixGPS 0.9mm Needle Sensor (non-sterile, reusable) (UXID 00.037.047)	♦	♦	♦	♦
SonixGPS Vascular Access Needle Kits (Single use, Sterile Pack of 10, Ga 17 x 70mm L) (UXID 00.037.041)	♦	♦	♦	♦
SonixGPS Nerve Block Starter Kit (contains 1x 00.037.048, 1x 00.037.055) (UXID 00.037.051)	♦	♦	♦	♦
SonixGPS 0.5mm Needle Sensor (non-sterile, reusable) (UXID 00.037.048)	♦	♦	♦	♦
SonixGPS Nerve Block Needle Kits (Single use, Sterile Pack of 10, Ga 19 x 80mm L) (UXID 00.037.055)	♦	♦	♦	♦
THIRD PARTY ACCESSORIES				
SonixGPS Needle Kits and Accessories:				
eTRAX™ Needle Starter Kit, Manufactured by CIVCO, Part Number 610-1055 (UXID 00.037.034)	♦	♦	♦	♦
Civco eTRAX™ Needle Kit, Manufactured by CIVCO, (Pack of 10), 16GA x 17.7cm (7") and 7.6 tapered to 3.8 x 147cm (3" tapered to 1.5" x 58") CIV-Flex needle cover, Part Number 610-1057 (UXID 00.037.039)	♦	♦	♦	♦
Sterile ATEC vacuum-assisted breast biopsy Tracking Bracket, Manufactured by CIVCO, (Pack of 12) Part Number 653-002 (UXID 00.037.037) (Supported models: 9 gauge Standard, Part Number 0909-20; 12 gauge Standard, Part Number 1209-20; 9 gauge Long, Part Number 0912-20; 12 gauge Long, Part Number 1212-20).	♦	♦	♦	♦
Note: *Only the Tracking Bracket is available from Ultrasonix Medical Corporation. Contact ATEC to purchase the needles.*				
Sterile Celero vacuum-assisted breast biopsy Tracking Bracket, Manufactured by Civco, (Pack of 12) Part Number 653-001 (UXID 00.037.036) (Supported model: Cerlero-12)	♦	♦	♦	♦
Note: *Only the Tracking Bracket is available from Ultrasonix Medical Corporation. Contact Hologic to purchase the needles.*				
Non-sterile reusable General Purpose Electromagnetic Sensor Drive bay trakSTAR 8mm, Manufactured by CIVCO, Part Number 610-1066 (UXID 00.037.035)	♦	♦	♦	♦

√ – Standard ♦ – Optional Ø – Not Available