USA

USA - User Manual

WARNING

Do not use the Baby DOPPLEX® 4000 in the presence of flammable gases such as anesthetic agents.

WARNING

The BD4000 and its range of options and accessories are not designed to be sterilized.

CAUTION

DO NOT:

Immerse the **main control unit** or probe in any liquid.

Use solvent cleaners.

Use high-temperature sterilizing processes (such as autoclaving).

Use E-beam or gamma radiation sterilization.

CAUTION

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

CAUTION

This product contains sensitive electronics, therefore, strong radio frequency fields could possibly interfere with it. This will be indicated by unusual sounds from the loudspeaker. We recommend that the source of interference is identified and eliminated.

IMPORTANT

Before using your Baby Dopplex® 4000, please study this manual carefully and familiarize yourself with the controls, displays, features and operating techniques.

Acoustic Safety

Continuous wave Doppler ultrasound instruments such as the **BD4000** have been used extensively for medical diagnosis in the United States for over 25 years. Throughout this period, there have been no reports of adverse effects to patients or instrument operators at the acoustic intensities recommended for diagnostic use. Despite this highly favorable safety experience, available data are not conclusive and the possibility remains that unwanted biological effects might be identified in the future.

Authorities therefore recommend that ultrasound procedures be performed in accordance with the "ALARA" principle, which states that the energy delivered to the patient should always be kept **A**s **L**ow **A**s **R**easonably **A**chievable. With the **BD4000**, the transmitted acoustic power is fixed and cannot be adjusted by the operator. Therefore, the user can best observe the ALARA principle by ensuring that each examination is medically indicated and by limiting the duration of the study to the extent appropriate for the clinical objectives.

Acoustic intensity data ($I_{SPTA.3}$) for the probe available for use with the **BD4000** is summarized in the following table. The values cited are based on measurements in water using a calibrated hydrophone and are stated as the estimated derated intensities. The derated intensity constitutes the most biologically relevant parameter available since true determinations of the actual absorbed dose in tissue would require invasive measurement techniques. The derated intensity is, therefore, calculated mathematically using a derating factor consisting of a constant (the assumed attenuation coefficient) and allowing for the frequency of the probe and the distance from the probe face to the hydrophone.

The calculated derated intensity values for the **BD4000** compare very favorably with previously reported acoustic safety data for Doppler ultrasound instruments and are appropriate for all clinical applications recommended in this manual.

Acoustic Output Reporting Table for Track 1 - Non-Auto-scanning Mode Transducer Mode : US1 Operating Mode : PW-Mode Application(s) : Fetal Monitoring					
Acoustic Output			MI	$I_{SPTA.3}$ (mW/cm²)	$I_{SPPA.3}$ (W/cm²)
Maximum Value			0.02	6.83	0.02
Associated Acoustic Parameters	pr.3 (MPa)		0.03		
	W_o (mW)			23.3*	23.3*
	f_c (MHz)		1.56	1.56	1.56
	z_{sp} (cm)		1.50	1.50	1.50
	Beam Dimensions	x_{-6} (cm)		0.564	0.564
		y_{-6} (cm)		0.502	0.502
	PD (μS)		130		130
	PRF (Hz)		3200		3200
	EBD (cm²)			0.785	
Operator Controls	Control #1		N/A	N/A	N/A

☞ ** Measured values were multiplied by seven to account for the seven crytals in the transducer.*

Notes Crystal Diameter = 1.0 cm, I_{SATA} = 4.24mW/cm²

1. Uncertainties:

   The uncertainties in the measurements were predominantlysystematic in origin; the random uncertainties were negligible in comparison. Systematic uncertainty overall (typically) = ±17% (max. ±23%)

2. Intended uses: refer to the **Recommended Clinical Applications** table.

Definition of Terms

ISPTA.3	the **derated spatial-peak temporal-average intensity** (milliwatts per square centimeter).
ISPPA.3	the **derated spatial-peak pulse-average intensity** (watts per square centimeter).
MI	the **Mechanical Index**.
pr.3	the **derated peak rarefactional pressure** (megapascals).
Wo	the ultrasonic power (milliwatts).
fc	is the **center frequency (MegaHertz)**
z_{sp}	is the axial distance at which the reported parameter is measured (centimeters).
X-6, Y-6	are respectively the in-plane (azimuthal) and out-of-plane (elevational) -6dB dimensions in the x-y plane where z_{sp} is found (centimeters).
PD	the **pulse duration** (microseconds).
PRF	the **pulse repetition frequency (Hz).**
EBD	the **entrance beam dimensions** for the azimuthal and elevational planes (centimeters).

Measurement uncertainties for acoustic quantities (**power, pressure, intensities, center frequency**) should be provided.

CONTENTS

1. Introduction

The **Baby DOPPLEX® 4000** fetal monitor (**BD4000)** provides a unique combination of options. Incorporating all the standard functions of conventional cardiotocographs (CTGs), it provides the most cost-effective and flexible approach to fetal monitoring.

The **BD4000** model is available in standard form for antepartum monitoring. Additionally, plug-in options are available to provide intrapartum and twins capability. These options are available separately and can be added retrospectively, simply by plugging them in when required.

The standard unit is supplied complete with:

BD4000 main unit

External Ultrasound transducer

External Contractions (toco) transducer

Patient Event Marker

Printer Paper (1 pack)

Gel (1x 250ml bottle)

Latex Free Transducer Belts (x2)

Power cable

User Manual

Fetal Movement Detector

The standard unit includes an automatic fetal movement detection system. This provides an indication of movement, detected from the low frequency components of the Doppler signal.

It should be noted that this system will be triggered by a low velocity movement above a set threshold (user adjustable) and may arise from other movements, such as transducer or maternal movement.

Upgrade Options

The following additional options may have been supplied with your unit or can be ordered separately to upgrade your unit:

Intrapartum upgrade Contains:

FECG Interface Module (LP2)

Leg plate interface cable

Twins upgrade Contains:

Interface cable (incorporating interface electronics)

Wide Twins paper (1 pack)

☞ *The twins option requires two BD4000 main units. When interconnected, one is automatically configured as the local unit, the second as the remote unit. See the twins set-up and operation section for more details.*

Intrauterine Pressure Option

Contains:

Pressure sensor kit and interface module

☞ *Note that details on the Intrauterine Pressure option, are covered separately in the instructions supplied with the option kit.*

Accessories

A wide range of accessories is available for use with the **BD4000** fetal monitor including:

Rolling Cart - optionally available with 2 shelves for twins system

Wall mounting bracket

Desk-top tray

Consumables - gel, paper, belts

Carry case

2. Recommended Clinical Applications

The **BD4000** is intended for use, by trained professionals, in all conventional fetal monitoring applications.

DO use **BD4000** for:

Antenatal monitoring in the hospital, health clinic, or birthing centre.

Hospital admission CTG's

Labor monitoring.

DO NOT use **BD4000** for:

Underwater monitoring in waterbirth management - a range of **Aqua Dopplex**® Dopplers are available for this

Monitoring in any environment where the patient, user or unit is likely to come into contact with water.

Guidelines on the use of BD4000:

Fetal monitors provide just one indicator of fetal condition. This should be assessed as part of an holistic approach to obstetric care together with other factors. A complete assessment must be made before appropriate action is taken.

Scalp electrodes are invasive and their use carries a degree of risk, including increased risk of cross-infection. They should only be used under the conditions outlined above. The decision to use them remains the responsibility of the clinician.

Ultrasound monitoring should be performed in accordance with current guidelines. The ALARA guideline (AIUM) recommends that ultrasound exposure should be kept As Low As Reasonably Achievable.

