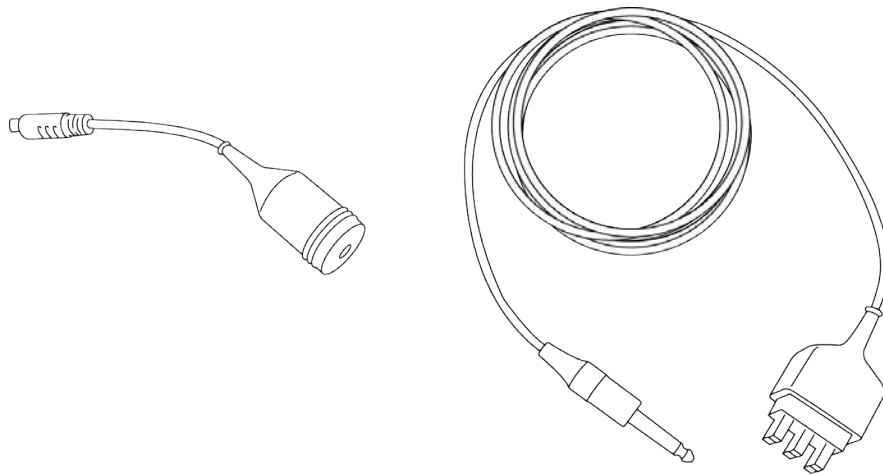


## **ECG Slave Cable and Adapter Kit**



## **User Guide**

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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 FUJIFILM 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 FUJIFILM Sonosite ECG module and FUJIFILM Sonosite X-Porte, Edge II, M-Turbo and FC1 ultrasound systems.

The ECG slave cable can be used on multiple FUJIFILM 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 FUJIFILM 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.

### Document 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.
- ▶ 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.
- ▶ Single-step procedures begin with ❖.

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.

## Getting help

For technical support, contact FUJIFILM Sonosite as follows.

United States and Canada	+1 877-657-8118
Europe and Middle East	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 and Pacific	+61 2 9938 8700
Other Regions	+1 425-951-1330, or call your local representative
Fax	+1 425-951-6700
E-mail	General: <a href="mailto:ffss-service@sonosite.com">ffss-service@sonosite.com</a> United Kingdom: <a href="mailto:uk-service@fujifilm.com">uk-service@fujifilm.com</a> Europe, Middle East, and Africa: <a href="mailto:eraf-service@fujifilm.com">eraf-service@fujifilm.com</a> Asia and Pacific: <a href="mailto:ffss-apacme-service@fujifilm.com">ffss-apacme-service@fujifilm.com</a>
Web	<a href="http://www.sonosite.com">www.sonosite.com</a>

# 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 kit includes the following components:

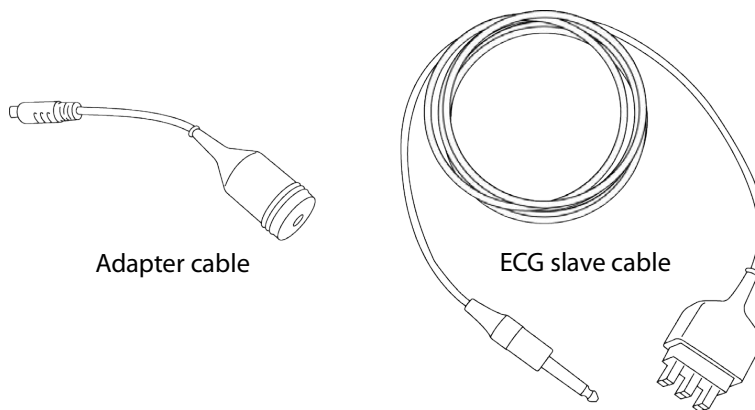


Figure 2-1 ECG slave cable kit components

### Intended uses

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

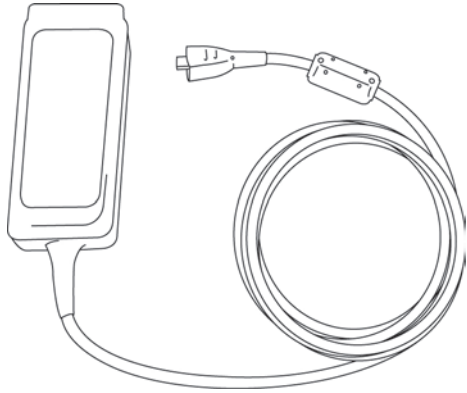


Figure 2-2 ECG module

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

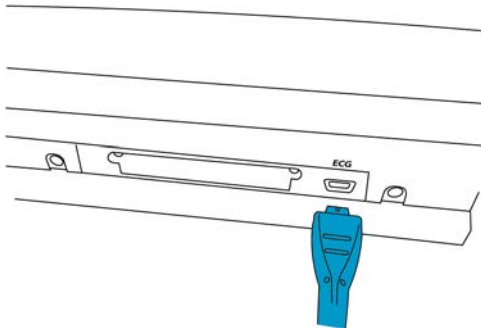
### Setting up the ECG slave cable and adapter cable

