



A100C Ultrasonic Fetal Doppler Operator's Manual



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Safety

1.1 *Instructions for the Safe Operation and Use of the A100C Doppler*

- Examine the Doppler and any accessories periodically to ensure that the cables, probes, and instruments do not have visible evidence of damage that may affect patient safety or performance. The recommended inspection interval is once per week or less. Do not use the Doppler if there is any visible sign of damage.
- Do not attempt to service the A100C Doppler. Only qualified service personnel should attempt any needed internal servicing.
- The A100C is not specified or intended for operation in the presence of electrosurgical equipment.
- The A100C is not specified or intended for operation in conjunction with any other type of monitoring equipment except the specific devices that have been identified for use in this Operator's Manual.
- Perform periodic safety testing to insure proper patient safety. This should include leakage current measurement and function testing. The recommended testing interval is once every two year.



1.2 Warnings

WARNING: EXPLOSION HAZARD — Do not use the A100C in a flammable atmosphere where concentrations of flammable anesthetics or other

WARNING: Use only patient cables and probes supplied with the Doppler. Use of any other patient cables may result in out-of-specification performance and possible safety hazards.

WARNING: Do not throw batteries in fire as this may cause them to explode.

WARNING: Do not attempt to recharge alkaline batteries, they may leak, and may cause a fire or even

WARNING: Replacing battery shell only be done outside the patient environment (1.5m away from the

WARNING: If the rechargeable lithium-ion battery is used, please charge it fully before use in order to

WARNING: A100C Series Ultrasonic Pocket Doppler is a tool to aid the healthcare professional and should not be used in place of normal fetal monitoring.



WARNING: Reversed polarity and short cut of the battery are prohibited as using the device.

WARNING: Don't touch signal input or output connector and the patient simultaneously.

WARNING: The length of connecting wire to probe cannot be exceed 2 meters, otherwise the connection will be possible to pull out from probe socket.

1.3 Cautions

CAUTION: Keep the operating environment free of dust, vibrations, corrosive, or flammable materials, and extremes of temperature and humidity. The unit should be kept clean and free of probe gel and other substances.

CAUTION: Do not operate the unit if it is damp or wet because of condensation or spills. Avoid using the equipment immediately after moving it from a cold environment to a warm, humid location.

CAUTION: Never use sharp or pointed objects to operate the front-panel switches.



A100C Ultrasonic Fetal Doppler

CAUTION: Do not immerse probes in liquid. When using solutions, use sterile wipes to avoid pouring

CAUTION: The battery must be taken out from the battery compartment if the device will not be used for a










CAUTION: The device shall only be used if the battery cover is closed.

CAUTION: Electromagnetic Interference-Ensure that the environment in which the device is operated is not subject to any sources of strong electromagnetic interference, such as radio transmitters, mobile telephone, etc. Keep them far away.

CAUTION: The battery must be proper disposed according to local regulation after their use.

CAUTION: Before connecting to other equipment, please make sure the connective equipment should meet IEC60601-1 / IEC1266 and IEC60950 requirement.

1.4 Definitions and Symbols

Symbol	Description
	Company Logo
FHR	Fetal Heart Rate Mark
	Type BF Equipment
	Symbol for CE certificate and certification number
	Batch code
	Date of manufacture
	Information of manufacture, including name and address
	Information of authorized representative in the European community
	Upper limit of temperature
	This symbol identifies a safety note. Ensure you understand the function of this control before using it. Control function is described in the operator's manual.



A100C Ultrasonic Fetal Doppler

<i>Warning:</i>	The information you should know to protect patients and medical staff from possible injury
<i>Caution:</i>	The information you should know to protect the equipment from possible damage
<i>Note:</i>	The important information you should know



2.1 General

This chapter provides a general description of the A100C fetal Doppler including:

- Brief Device Description
- Product Features
- Options and Accessories

2.2 Brief Device Description

A100C Ultrasonic Fetal Doppler is a high performance fetal heart beat detector with color OLED display with FHR curve, which can meet routine examination requirements of obstetricians. It is applicable for midwives, private obstetrician's office, obstetrical department of hospital and remote monitoring situations.




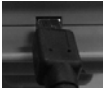

The device performs the following procedure: ultrasonic signal emit, analog signals process, fetal heart rate calculate and display. A100C has six modes, include real-time FHR display mode, Curve mode, Replay mode, Manual Count mode, Averaged FHR display mode and Count down mode. It also has audio output, and can be connected with earphone or recorder with audio input. A100C use rechargeable battery and charger as standard accessories, and support standard 9 Volt DC alkaline battery as optional accessories.