3. Product Description

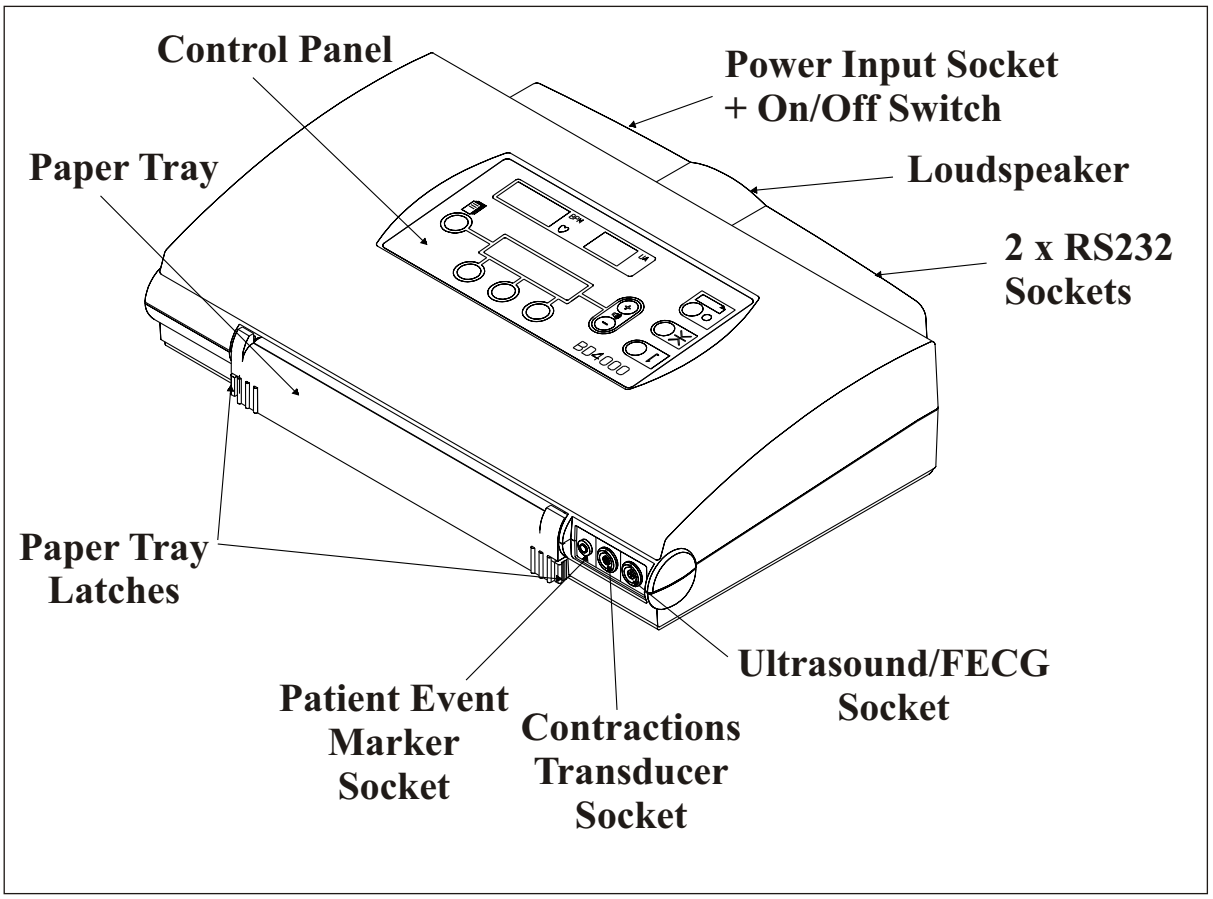


Figure 1 BD4000 Front View

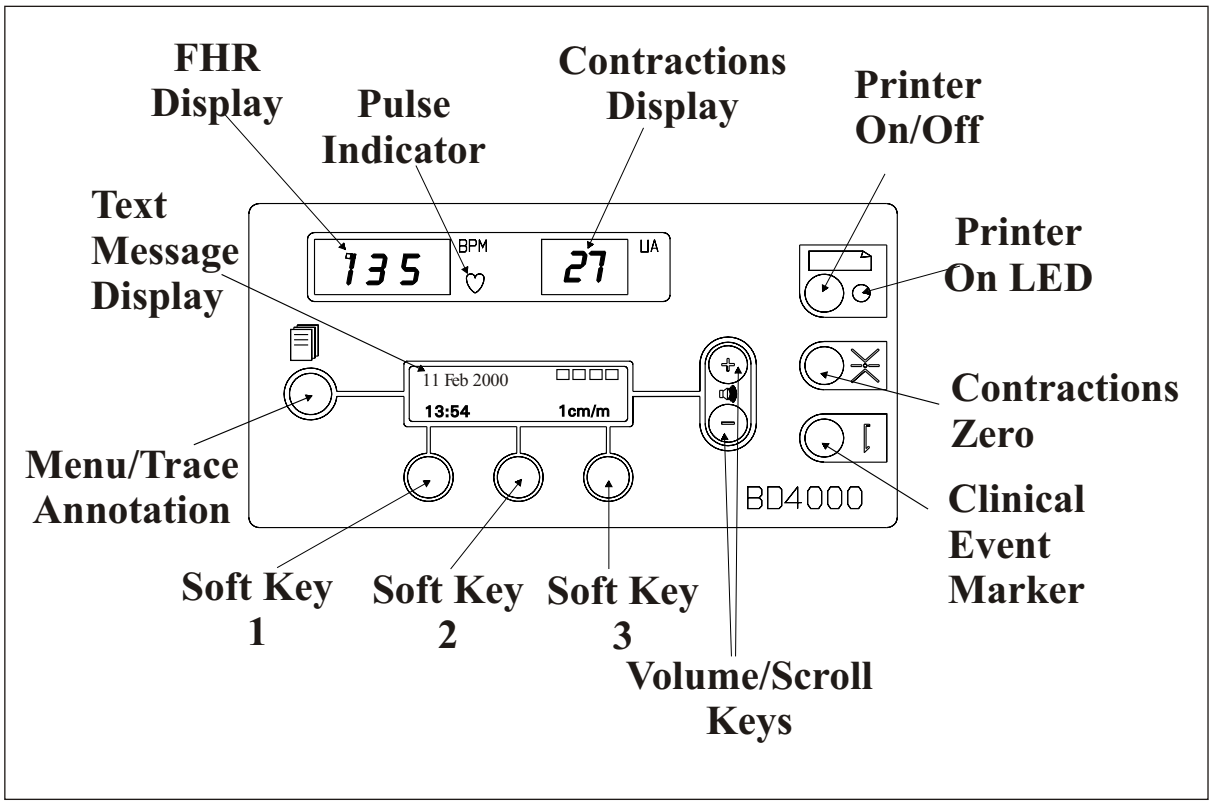


Figure 2 BD4000 Control Panel

4. Setting Up the BD4000

Power Connection/ Switching On

Connect the unit to a suitable power source using the cable supplied. The **BD4000** will operate at any A.C. power voltage in the range 100 to 250V, at 50 or 60Hz. No adjustment is necessary.

Switch the unit on.

Paper Loading

Open the paper tray by simultaneously depressing the latches at each end, as shown in Fig. 3. Slide the paper tray forward. Note that the LCD text display shows '**PAPER TRAY OPEN**'.

