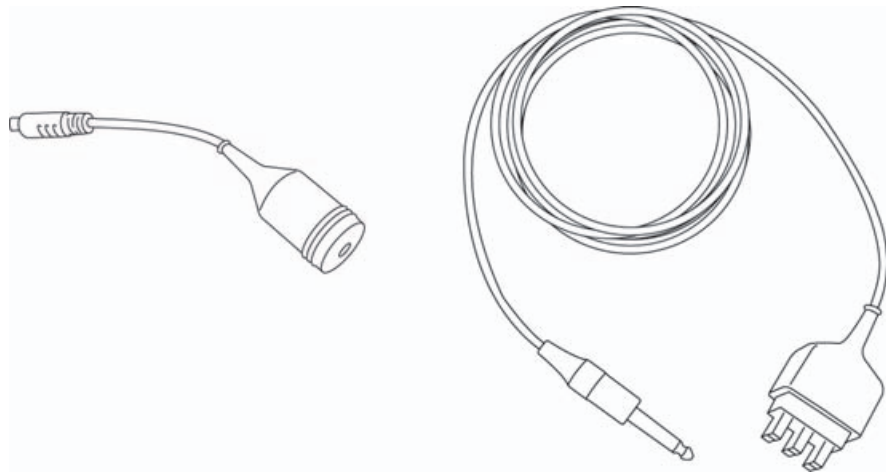


ECG Slave Cable & Adapter Kit



User Guide

Manufacturer

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Caution | Federal (United States) law restricts this device to sale by or on the order of a physician.



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CHAPTER 1

Introduction

The ECG slave cable and adapter kit is an optional medical accessory used for connecting with a facility's existing physiological/ECG patient monitor to display an ECG trace on the screen of a SonoSite ultrasound system, without having to add extra leads/sensors to the patient.

The ECG slave cable and adapter kit contains the ECG slave cable and ECG adapter cable. The ECG slave cable and adapter kit are approved for use with the SonoSite ECG module and SonoSite ultrasound products.

The ECG slave cable can be used on multiple SonoSite Ultrasound products.

WARNING

To help avoid conditions that may cause harm to the patient or damage to the cable, it is important that personnel using or handling this cable read and understand the instructions, warnings, cautions, and training material contained in this user guide. If you have questions about any of the information contained in this user guide, contact FUJIFILM SonoSite or your local representative.

About the user guide

This user guide provides information on the SonoSite ECG slave cable and adapter cable. It is intended for a reader familiar with ultrasound and other diagnostic equipment; it does not provide training in sonography, cardiology, or clinical practices. For information about the ultrasound system, see its user guide and other appropriate literature.

To aid in safeguarding the patient and ensuring reliable operation of the equipment, FUJIFILM SonoSite recommends having this user guide available for reference during all stages of ECG module and slave cable operation.

Conventions

The user guide 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.
- ▶ Single-step procedures begin with ❖.
- ▶ Items in bulleted lists do not require performance in sequence.

For labeling symbols used, see the ultrasound system user guide.

Warranty statement

The ECG slave cable and adapter cable are warranted for material and workmanship only, for a period of 12 months from date of shipment from FUJIFILM SonoSite.

The warranty does not cover damage caused by misuse by the end user, disinfecting or sterilizing incorrectly or with chemicals not recommended by FUJIFILM SonoSite, or circumstances beyond what is considered normal for the product's intended application.

Technical Support

For technical support, contact FUJIFILM SonoSite as follows.

Phone (U.S. or Canada)	877-657-8118
Phone (Outside U.S. or Canada)	425-951-1330, or call your local representative
Fax	425-951-6700
E-mail	service@sonosite.com
Web	www.sonosite.com
Europe Service Center	Main: +31 20 751 2020 English support: +44 14 6234 1151 French support: +33 1 8288 0702 German support: +49 69 8088 4030 Italian support: +39 02 9475 3655 Spanish support: +34 91 123 8451
Asia Service Center	+65 6380-5581

CHAPTER 2

Getting Started

About the ECG slave cable

Caution

To avoid inadvertent damage to the cable, read this user guide before handling and cleaning the ECG slave cable.

The ECG slave cable includes the following components:

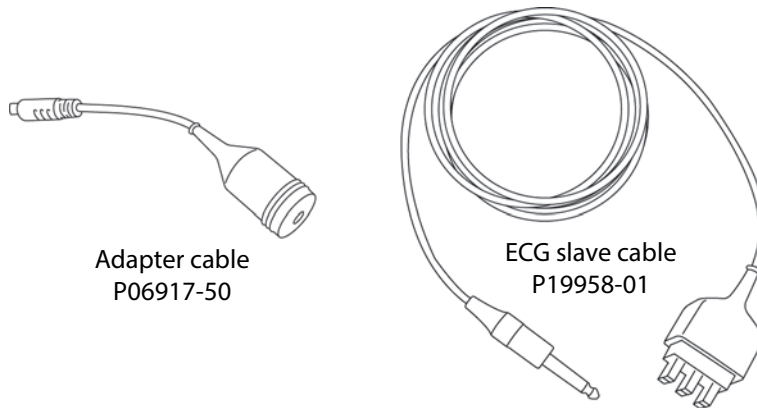


Figure 2-1 ECG slave cable components and part numbers

Intended uses

The ECG slave cable is intended to work with SonoSite ultrasound equipment and the SonoSite ECG module.

