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FDECG Legplate Adapter Cable

User Manual

Intended Use & Indications for Use

The FDECG Legplate Adapter Cable, hereafter called the “Adapter Cable”, used to monitor fetal heart rate during labor and midwifery. Provide a signal path between the spiral electrode, attachment electrode, and fetal monitor, products are intended to be used by trained operators in a professional medical environment or under the direction of a trained medical professional.

Operating Conditions

- Ambient temperature: 0°C ~ 40°C
- Relative humidity: 15% ~ 85%
- Atmospheric pressure: 86 kpa ~106 kpa

Packaging & Storage

Each product is individual packaged, packaged products should be stored in a well-ventilated room without corrosive gases.
Storage conditions are as follows:

- Ambient temperature: -10°C ~ 40°C
- Relative humidity: 15% ~ 85%
- Atmospheric pressure: 86 kpa ~106 kpa

Instruction for Using the Adapter Cable

Before You Begin

- Always adhere to these Instruction for Use. Otherwise will result in poor signal quality.
- If the Adapter Cable was previously used, verify that it has been cleaned and disinfected.
- Use the Adapter Cable that is compatible with your fetal monitor.
- Connect only compatible Electrodes to the Adapter Cable.

Connecting the Adapter Cable

Follow these steps to continue:

- Plug the Adapter Cable connector into the fetal monitor.
- Connect the attachment electrode using a snap- connector.
- Apply the attachment electrode to the mother, following instructions supplied with the attachment electrode.
- Apply the spiral electrode to the fetus, following instructions supplied with the spiral electrode.
- Check that the electrical connector from the spiral electrode is dry, then plug it into the Adapter Cable's spiral electrode input port.

Shelf Life

5 years.

Cleaning & Disinfection

- Refer to the disinfectant manufacturers' specification for information about achieved levels of disinfection.
- The Adapter Cable exterior must be cleaned after each use, and then disinfected.

Cleaning Agents and Disinfectants

Use only the recommended cleaners and disinfectants list below, Otherwise may damage the Adapter Cable and shorten product lifetime or cause safety hazards.

- Recommended cleaners

  Soapy water or Isopropanol 70-80%
- Recommended disinfectants

  Ethanol 70% or Isopropanol 70%

Warning:

- Never sterilize the Adapter Cable by any means.
- Do not soak the Adapter Cable.
- Do not allow humidity or liquids enter into the product.
- Select recommended cleaning agents and disinfectants carefully, because some products with similar names, but have different compositions.
- Always dilute cleaning agents and disinfectants according to manufacturer's instructions.
- Do not use strong oxidants or bleaches containing sodium hypochlorite (e.g. Clorox™).
- Do not use Povodine, Sagrotan, Mucocit-P or strong organic solvents.
- Do not use disinfectants containing iodine complexes.

Caution

Federal (U.S.) Law restricts this device to sale by or on the order of a physician.

Exterior Cleaning and Disinfectio

Perform the following procedure after every use

Step	Cleaning and Disinfection After Every Use
1	Spray cleaning agent directly onto the Adapter Cable or onto a soft, clean cloth.
2	Wipe all Adapter Cable surface and clean from one end to the other.
3	Change to a dry cloth and dry the Adapter Cable completely.
4	Repeat steps 1-3 using a recommended disinfectant.

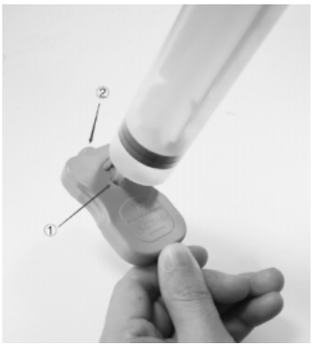
5	Using a clean,dry cloth,wipe all residual disinfectant from the Adapter Cable. ⚠ WARNING: Any residual disinfectant left on the cable could cause severe skin irritation or blistering if it comes in contact with a patient.
6	Check for signs of any deterioration or damage. If damage is noticed, discard the Adapter Cable immediately.

⚠Warning

⚠1. The following operations only apply to Adapter Cable fitted with Philips fetal spiral electrode.

⚠2. If you suspect that liquid has entered into the internal cavity of the cable, perform the following procedure:

⚠2.1 During the following procedure, always point the Adapter Cable's spiral electrode input 2 away from your face to avoid being sprayed.