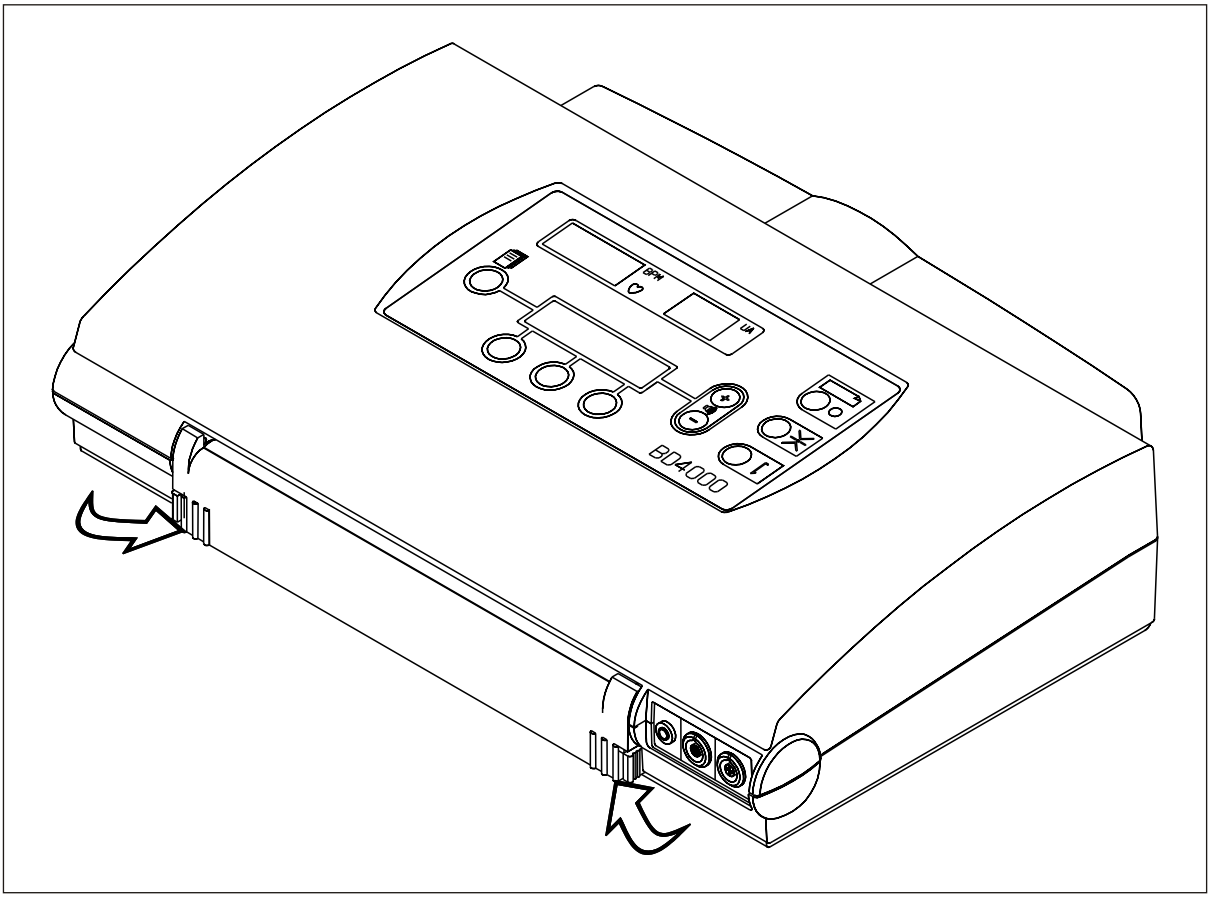


Figure 3 Paper Loading Instructions

Twins

Special wide paper, supplied with the Twins option pack, provides optimal presentation of the two traces on separate, full range, FHR scales, together with contractions, movement and event marker data.

Alternatively, using standard paper, the two traces are superimposed on the standard FHR scale.

Adjusting Paper Width

Ensure that the adjustable paper guide is set to the correct position for the paper.

☞ *Note that this can only be adjusted, by sliding left/right, when the paper tray is fully open.*

Ensure that it is located in the appropriate position indent. The paper tray cannot be closed if this is not located correctly.

Inserting Paper

Remove the paper pack outer film, discard the top and bottom card inserts, and insert pack into the tray. Ensure that the sensitive side is facing up. To confirm this, ensure that the pre-printed sheet numbers are visible on the right hand side of the pack (see Fig. 4). Refer to the paper loading guide in the paper tray. This guide should be left in place for future reference.

☞ *Note that the small hole in this guide must be positioned towards the front right hand side to ensure end-of-paper detection.*
A marker strip on the last few sheets of paper will indicate when the paper is about to run out. When no paper is left in the tray, the display will indicate 'END OF PAPER'.

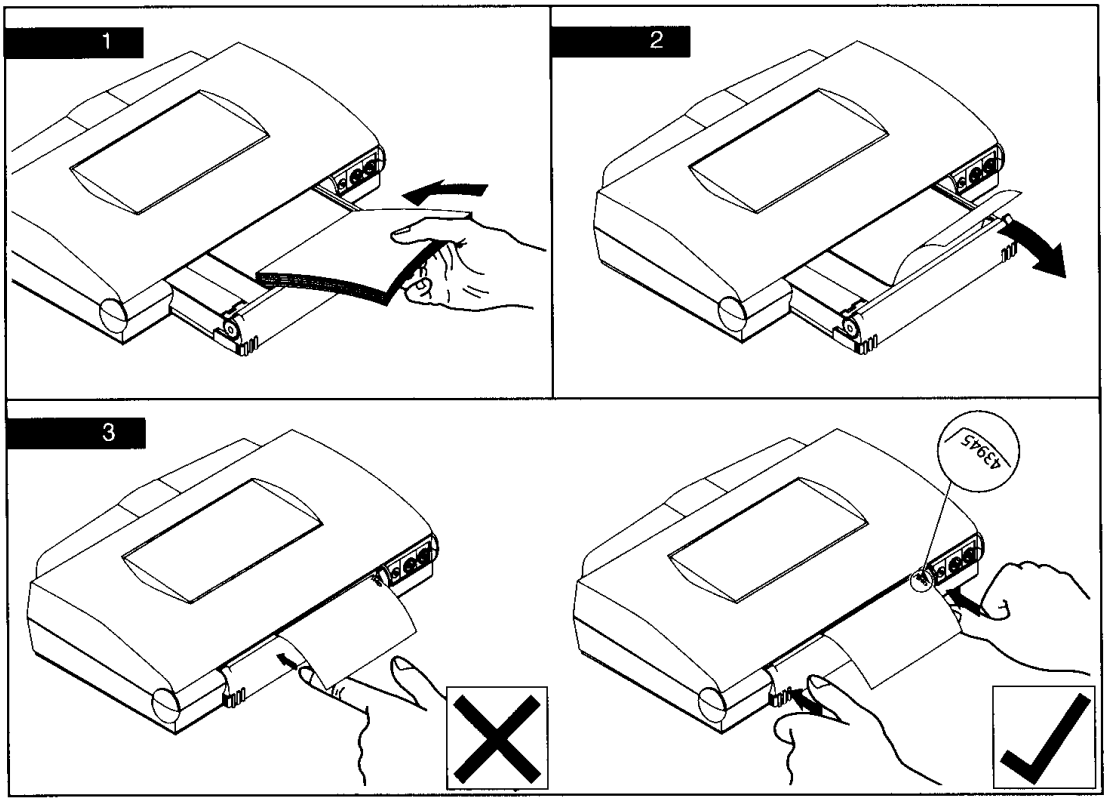


Figure 4 paper Loading Guide

Pull the top sheet out over the roller.

Using both hands, push the paper tray firmly shut.

☞ *Ensure that the latches at both ends are securely locked. (See Fig. 5). If the tray is not properly latched shut at both ends, the unit may not print, or poor print quality may be observed.*