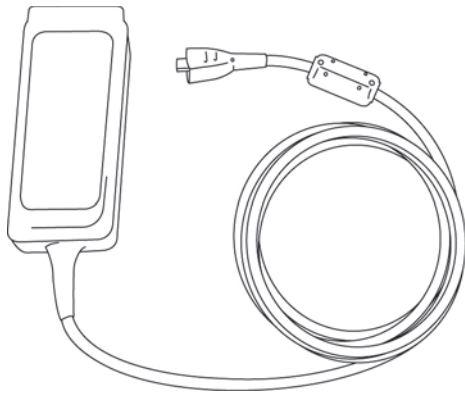


Figure 2-2 ECG module

The ECG Slave Cable Kit shall be able to receive an ECG signal from the following physiological/ECG patient monitors:

Caution

Use the ECG slave cable only with ECG monitors or physiological equipment that has been approved for use with the ECG slave cable kit.

- ▶ Philips Intellivue MP70, including ECG cables. (1/4" phone connector)
- ▶ GE Solar 8000i, with TRAM-RAC 4A and TRAM 451N, and ECG cables. (7 pin connector)

The ECG slave cable & adapter kit is designed to function in the following operating environment:

- ▶ **Temperature:** 10 °C to 40 °C
- ▶ **Humidity:** 15% RH to 95% RH
- ▶ **Atmospheric pressure:** 700 hPa (approximately 3011 meters or 9879 ft) to 1060 hPa.(-382 meters or -1253 ft)

Contraindications

There are no contraindications for using the ECG slave cable.

Unpacking

Follow the unpacking procedures. Contact FUJIFILM SonoSite or your local representative immediately to report any damage or discrepancies.

To unpack the ECG slave cable

- 1 Visually examine the shipping box, shipping case, and the ECG slave cable for any damage.
- 2 Note any breakage or other apparent damage, retain the evidence, and notify the carrier or shipping agency.

3 Verify that the shipping case contains the components listed on the packing list:

- ▶ ECG slave cable
- ▶ Adapter cable
- ▶ *ECG Slave Cable and Adapter Kit User Guide*

Inspecting contents

After unpacking the contents, perform a visual and tactile inspection of the ECG slave cable and adapter cable. Contact FUJIFILM SonoSite or your local representative immediately to report any damage or discrepancies.

CHAPTER 3

Setup and use

Setting up the ECG slave cable and adapter cable

Caution

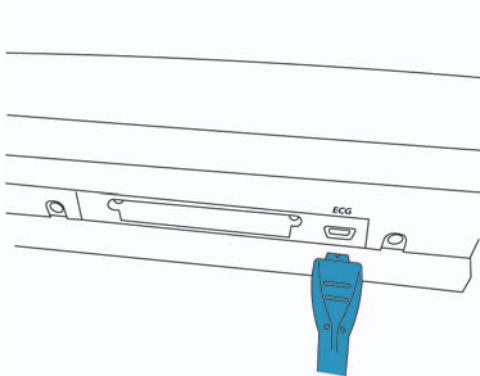
Only use the ECG slave cable and adapter kit with an approved SonoSite ECG module.

Caution

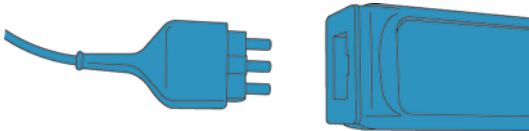
Use the ECG slave cable only with ECG monitors or physiological equipment that has been approved for use with the ECG slave cable kit. For a list of approved equipment, see “[Intended uses](#)” on page 3

To connect the ECG slave cable

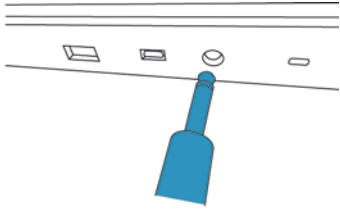
- 1 Plug the SonoSite ECG module into the ultrasound system.



- 2 Plug the ECG slave cable into the ECG module.