2.3 *Product Features*

- Lightweight and Easy-To-Use.
- 1.54 inch color OLED display FHR value, FHR intensity, improper FHR alarm signal, speaker volume, battery capacity Indicator, working mode, type of probe and FHR synchronization symbol.
- Accurate FHR detection. It has real-time FHR display mode, Curve mode, Replay mode, Manual Count mode, Averaged FHR display mode and Count down mode.
- FHR curve display and maximum 30 minutes FHR curve replay function.
- Detection and Indication of probe off.
- Improper FHR alarm value adjusted. The red/green/orange color indicates different alarm class.
- Change to power saving mode automatically without signal within 30 seconds.
- Auto shut off without signal within 2 minutes.
- Earphone port support FHR sound output to earphone or recorder.
- Friendly human-machine interface for menu selection.
- Standard 9V alkaline battery is available for power supply.
- Support multinational language user interface according to the customer requirement.

2.4 Options and Accessories**Table 2.4.1 A100C Accessories**

Accessory	Name	Description
Standard Accessories:		
	Portable FHR probe	Continuous wave Doppler probe
	Rechargeable battery (300mAh 9V)	GP, 21-64015
	USB port charger	 Input: 100-240VAC Output: 12VDC 500mA Connecting method is as shown on the right figure
Optional Accessories:		
	Ultrasound Gel	Ultrasound transmission gel (optional accessory)

Installation, Setup, and Operation

3.1. Description of the Front Panel & Rear Panel (as Figure 3.1.1)

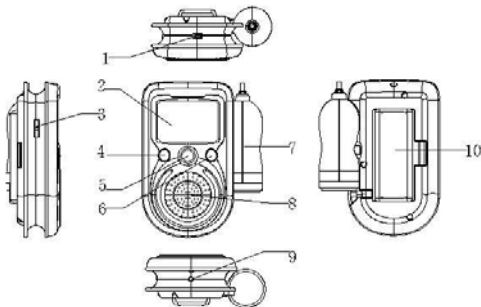


Figure 3.1.1

Table 3.1.2 Part Definition and Description

Item	Description	Item	Description
1	Data Port & Charger Port	6	START/STOP Button
2	OLED Panel	7	Probe
3	Volume control & toggle switch	8	Speaker
4	MODE selection Button	9	Earphone Socket
5	Power on/off Button	10	Battery Compartment

3.2 Display

After self-testing, the OLED display of A100C for six modes is as follows:

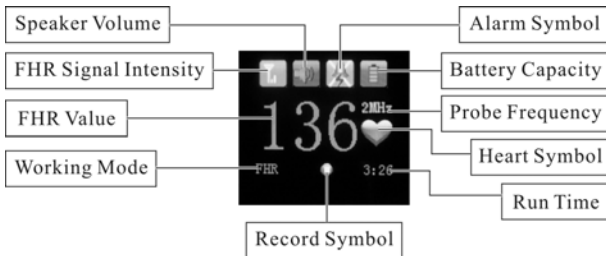


Figure 3.2.1 Real-time FHR mode

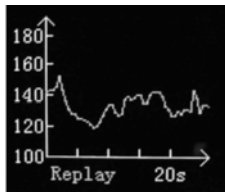
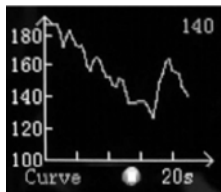


Figure 3.2.2 FHR Curve mode

Figure 3.2.3 FHR Replay mode

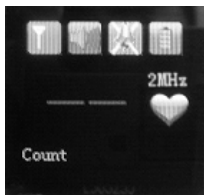


Figure 3.2.4 Manual Count mode

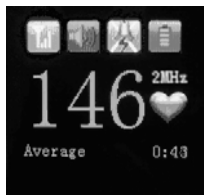


Figure 3.2.5 Average FHR mode







Figure 3.2.6 Countdown mode

3.3 Button definition and Description:

There are three button (Power, MODE, START/STOP) and a volume control rotary button on the left surface of A100C Ultrasonic Fetal Doppler. Their primary functions are as follows:

Table 3.3.1 Button Definition and Description

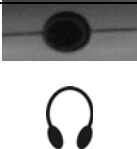
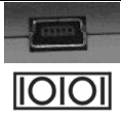
Symbol	Name	Description
	Power On/Off Button	The machine turn on after pressing the button for 2 seconds, and turn off after pressing the button for 2 seconds again.
	Mode Selection Button	Press this button to select the working mode. The modes will circle in turn after pressing the button.
	Start/stop operation button & Recording button	The button is used as Star/stop function, and used as recording function in FHR mode/curve mode.