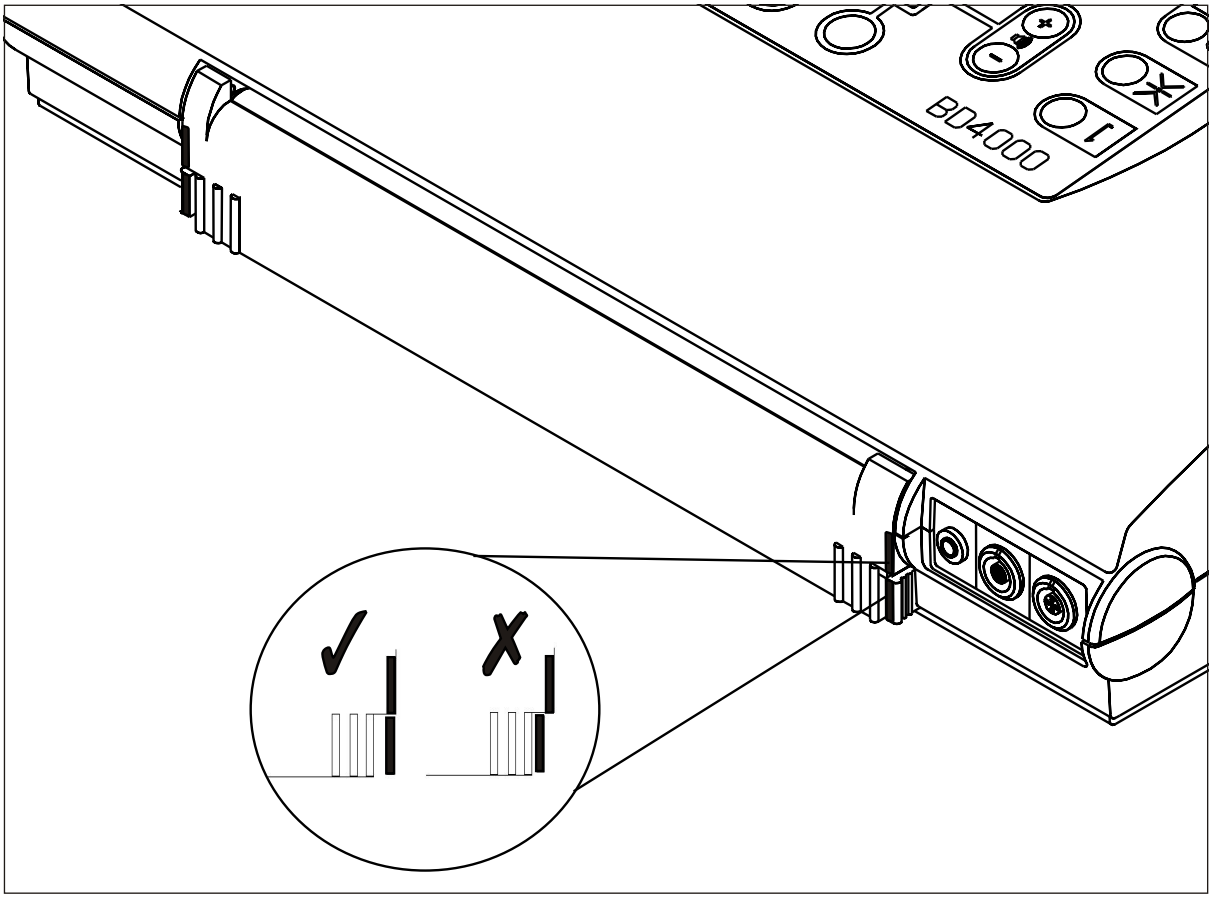


Figure 5 Paper Tray Firmly Shut

Use only the correct paper packs supplied by Huntleigh Healthcare Inc. Paper quality varies widely. Use of inferior quality paper may result in poor trace quality, may damage the unit and invalidate the warranty.

⚠ CAUTION

Do not use pre-printed paper designed for use in other fetal monitors - the registration of the trace to the pre-printed scale will not be accurate.

System Set-Up Option

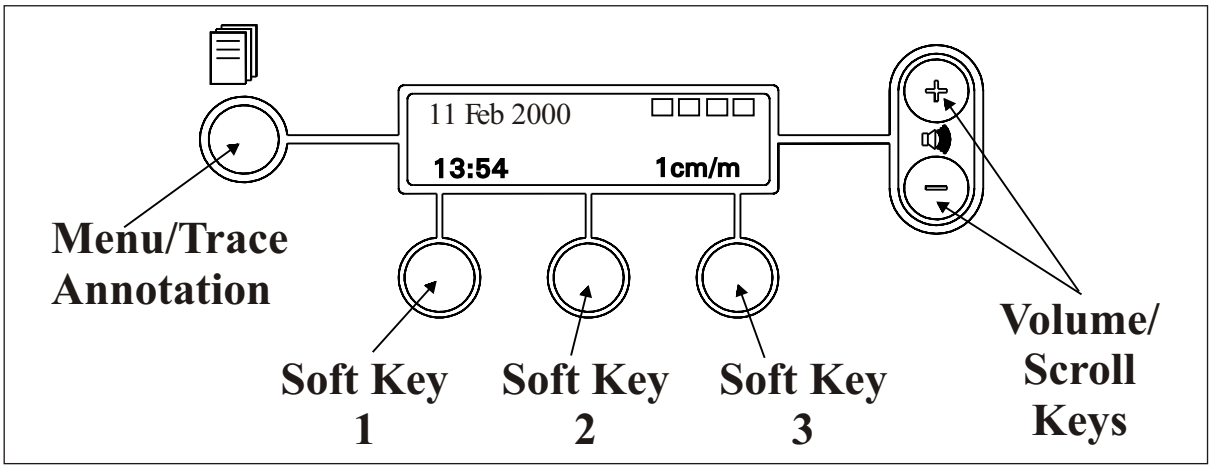


Figure 6 User Selectable Options

The following user selectable options can be selected, using the keys on the control panel (refer to Fig. 6).

These settings should be set as required when the unit is first installed. The saved settings will be retained when the unit is switched off.

Fetal movement detector

Chart speed - select 1, 2 or 3 cm/min

Time

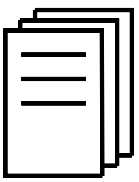
Date

Grid (beats/cm) - select 20 or 30 bpm/cm

Language

Alarms

Set-up Procedure



Ensure the unit is not printing - the 'Printer On' LED must not be lit.

Press the 'Menu' button. The display will show 'User Setup' with flashing arrows pointing to the Volume/Scroll keys. Use either key to scroll through the options listed above. Each key press will move on to the next option, moving either up ('+' key) or down ('-' key) through the options.

When the desired option is displayed in the text display, use the 3 keys below the display to adjust the option as required. These operate as 'soft keys' where their function is defined by labels in the text display, as described below:

Fetal Movement Detector

Soft key 1 : Toggle function off/on.
Soft key 3 : Increment trigger threshold
Soft key 2 : Decrement trigger threshold

☞ *Notes:*

1. *Default setting is 40%. (Recommended setting for normal use).*
2. *This function is intended for antenatal use only and should be disabled during labour monitoring.*
3. *For reliable operation, the ultrasound transducer should be correctly fitted with the supplied belt. Do not hand hold as movement of the transducer may falsely trigger the detector.*
4. *Function not available in FECG mode.*

Chart Speed

Soft key 1 : 1 cm/min (standard European setting).
Soft key 2 : 2 cm/min.
Soft key 3 : 3 cm/min (standard USA setting).

Time

Soft key 1 : Select hours/minutes.
Soft key 2 and 3 : Increment/decrement the selected value as required.

Date

Soft key 1: Selects Day/Month/Year.
Soft key 2 and 3 : Increment/decrement the selected value as required.

Grid (beats/cm)

Soft key 1 : 20 bpm/cm (standard European setting).
Soft key 3 : 30 bpm/cm (standard USA setting).

Language

Soft key 3 : Selects the desired language.

Alarms

Applicable from Serial Number: 614-98-B-0407

Loss of Contact (LOC) alarm

Detects when loss of contact (drop-out) occurs for a percentage (%LOC) of a preset time period. Both the percentage threshold and time are user selectable. The alarm can be disabled or can operate in silent or audio modes.

- ❒ Time range : 0 to 20 minutes (default setting - 10 minutes)
- ❒ %LOC range : 0 to 99 (default setting – 50%)
- ❒ Modes
  - ♦ *Off – alarm function is disabled (default mode)*
  - ♦ *Silent – alarm condition indicated on LCD display and print-out*
  - ♦ *Audio – display and print-out as per Silent mode accompanied by bleeping audio tone*

Set-up:

Enter set-up mode and use the 'Volume/Scroll' keys to
scroll through the menu to select 'LOC.alarm ...'

Soft key 1 : Selects time/%/mode
When time/% selected:
Soft keys 2 & 3: Increment/decrement value
When mode selected:
Soft key 3 : Selects Off/Silent/Audio

Tachycardia alarm

Detects when fetal heart rate (FHR) has remained above a user selectable threshold, for a user selectable time. The alarm can be disabled or can operate in silent or audio modes.

- ❒ FHR threshold range: 150 – 200 bpm (default setting – 180 bpm)
- ❒ Time range: 0–20 mins (default setting –10 minutes)
- ❒ Modes
  - ♦ *Off – alarm function is disabled (default mode)*
  - ♦ *Silent – alarm condition indicated on LCD display and print-out*
  - ♦ *Audio – display and print-out as per Silent mode accompanied by bleeping audio tone*

Set-up:

Enter set-up mode and use the 'Volume/Scroll' keys to
scroll through the menu to select 'Tach.alarm ...'

Soft key 1 : Selects time/rate/mode
When time/rate selected:
Soft keys 2 & 3: Increment/decrement value
When mode selected:
Soft key 3 : Selects Off/Silent/Audio

Bradycardia alarm

Detects when FHR has remained below a user selectable threshold, for a user selectable time. The alarm can be disabled or can operate in silent or audio modes.

- ❒ FHR threshold range : 50 - 120 bpm (default setting – 100 bpm)
- ❒ Time range: 0–20 mins (default setting –10 min)
- ❒ Modes
  - ♦ *Off – alarm function is disabled (default mode)*
  - ♦ *Silent – alarm condition indicated on LCD display and print-out*
  - ♦ *Audio – display and print-out as per Silent mode accompanied by bleeping audio tone.*

Set-up:

Enter set-up mode and use the 'Volume/Scroll' keys to
scroll through the menu to select 'Brad.alarm ...'

Soft key 1 : Selects time/rate/mode
When time/rate selected:
Soft keys 2 & 3: Increment/decrement value
When mode selected:
Soft key 3 : Selects Off/Silent/Audio

Clearing an Alarm

To reset the alarm following an alarm condition, press softkey 2. The alarm remains enabled and will detect any subsequent alarm conditions as per the selected time / threshold settings.
A marker will be printed on the print-out to log when the alarm is reset.