Step	Clean the Internal Cavity	
1	Fill a 10cc syringe with a recommended clean solution.	
2	Lift open the cover on the Adapter Cable Flush-Cleaning Port .	
3	Hold the Adapter Cable over a sink, then: A. Insert the syringe①into the Flush-Cleaning Port and slowly inject the cleaning solution into the cavity. B. When the cavity is filled, press the Flush-Cleaning Port cover closed. C. Rest the Adapter Cable in the②sink with the spiral electrode input pointing up, allowing the internal cavity to soak for 5-10 minutes.	Slowly inject the cleaning solution into the cavity  ①

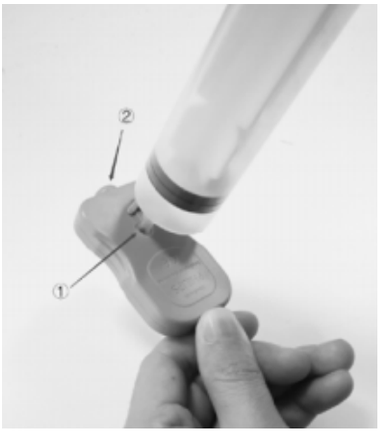
4	After 5-10 minutes: A. Take out the Adapter Cable and open the cover on the Flush-Cleaning Port①. B. Fill the syringe with clean water. C. Insert the syringe into the Flush-Cleaning Port① and rapidly inject the cavity, discharging the rinse water into the sink. D. Repeat the clean water injection 2-3 times to assure a thorough rinse.	Rapidly inject the cavity, discharging the rinse water into the sink  ②
5	Using a empty syringe, inject air into the Flush-Cleaning Port①. Repeat 4-5 times to remove excess water. Close the Flush-Cleaning Port①cover before returning the Adapter Cable to use.	

⚠3. Disinfecting the Internal Cavity

Perform the following procedure if you suspect that the Adapter Cable's internal cavity has become contaminated.

⚠ 3.1Always clean and rinse the Adapter Cable's internal cavity before disinfecting (reference the previous procedure, cleaning the internal cavity).

⚠ 3.2 During the following procedure, always point the Adapter Cable's spiral electrode input② away from your face to avoid being sprayed by the discharged disinfectant and rinse.

Step	Disinfecting the Internal Cavity	
1	Fill a 10cc syringe with a solution of recommended disinfectant.	
2	Lift open the cover on the Adapter Cable Flush-Cleaning Port .	
3	Hold the Adapter Cable over a sink, then: A. Insert the syringe into the Flush-Cleaning Port①and slowly inject the disinfectant into the cavity. B. Allow the disinfectant to discharge from the spiral electrode input②into the sink.	Slowly inject the cleaning solution into the cavity  ①
4	Fill the syringe with clean water and repeat steps 3A and 3B to rinse the cavity. Repeat the clean water rinse injection 2-3 times to assure a thorough rinse.	
5	Using a empty syringe, inject air into the Flush-Cleaning Port①. Repeat 4-5 times to remove excess water. Close the Flush-Cleaning Port①cover before returning the Adapter Cable to use.	

Replacement and Waste Disposal

Replacement: If the cable is broken or damaged, replace the cable with a new one in time.
Discard: The discarded cables are medical waste. Please contact a professional department for recycle.

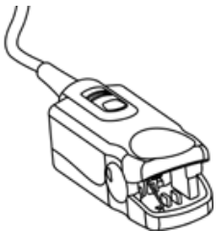
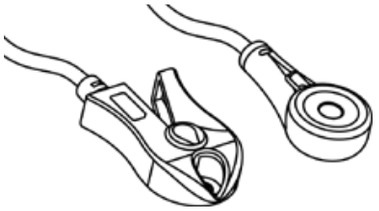
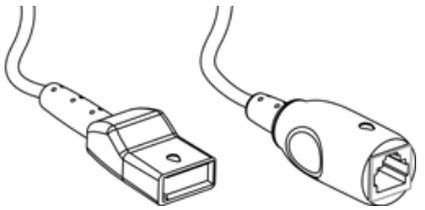
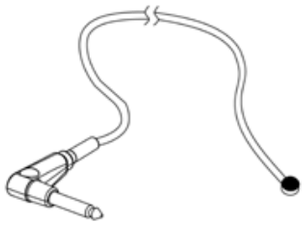
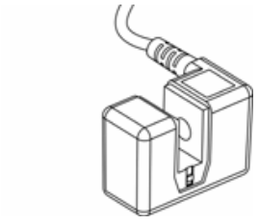
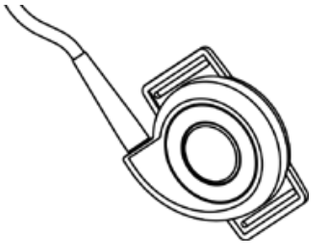
Title of Symbol

	Manufacturer
REF	Catalogue number
LOT	Batch code
SN	Serial number
	Not made with natural rubber latex
	Refer to instruction manual /booklet
	Non-sterile
Rx only(U.S.)	U.S. federal law restricts this device to sale by or on the order of a physician.
IPX2	Protection against vertically falling water drops when ENCLOSURE tilted up to 15°

	Date of manufacture
	Crossed out wheelie bin indicates separate treatment from general waste at end of life. Waste of Electrical and Electronic Equipment Directive (WEEE)
CE	CE Mark
	Warning
EC REP	Authorized Representative in the European Community
MD	Medical device
UDI	Unique Device Identifier
	Caution

Support

To get the support, please contact the representative of manufacturer or local distributor.
The categories shown below are available for sale through the local distributors or e-commerce.

			
SpO_2	ECG	NIBP	IBP
			
TEMP	$EtCO_2$	FETAL	EEG

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