	<p>toggle switch & Volume control</p>	<p>Adjust audio volume by rotating this button. And it is also used as toggle switch for menu selection.</p>
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3.4 Port definition and Description

There are two ports on the A100C Fetal Doppler. Their primary functions are as follows:

Table 3.4.1 Port Definition and Description

Symbol	Name	Description
	<p>Earphone socket</p>	<p>This socket is used for connecting the earphone with the Doppler.</p>
	<p>Data Port & Charge port</p>	<p>This socket is used for charge Ni-MH battery</p>

3.5 Operation

3.5.1 Turn the Doppler on

Press **power on/off** button for 2 seconds to turn the Doppler on after connecting FHR probe. The Doppler is on FHR mode after self-testing.

3.5.2 Monitoring Fetal Heart Rate

Step 1: Preparing works

Check the portable ultrasound probe to verify proper attachment to the Doppler. Adjust heart rate channel one speaker volume to mid level. Apply ultrasound gel to the face of the probe

Step2: Acquiring the Fetal Heart Signal

Determine the location of the fetal heart using palpation or a fetoscope. Place the probe on the maternal abdomen and listen for the fetal heart signal. Reposition the probe for the loudest fetal heart signal and fetal heart rate blinking in OLED display. Readjust the volume settings for the desired loudness.

CAUTION: Do not knock on or drop the probe, It will damage the probe

3.5.3 Real-time FHR Display Mode

In this mode, OLED display of Doppler will display the blinking of heart symbol, and display real-time FHR simultaneously. And

you can record and stop recording these data by pressing **START/STOP** button. These stored data will display FHR curve in replay mode.


CAUTION: *The FHR value can't be saved if the recording time is less than 10 seconds.*

3.5.4 Curve Mode

In this mode, when the Doppler detect the FHR signal, it will display the FHR curve in the central and FHR value in the upper right corner. When FHR exceeds alarm upper limit and lower limit, the fetal Doppler will emit alarm sound, and the FHR value on the OLED will change into yellow color or red color. (Yellow color is for first level alarm limit, and red color is for higher-level alarm limit). Press **START/STOP** button, it will start recording or stop recording.

NOTE: *The FHR value can't be saved if the recording time is less than 10 seconds.*

3.5.5 Replay Mode

The latest FHR record in Real-time FHR mode /Curve mode can be replayed. The OLED will replay FHR curve when you switch to Replay mode. You can observe the whole FHR curve replay in automatic way or through rotating  toggle switch in manual way. Automatic way and manual way can be switched by pressing **START/STOP** button.

3.5.6 Manual Count Mode

This mode is used for the FHR signal is not enough to display for Doppler but can be audible. You can use the manual count function in this case. The manual count is operated as pressing the **START/STOP** button on the first fetal heart beat and pressing it again on the eleventh beat.

- Find an audible fetal heartbeat.
- Press the **START/STOP** button. The symbol **?** is shown on the display.
- Count the 11th beat since the first beat and press the **START/STOP** button, The FHR value is displayed.

NOTE:** If FHR value is detected beyond 250 or below 30, it will display error symbol ***.*

3.5.7 Averaged FHR Display Mode

This mode is used to obtain more stable heart rate readings. It will display the blinking heart symbol and averaged FHR value. The FHR value is averaged and displayed during the setting time.

3.5.8 Count Down Mode

It will display the FHR value and the count down time simultaneously. Press **START/STOP** button, the Doppler begins to count down. When it counts down to zero, it will give off alarm sound. Press **START/STOP** button when it hasn't counted down to zero, the count down time will pause. And if you press

START/STOP button again, the count down will restart.

3.5.9 Parameter Setting



























- Press **power on/off** button, the Doppler will enter into main menu and make parameter setting. Rotate (move up and down)  to select the setting item. Press  to enter into the setting. Press  again after setting, it will save the changed value.
- Select **Return** item, it will be back to main menu.
- Select **EXIT** or press **power on/off** button, it will return to FHR detecting situation.





Table 3.5.9 Parameter setting

Main Menu	Submenu	Button activity & Desired Result
	Curve 	Press  and rotate it to make selection of “Mal” and “Auto” for replay mode. Press  to save the changed value.
	Language 	Press  and rotate it to make selection of language. Press  to save the changed value.