☞ *NOTES:*

1. *The volume of the alarm beep (when enabled) is set independently to a factory default level, ensuring that alarms will be heard even when the user adjustable volume level is turned down. When the alarm is reset, the volume level is restored to the user set level.*
2. *Under no circumstances must these alarm features be relied on for monitoring the patient. Normal clinical practice with regular visual checking of the CTG trace must be maintained.*
3. *In twins mode, alarms can be independently set on each unit (disconnect twins cable from remote unit to change remote settings). Alarm conditions on either unit will be displayed and printed out on the local unit (alarm identified as FHR1(local) or FHR2 (remote)). Alarms in either unit are cleared by pressing soft key 2on the local unit.*

Saving Set-up Changes

When any change to the set-up is made, the change must be saved to initiate the new set-up.

Press the 'Menu' button.
The display will show 'Save changes - Yes or No'.
Using the soft keys, select 'Yes' or 'No' as required.
The unit will return to normal operation and initiate any saved changes.

☞ *Note that, during set-up, if no key presses are detected for a period of 30 seconds, the unit will return to normal operation and will restore the last saved set-up.*

5. Operation

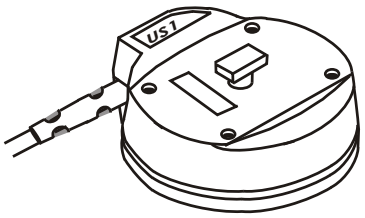
Before each monitoring session, check that system set-up is correct (date, time, chart speed, etc.) and that there is sufficient paper.

Check that the unit is not damaged in any way and ensure that cleaning procedures have been followed.

Antepartum Operation

Connecting the Transducers

Ultrasound Transducer

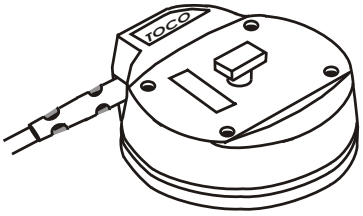


Plug the ultrasound transducer (marked ‘US1’, color coded red) into the 'Ultrasound/FECG' socket on the front panel of the main unit.

This socket is also color coded red. Align the red dot on the metal connector with the red dot at the top of the socket and press the connector in firmly.

Do not use excessive force.

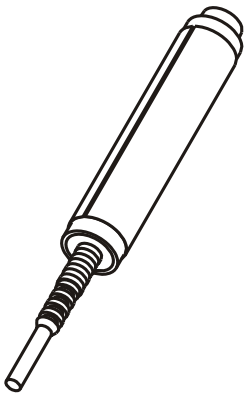
Contractions Transducer



Similarly, plug the contractions transducer (marked ‘TOCO’, color coded blue) into the ‘TOCO’ socket on the front panel.

This is also color coded blue.

Patient Event Marker



Plug the patient event marker into the left hand socket (3.5mm jack socket).

Ensure plug is fully inserted.

The unit is now ready for use.

Monitoring

Position the patient as required - typically in the semi-supine position and pass the elastic belts around the patient's abdomen.

Typically, the contractions transducer is positioned at the level of the fundus of the uterus, while the ultrasound transducer is positioned lower on the abdomen at the level of the fetal heart.

Ultrasound Transducer

To locate the best position for the ultrasound transducer, note the gestational age - with increasing gestational age the heart will be higher up the abdomen - and palpate. Best results will be achieved with the transducer placed over the fetus's upper back over the left scapula.

Gel

Apply sufficient gel to the abdomen (or to the face of the transducer) to ensure good contact over the full face of the transducer.

Apply the transducer by hand with firm pressure to maintain contact.

Locate Fetus

Adjust the position for the best signal. For best result, position the transducer to detect fetal heart sounds, not umbilical sounds. Note that umbilical sounds will be at the fetal heart rate but do not contain the characteristic 'slapping' valve sounds heard from the heart itself.

Check Signal

Confirm the signal is fetal by comparing the rate with the maternal rate. The fetal heart rate is typically about double the maternal rate.

Volume

Adjust the audio volume using the '+' & '-' keys as required. While either key is pressed, the display will show volume level setting in the form of a bar-graph.

Belt Attachment

Attach one end of the belt to the transducer by engaging one of the holes in the belt over the button on the top of the transducer. Keeping the transducer in position, tension the other end of the belt and engage the belt over the button, ensuring sufficient tension to keep the transducer in firm contact with the abdomen. Avoid over-tightening as this will cause unnecessary discomfort to the patient.

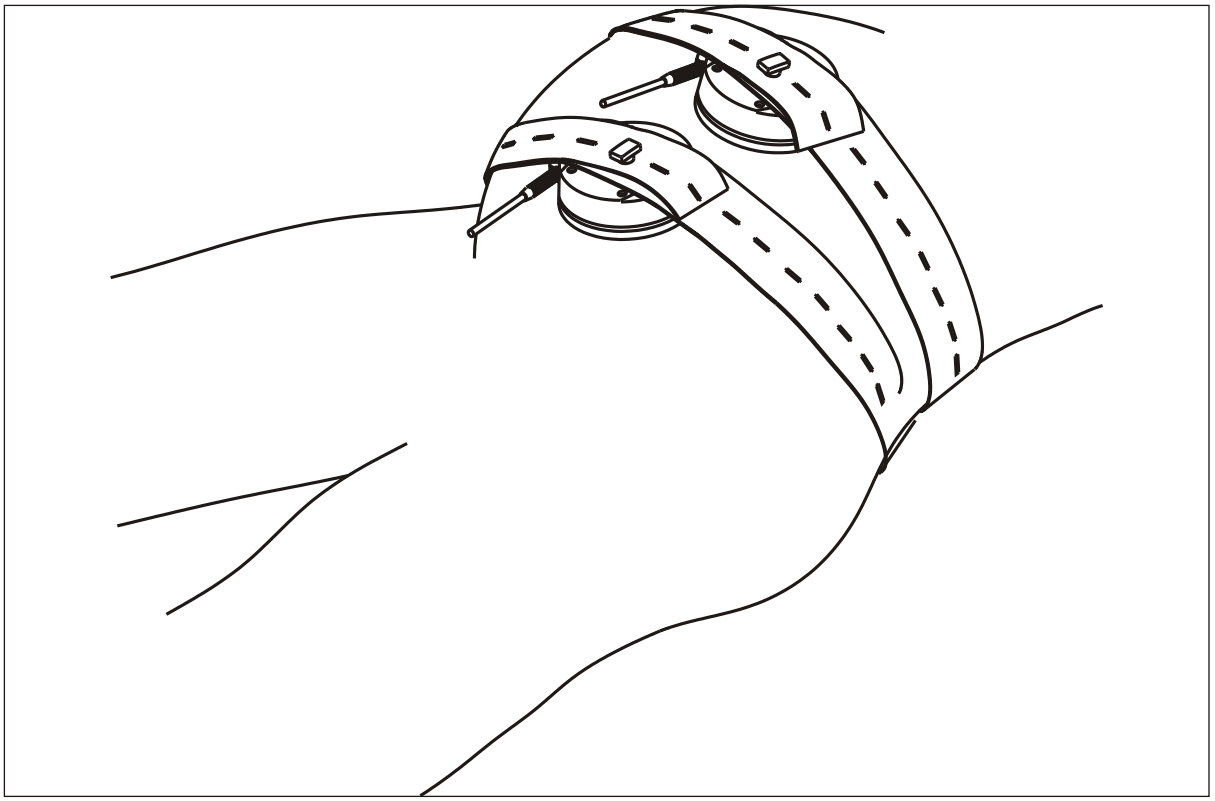


Figure 7 Transducer Belt Positioning

Re-adjust the transducer position to get the best possible signal.

If the fetus moves it may be necessary to adjust the transducer to restore signal.

Ultrasound Signal Quality indicator

□□□□

A signal quality indicator, in the form of a 4 level bar-graph, is provided in the top right hand corner of the text display. For best performance, all four elements should be showing. In the absence of signal, no elements will be seen.

Rate Display

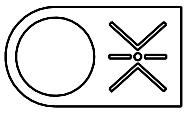
The FHR display on the control panel shows fetal heart rate in real time.

When no signal, or poor quality signal, is present, the display will show '- - -'.

Contractions Transducer

Attach the contractions transducer in the same way as the ultrasound transducer. Do NOT use gel. Position over the fundus for best performance.