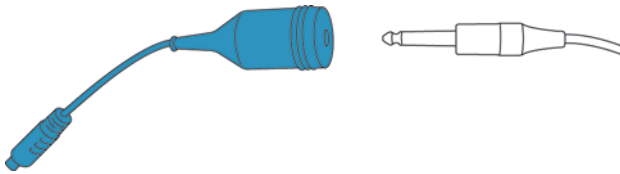


3 If connecting to a Philips Intellivue MP70 patient monitor, plug the ECG slave cable into the patient monitor.

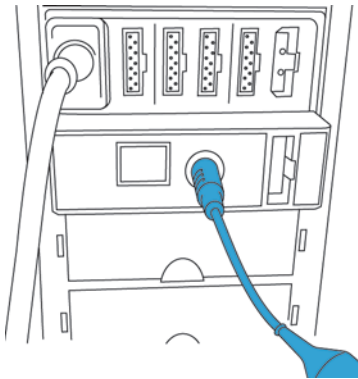


4 If connecting to a GE Solar 8000i patient monitor, do the following:

a Plug the ECG slave cable in to the adapter cable.



b Plug the adapter cable in to the patient monitor.



Operating the ECG slave cable

For best results when using the ECG slave cable, the output of the patient monitor should be 5V peak-to-peak AC-coupled.

WARNING

To prevent misdiagnosis, do not use the ECG trace to diagnose cardiac rhythms. The FUJIFILM SonoSite ECG module and slave cable is a non-diagnostic accessory.

WARNING

Do not allow patient contact with the ECG Module, slave cable, or adapter cable.

Caution

Excessive bending or twisting of ECG slave cable can cause failure or intermittent operation.

Caution

Defibrillation of a patient while the ECG module is connected to the ultrasound system may cause the ECG signal to display incorrectly or render the ECG module inoperable.

Caution

Be sure to disconnect the ECG slave cable from the patient monitor before transporting the ultrasound system.

Note

When using an ECG slave cable, the temporal alignment between the ECG display and the displayed ultrasound 2D image or scrolling data may vary depending on the latency imposed by the patient monitor.

Pre-exam Inspection

Perform a visual and operational pre-exam inspection of the ECG slave cable and adapter cable prior to each use.

To perform a pre-exam inspection

- 1 Examine the ECG slave cable and adapter cable for damage, such as cracks or splitting.
- 2 Once the ECG slave cable is connected, verify proper display of ECG on the FUJIFILM SonoSite ultrasound system.

CHAPTER 4

Cleaning, disinfecting, and storage

Cleaning and disinfecting

Caution

To avoid damaging the ECG slave cable and adapter cable, do not sterilize.

Use the following approved cleaners and disinfectants on the ECG slave cable and adapter cable:

- ▶ Sani-Cloth Plus
- ▶ Isopropanol
- ▶ Caviwipes
- ▶ Super Sani-Cloth
- ▶ Hydrogen Peroxide 3%

To clean and disinfect the ECG slave cable and adapter cable (wipe method)

- 1 Remove the cable from the system.
- 2 Examine the ECG slave cable and adapter cable for damage, such as cracks or splitting.
- 3 Clean the surface using a pre-moistened wipe, or a soft cloth lightly dampened with a mild cleaning solution. Apply the cleaning solution to the cloth rather than to the cable.
- 4 Wipe the cable surfaces with a FUJIFILM SonoSite-approved cleaner/disinfectant
- 5 Allow the cable to air dry.

Storing and transporting the ECG slave cable

Do not exceed the following environmental conditions when transporting or storing the ECG slave cable.

- ▶ Temperature: -35 ° C to 65 ° C
- ▶ Humidity: 15% to 95%
- ▶ Atmospheric pressure: 500 hPa to 1060 hPa.

Disposing of the ECG slave cable

Contact FUJIFILM SonoSite or your authorized representative for disposal instructions.

Safety






Patient safety is ensured only when a well-designed product is used in a safe and responsible manner.






The ECG slave cable & adapter kit is designed to function in the following operating environment:

- ▶ **Temperature:** 10 °C to 40 °C
- ▶ **Humidity:** 15% RH to 95% RH
- ▶ **Atmospheric pressure:** 700 hPa (approximately 3011 meters or 9879 ft) to 1060 hPa.(-382 meters or -1253 ft)

ECG slave cable labeling symbols

The following symbols are used on the products, packaging, and containers.

Symbol	Definition
	Class 1 device requiring verification by the Notified Body of sterilization or measurement features, or to a Class IIa, IIb, or III device requiring verification or auditing by the Notified Body to applicable Annex(es) of 93/42/EEC.
	Attention, see the user guide.
	Catalog number.
	Authorized representative in the European Community.
	Collect separately from other household waste (see European Commission Directive 93/86/EEC). Refer to local regulations for disposal.

Symbol	Definition
	Corrugated recycle.
	Manufacturer.
	Do not get wet.
	Fragile.
	Paper recycle.
	Temperature limitation.
	Atmospheric pressure limitation.
	Humidity limitation.
	Follow instructions for use.
	Complies with China RoHS regulations for maximum hazardous substance concentration.

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