Brightness 	Press  and rotate it to make adjustment of the brightness value. Press  toggle switch to save the changed value.
Energy Save 	Press  and rotate it to make the selection of “on” and “off”. Press  toggle switch to save the changed value.
Volume 	Press  and rotate it to make the selection of “on” and “off” for alarm. Rotate  toggle switch to make the adjustment of volume value. Press  toggle switch to save the changed value.
Time 	Press  and rotate it to make the adjustment of countdown time value. Rotate  toggle switch to make the adjustment of average time value. Press to save the changed value.
Alarm 	Press  and rotate it to make the adjustment of upper limit and lower limit (Alm L1 min, Alm L1 Max, Alm L2 Min, Alm L2 Max). Press  toggle switch to save the changed value.



A100C Ultrasonic Fetal Doppler

	Restore 	Press  toggle switch, all settings will be restored to factory default value.
	Return 	Press  toggle switch to exit present menu and return to FHR detecting situation.

3.5.10 Replacing Battery

3.5.10.1 Taking out Battery

Open the battery compartment along the direction of arrowhead, then takes out the battery from the battery compartment after unplugging the battery from connector.



Figure (1) Open the battery compartment



Figure (2) Unplug battery form connector

3.5.10.2 Replacing Battery

Plug new battery to battery connector and put it into the battery compartment (the direction of battery plug is inward), then close the battery compartment along the direction of arrowhead.

3.5.11 Recharge Battery

If the machine uses rechargeable battery, please connect the recharge battery with the socket in charger after taking out the battery. The charging time is 4-6 hours for full charge.

WARNING: Do not attempt to recharge normal alkaline batteries, they may leak and may cause a fire or even explode.

3.5.12 Taking out and Placing Probe (As figure 3.5.12)

3.5.12.1. Hold the head of the probe tightly, and draw it from the bracket along the direction of “OUT”.

3.5.12.2 Hold the head of the probe tightly, and insert into the bracket along the direction of “IN”.

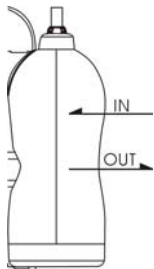


Figure 3.5.12



Cleaning and Disinfection

4.1 Cleaning

Switch off the power and take out the batteries before cleaning,

Keep the exterior surface of the device clean and free of dust and dirt. Cleaning exterior surface (OLED display screen included) of the unit with a dry and soft cloth. If necessary, clean it with a soft cloth soaked in a solution of soap, or water and wipe dry with a clean cloth immediately.

Wipe the probe with soft cloth to remove any remaining coupling gel and clean with soap and water only.

CAUTION: Don't use strong solvent. For example, acetone.

CAUTION: Never use an abrasive such as steel wool or metal polish.

CAUTION: Do not allow any liquid into the product, and do not immerse any parts of the device into any liquids.

CAUTION: Avoid pouring liquids on the device while cleaning.



CAUTION: Don't remain any cleaning solution on the surface of the device.

NOTE: Wipe the surface of probe with 70% ethanol or isopropanol alcohol and self-air dry, or clean with a clean and dry cloth.

4.2 Disinfecting

After Cleaning the equipment exterior surface and probe, Immerse the probe into the solutions of benzalkonium Bromide, 0.5% Chlorhexidine, 2% Glutaraldehyde or 75% ethanol to disinfect the water proof probe. Wipe the probe with a clean and dry cloth to remove any remaining moisture.

Note: Please pay attention to the height when the probe is immersed in order to prevent the sterilant from entering the probe socket.

CAUTION: Never try to sterilize the probe or equipment by low temperature steam or other methods.



Troubleshooting and Maintenance

5.1 Maintenance

The probe acoustic surface is frangible and must be handled with care. Gel must be wiped from the probe after use. These precautions will prolong the life of the unit. The user must check that the equipment does not have visible evidence of damage that may affect patient safety or A100C series capability before use. The recommended inspection interval is once per month or less. If damages are evident, replacement is recommended before use.

The equipment should undergo periodic safety testing to insure proper patient isolation from leakage currents. This should include leakage current measurement. The recommended testing interval is once every two years or as specified in the institution's test and inspection protocol.

The accuracy of FHR is controlled by the equipment and cannot be adjusted by user. If the FHR result is distrustful, please use other method such as stethoscope to verify immediately or contact local distributor or manufacturer to get help.