Tighten the belt to ensure good contact.



Press the contractions ‘zero’ button. This removes the pre-load due to the belt tension and sets the contractions trace to the baseline on the print-out and ‘UA’ display (set to 20% on standard units).

Uterine activity (UA) is displayed adjacent to the FHR display. Note that these are relative units displayed as percentage of full scale.

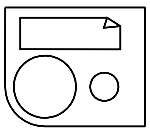
If the trace drops below ‘0’ the display width shows ‘L’. Check belt tension (too loose?) and re-zero.

Similarly, ‘H’ will be displayed if the trace rises above the top of the scale. Check belt tension (too tight?) and re-zero.

Patient Event Marker

This should be held by the patient. Instruct the patient to press the button whenever any fetal movement is felt.

Printing



To initiate printing, press and release the printer On/Off button. The Printer On indicator will illuminate while printing is in progress. If printing does not start, check that paper is installed and that the paper tray is properly latched shut.

To stop printing, press and release the printer On/Off button. After a short fast-feed of the paper, the printer will stop. (See Fig. 8).

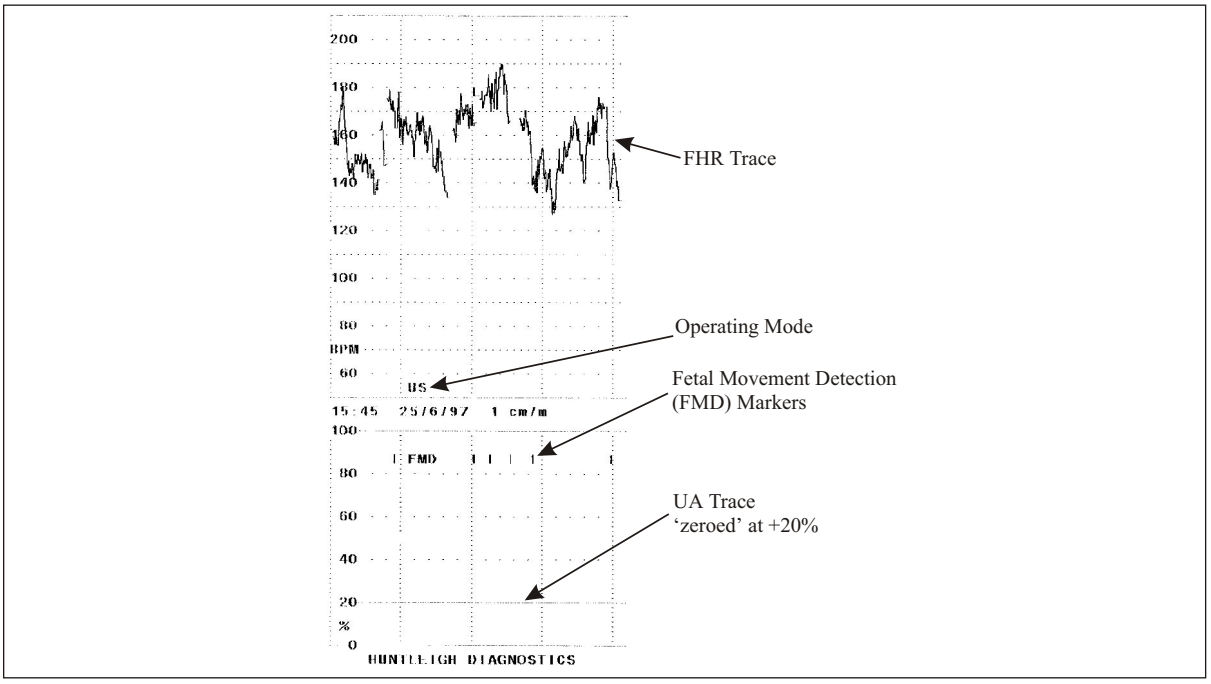
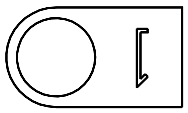


Figure 8 Single Channel Printout

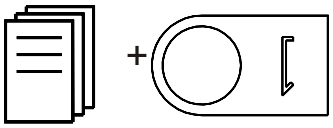
Clinical Event Marker



While printing, the clinical event marker button can be pressed to mark clinical actions. This prints a different style event mark at the top of the FHR channel to distinguish it from normal patient event marks.

Trace Annotation

While printing, the 'Menu' button can be used to scroll through a selection of trace annotation messages.



Select the message required on the display using the 'Menu' button and then press the clinical event marker button. The selected message will be printed above the FHR channel immediately after the clinical event mark. This allows clinical actions to be immediately and reliably recorded with accurate indication of timing.

The unit is supplied with a standard set of messages programmed in including: Pethidine, Oxygen, Epidural, Vaginal examination, etc. However, these can be customized to suit your requirements. Refer to your service department or supplier for further information.

Trace Interpretation

The print-out is presented in internationally standardized formats (depending on set-up options selected - see **Set-Up** section) to ensure consistent presentation.

Interpretation of this information is beyond the scope of this document and should only be undertaken by experienced, qualified clinicians.

It is important to note that:

1. FHR is just one single indicator of fetal condition and that it must only be considered within an holistic approach to obstetric management.

2. In poor/difficult signal conditions, false data may be displayed/printed. Rate can be confirmed by listening to the audio signal.

After Use

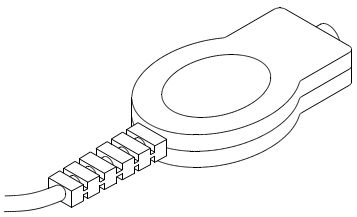
The system should be carefully cleaned. Refer to **"Cleaning Instructions"** for details.

Intrapartum Operation

For external ultrasound monitoring refer to the “Antepartum Operation” section.

Connecting the Transducers

Leg Plate Interface Cable



Plug the FECG interface module (marked ‘LP2’, connector color coded red) into the ‘US/FECG’ socket, also color coded red on the main unit, in place of the ultrasound transducer.

This automatically reconfigures the - system for intrapartum operation.

The display will show **FECG** in the top right corner.

Insert the Leg plate interface cable plug (color coded green) into the green socket on the FECG interface module (LP2), refer to Figure 9.

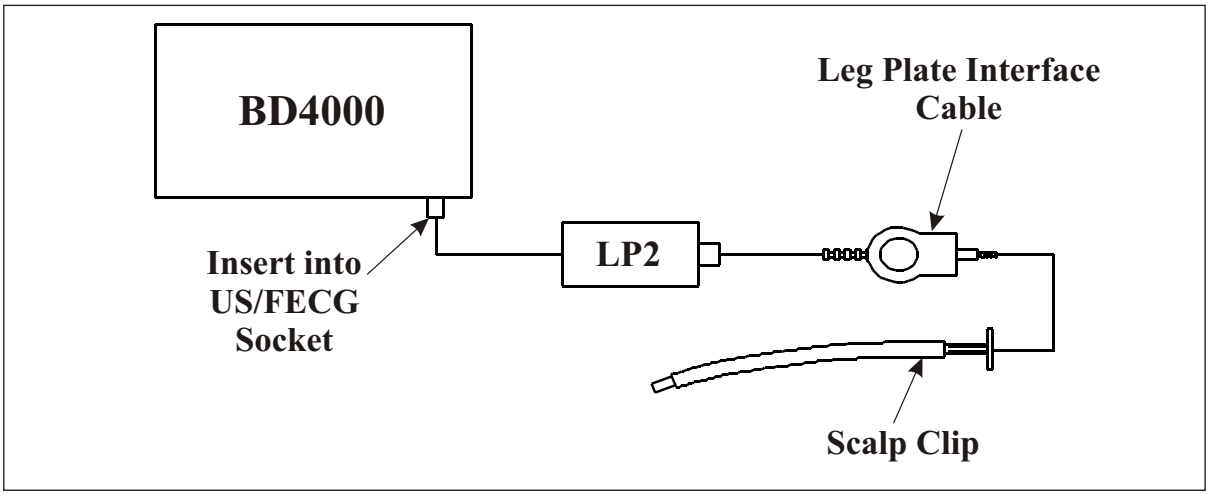


Figure 9 LP2 & Scalp Clip Connection

The signal quality indicator is disabled in FECG mode. However, a ‘Leads Off’ indicator will detect loss of FECG signal.

Contractions Transducer

Connect as for antepartum operation - refer to Antepartum Operation section.