**Cautions** Only use the ECG slave cable and adapter kit with an approved FUJIFILM Sonosite ECG module.

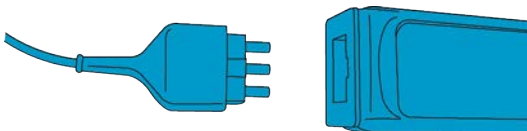
**Cautions** Use the ECG slave cable only with ECG monitors or physiological equipment that has been approved for use with the ECG slave cable kit. For a list of approved equipment, see "Intended uses" on page 2-1

#### To connect the ECG slave cable

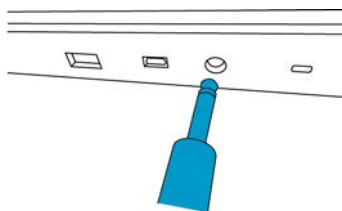
- 1 Plug the FUJIFILM Sonosite ECG module into the ultrasound system.



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

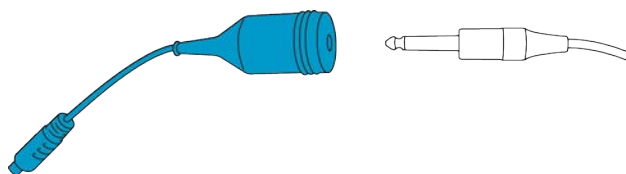


**3** If connecting to a Philips Intellivue MP70 patient monitor, plug the ECG slave cable into the patient monitor.

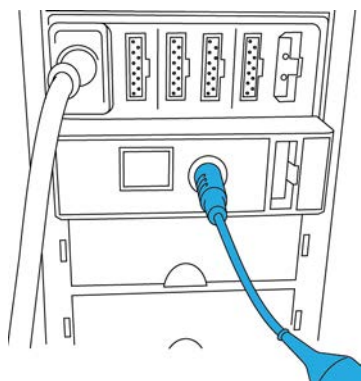


**4** If connecting to a GE Solar 8000i patient monitor, do the following:

**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.

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

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



# Chapter 5

## 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	Title	Standards development organization (SDO)	Reference number	Description
	Manufacturer	ISO 15223-1:2016 Medical devices – symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements	5.1.1	Indicates the medical device manufacturer, as EU directives 90/385/ EEC, 93/42/EEC and 98/79/EC
	Lot	ISO 15223-1:2016 Medical devices – symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements	5.1.5, 5.1.7	Indicates the manufacturer's lot number so that the medical device can be identified
	Catalog Number	ISO 15223-1:2016 Medical devices – symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements	5.1.6	Indicates the manufacturer's catalogue number so that the medical device can be identified
	Unique device identifier	ISO 15223-1:2021 Medical devices – symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements	5.7.10	Indicates a carrier that contains unique device identifier information

Symbol	Title	Standards development organization (SDO)	Reference number	Description
	Caution	ISO 15223-1:2021 Medical devices – symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements	5.4.4	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot for a variety of reasons, be presented on the medical device itself
	Fragile handle with care	ISO 15223-1:2016 Medical devices – symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements	5.3.1	Indicates a medical device that can be broken or damaged if not handled carefully
	Keep dry	ISO 15223-1:2016 Medical devices – symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements	5.3.4	Indicates a medical device that needs to be protected from moisture
	Temperature limit	ISO 15223-1:2016 Medical devices – symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements	5.3.7	Indicates the temperature limits to which the medical device can be safely exposed
	Atmospheric pressure limitations	ISO 15223-1:2016 Medical devices – symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements	5.3.9	Indicates the range of atmospheric pressure to which the medical device can be safely expose

Symbol	Title	Standards development organization (SDO)	Reference number	Description
	Humidity limitation	ISO 15223-1:2016 Medical devices – symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements	5.3.8	Indicates the range of humidity to which the medical device can be safely exposed
	Stacking limit by number	ISO 7000:2014 Graphical symbols for use on equipment	2403	Do not stack over n high, where n represents the number on the label.
	Consult instructions for use	ISO 15223-1:2016 Medical devices – symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements	5.4.3	Indicates the need for the user to consult the instructions for use
	Corrugated recycle	—	—	Shipping box is made of corrugated cardboard and should be recycled accordingly
	RESY – Recycling Symbol	—	—	Paper recycle
	CE marking	Council Directive 93/42/EEC	Article 17 Annex XII	Signifies European Technical Conformity
	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.

Symbol	Title	Standards development organization (SDO)	Reference number	Description
	Recycle: Electronic Equipment	BS EN 50419:2016 Marking of Electrical and Electronic Equipment in accordance with Directive 2012/19/EU for the Waste of Electrical and Electronic Equipment (WEEE) and Directive 2006/66/EC on Batteries and Accumulators and Waste Batteries and Accumulators	Annex IX	Do Not Throw in Trash
	China Pollution Control (10)	ISO 7000:2014 Graphical symbols for use on equipment	1135	Pollution Control Logo. (Applies to all parts/products listed in the China RoHS disclosure table. May not appear on the exterior of some parts/products because of space limitations.)
	European community authorized representative	ISO 15223-1 Medical devices - symbols to be used with medical device labels, labelling and information to be supplied	5.1.2	Indicates the Authorized representative in the European Community





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