5.2 Troubleshooting

5.2.1 *Power troubleshooting*


1. OLED display is not light: Battery capacity is lower, Change or charge the battery immediately.

2. Automatic turn off: If battery is lower, the Doppler will automatic turn off.

5.2.2. False FHR troubleshooting

1. Electromagnetic Interference: Move all line cords and line-powered equipment at least 6 feet away from the A100C and remove the line cord from the Doppler's power supply. Turn off the mobile phone and other electronics appliance, which can cause electromagnetic interference. If the artifact heart rate indication ceases, the Doppler may be used normally.
2. Weak fetal heart signal: Reposition the probe until the loudest fetal heart signal is heard.◦
3. It is normal when FHR for adult is detected twice than actual FHR.◦

5.2.3 No fetal heart signal troubleshooting

1. No audio from speaker: check whether the Doppler probe inserts correctly.
2. No audio from speaker or little sound from speaker: Check the  volume control button to increase the volume of sound.

NOTE: The speaker is broken or the control circuit have problem if the above ways can't valid.

5.2.4 Others troubleshooting
Table 5.2.4 Others troubleshooting

Position	Problem	Possible Reason	Troubleshooting way
Speaker	Weak fetal heart signal	Volume adjust fault	Increase Volume
		FHR probe insert incorrect	Reinsert the FHR probe
		No ultrasonic Gel between probe and body	Adding ultrasonic GEL
		Ultrasonic probe broken	※replacing
		Speaker broken	※replacing or maintain
Battery	OLED display not light	Battery can support half hours working time.	※maintain OLED
		Battery broken	※replacing
	Automatic Turn off	Battery capacity is lower	Charge or change the battery
	Can't charge to Battery	Battery broken	※replacing



NOTE: It should be maintained by professional personnel with these items marking ※

Section 6

Specifications

A100C Fetal Monitor Specifications:

Physical Characteristics

Machine:

Dimensions – 142 mm (L) x 112mm (W) x 42mm (D)

Weight – approx: 0.30kg (including one battery)

Outer box:

Dimensions-210mm (L) X180mm (W) X60mm (H)

Gross Weight: 0.46kg

Outer carton:

Dimensions-630mm (L) X220mm (W) X370mm (H)

Gross Weight: 10kg



A100C Ultrasonic Fetal Doppler

Complies with standards :

Performance requirements and methods of measurement and reporting : IEC1266

Safety: IEC60601-1 / IEC1266 and IEC60950

EMC: IEC 60601-1-2

Acoustic output: IEC 61157

Classification :

Anti-electric Shock Type: Internally powered equipment

Anti-electric Shock Degree: Type B equipment

Mode of operation: Continuous Operation

Probe: IPX4 level

Power

Internal:	9V DC alkaline battery support 300 minutes working time.
	Rechargeable battery (cycle life>500 times) 4 hours to full recharge at 160mA charge current
Power Dissipation:	3 watts, maximum



A100C Ultrasonic Fetal Doppler

Environmental

Operating Temperature:	-5°C to 40°C
Storage Temperature:	-10°C to 50°C
Relative Humidity:	20% to 93% non-condensing
Altitude:	-150-4000m

Doppler Ultrasound FHR Monitoring

Parameter	Value
Intensity at the probe face:	$< 10\text{mW/cm}^2$
Ultrasonic frequency:	2.0 MHz $\pm 10\%$
BPM Range:	30-240 BPM
Accuracy:	± 1 BPM

Others

Potable FHR probe	Detect the FHR and make fetal heart sound in early pregnancy.
Speaker	0.5W speaker, support volume adjusted
Probe line length	Less than 1.5m



A100C Ultrasonic Fetal Doppler

- ※ Thank you for purchasing A100C Time Fetal Doppler.
- ※ This product is manufactured and passed through strict quality control and inspection according to ISO13485.



Product Warranty Card

NAME:	DATE OF PURCHASE:
ADDRESS:	PURCHASE FROM:
ITEM PURCHASED: TMS A100C Ultrasonic Fetal Doppler	REGISTRATION DATE:

Inmed Corporation warrants this product to be free from defects in material or workmanship within 1 year from date of purchase under normal use. If fault is found, please return the equipment, freight prepaid, in its original packaging along with the purchase receipt to the address below. Inmed Corporation will repair or replace any defective parts free of charge subject to the terms and conditions stated herein.

For service, the unit is to be returned freight prepaid to:

Inmed Corporation

5 Calle Industria, Bagumbayan,
Quezon City 1110, Philippines
Tel: 02.571.1888 | Fax: 02.571.9912

Please register your unit online at www.inmed.com.ph