⚠ WARNING

The FECG interface module contains sensitive electronics and provides the additional electrical isolation (type BF) required for safe connection to the fetus. Inspect carefully before use for any damage as this may affect electrical isolation.
If any damage is found, do not proceed.

Intra Uterine Pressure (IUP) Monitoring Option

For use in intrapartum monitoring instead of the external contractions transducer. For set-up and operation, refer to the instructions supplied with the IUP option pack.

Patient Event Marker

If required, connect as for antepartum operation - refer to Antepartum Operation section.

Fetal Movement Detector

This is intended for antenal use and should be disabled during labor monitoring (refer to “System Configuration” section). It is automatically disabled in FECG mode.

The unit is now ready for use.

Monitoring

Leg Plate

Secure the leg plate on the thigh using an attachment pad, with the cable leading down towards the feet as shown below in Figure 10.

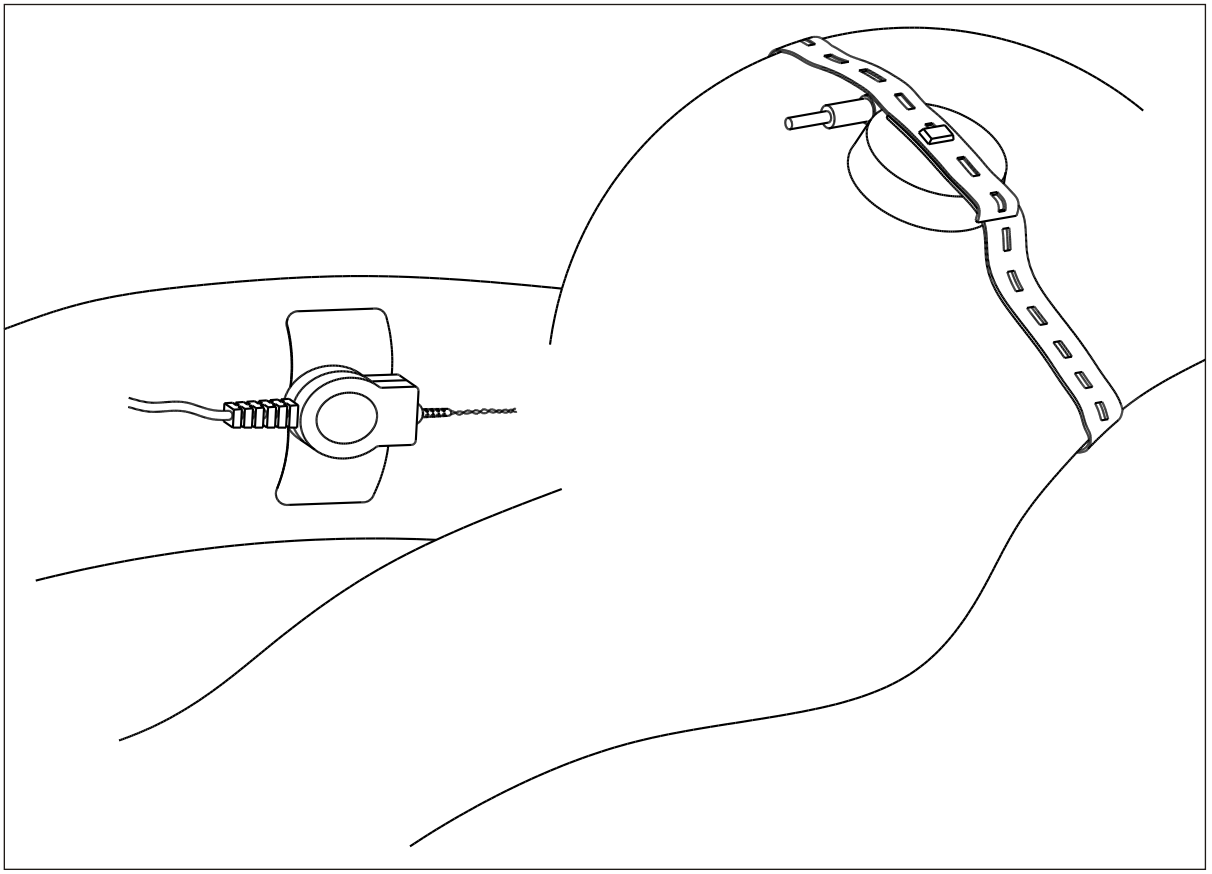
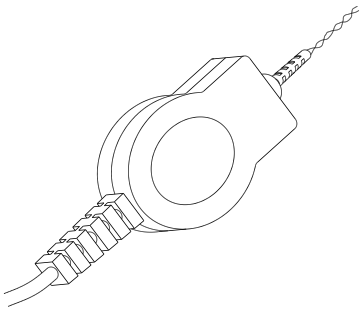


Figure 10 Leg Plate Positioning

Scalp Electrode



The **BD4000** is designed for use with the **Corometrics** Qwik Connect Plus spiral electrode. These and the legplate attachment pads are supplied separately, individually sterile wrapped for single use only. Before opening, inspect sterile pack carefully. If there is any breach of the sterile packing, the electrode must be discarded. Using sterile technique, apply the scalp electrode in accordance with the manufacturer's instructions.

Plug the scalp electrode connector into the leg plate socket. (See Fig. 9).

Allow the scalp electrode/fetal connection to stabilize (this may take several minutes) and check for signal.
A regular audio beep at the fetal heart rate should be heard (adjust volume as required) and fetal heart rate should be displayed on the FHR display. Also, the fetal pulse indicator should flash with each detected pulse.

If signal quality is poor, check the scalp electrode connections and the system wiring. Check that the transducer is firmly held in contact with the maternal thigh and, if necessary, re-apply the electrode.

Leads-off Detector

If at any time contact is lost, after a short delay the text display will show 'CHECK LEADS'. Check all leg plate connections, maternal contact and scalp electrode attachment. If necessary re-apply or replace electrode.

Printing

Ensure sufficient paper is available in the paper tray. Initiate printing as for antepartum monitoring.

Trace Interpretation

This is beyond the scope of this document. It is assumed that the user is clinically qualified and experienced, both in the use of similar fetal monitoring equipment, the application of the electrode and in interpreting the data provided.

As with antepartum monitoring, it must be recognized that FHR is just one indicator of fetal condition, which should be interpreted within an holistic approach to labor management.

As with any similar device, in poor/difficult signal conditions, false data may be displayed/printed. Additional educational material and support is available from Huntleigh Healthcare Inc.

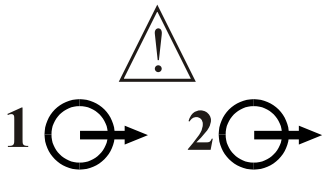
After Use

The system should be carefully cleaned and decontaminated. Refer to Care of Your Baby Dopplex cleaning instructions for details.

Twins Monitoring

Equipment Set-up

This requires two **BD4000** main units connected together to provide twins capability.



Please consult this User Manual.

Identify the 2x RS232 sockets on the rear panel, marked as shown.

Using the interface cable provided with the twins option pack, plug the female plug (marked '1') into socket number ‘1’ on one of the units ensuring fixing screws are tightened securely. This unit will automatically be configured as the local unit.

The text display will show ‘Remote FHR =’ in the top line of the text display, with the remote unit’s FHR data displayed immediately below (shown as ‘- - - bpm’ with no signal).

Connect the other end, a male plug (marked ‘2’), to socket number ‘2’ on the second unit. This unit will automatically be configured as the remote unit. All controls on the remote unit will be disabled except for the volume control.

The remote unit display will read ‘Twins Remote Unit’.

The system is now automatically configured for twins operation.

CAUTION

If RS232 outputs 1 and 2 are used simultaneously, the system should comply with EN60601-1-1.

Any equipment connected to outputs 1 or 2 should comply with EN60601-1, EN60950, EN60065, EN60335 or EN61010.

Transducers/Operating Modes

2 Channel Fetal Heart Rate

The user can optionally use:

Ultrasound transducers on both local and remote units

Ultrasound on one (either) unit and FECG (scalp electrode) on the other unit.

Connect the ultrasound transducers/leg plate as required, and set up on patient as normal.

☞ *The ultrasound signal quality indicator is not available in twins modes.*

When using the leg plate on either unit, a 'leads off', or poor contact, condition will be indicated on the local unit display as 'Check Leads'.

Contractions

Connect the contractions transducer to the 'local' unit and set up on the patient as normal. Note that the remote unit contractions function is disabled in twins mode.

Patient Event Marker

Connect to the 'local' unit. Note that the remote unit event marker function is disabled in twins mode.

Paper

In the local unit, optionally replace the standard paper pack with the special wide paper pack supplied with the Twins pack. (Refer to "**Paper Loading**" instructions).

The two FHR traces will then be printed separately on two separate full size FHR scales. A single contractions channel, slightly reduced in size is printed below the two FHR channels. The patient event marks will appear at the bottom of the lower FHR grid, while the clinical event marker and trace annotation text will appear above the top FHR grid. (See Fig. 11).

The two scales are labelled 'Local' and 'Remote'.

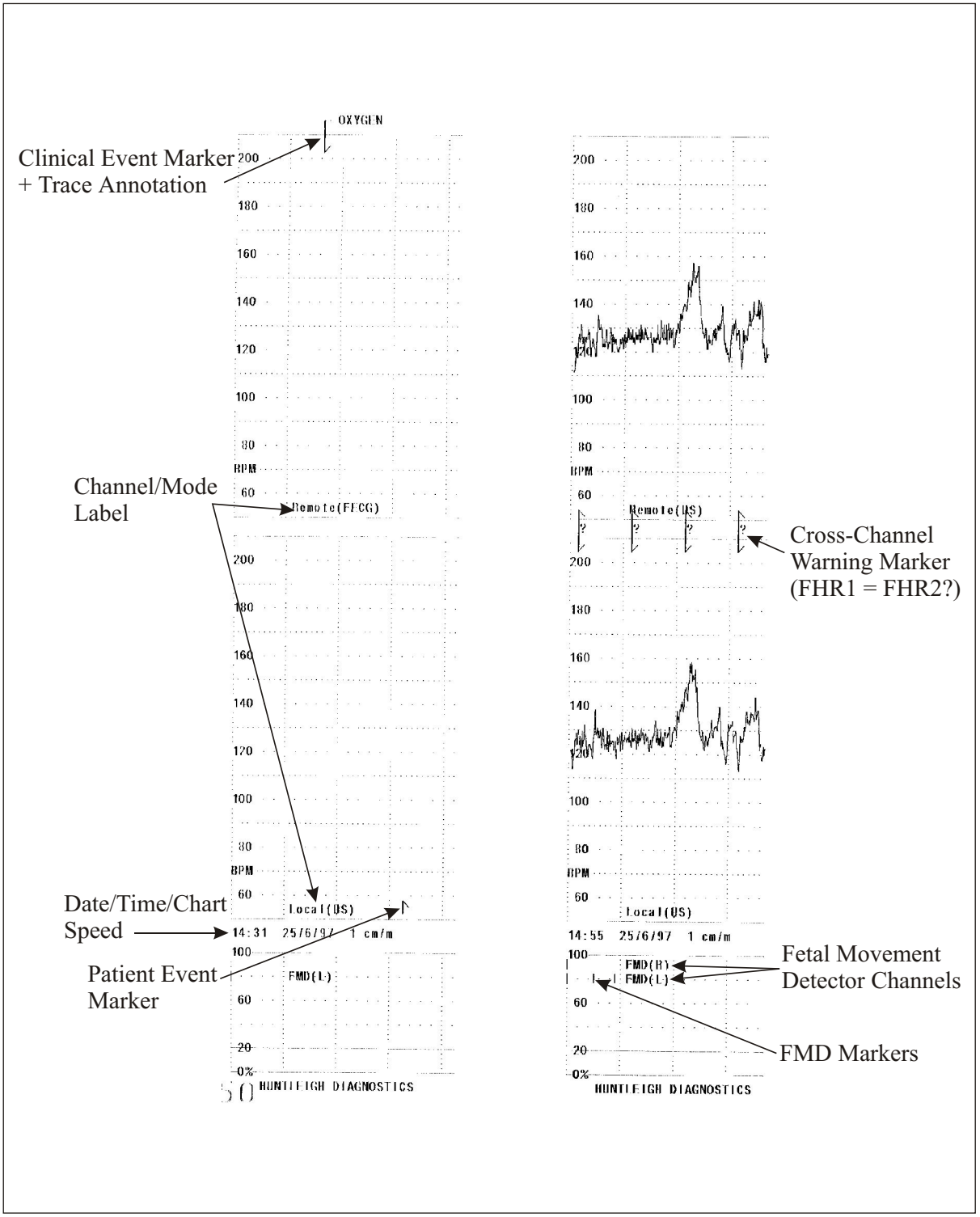


Figure 11 Twins Printout on Wide Paper

Alternatively, the standard paper can be used. The unit will automatically detect which paper width is installed and adjust the print-out accordingly. With standard paper, both traces will be superimposed on the standard FHR scale. The two traces will be labelled 'L' and 'R' at regular intervals to avoid confusion. (See Fig. 12).

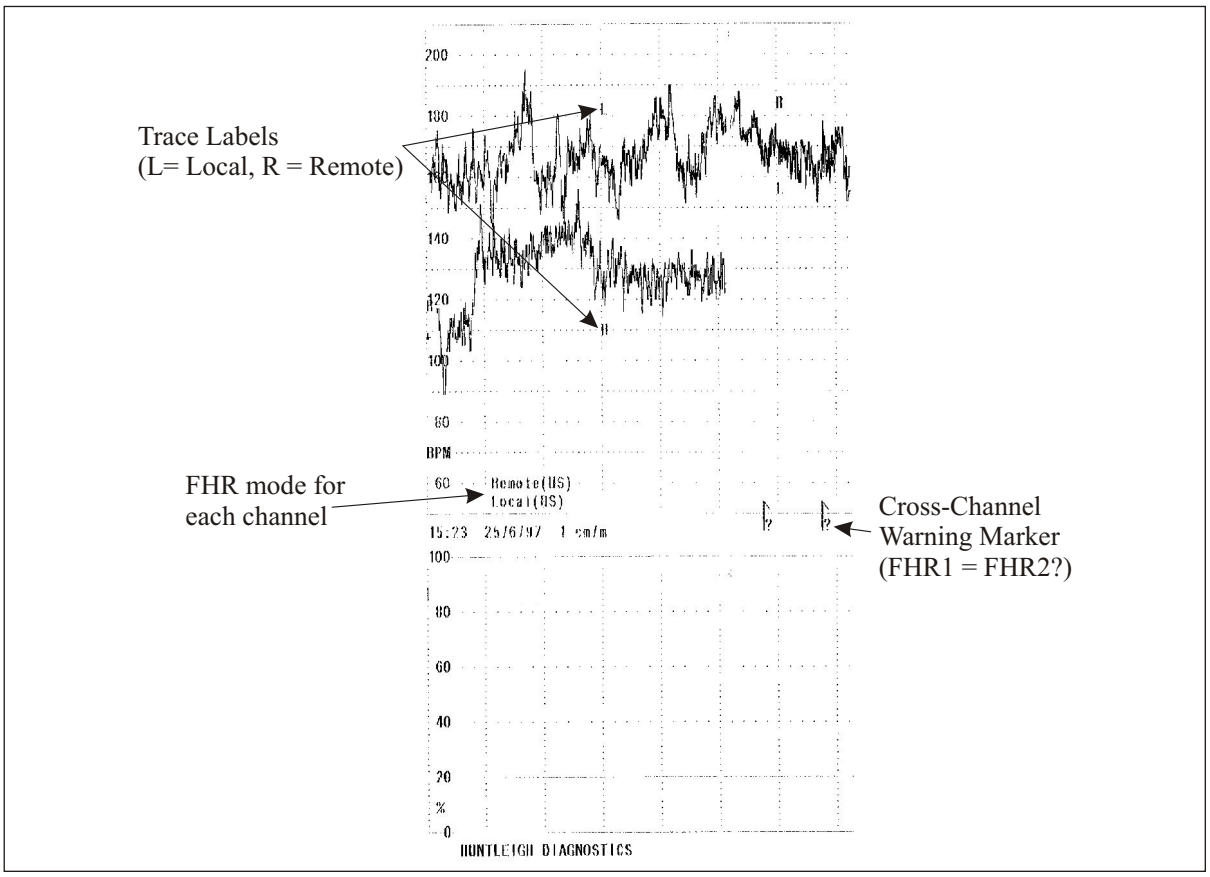


Figure 12 Twins Printout on Standard Paper

Printing

The twins system is now ready for recording twins. To commence monitoring, switch the local unit printer on, by pressing and releasing the printer On/Off button.

Cross-channel Warning

Check that different rate patterns are shown on the two traces. The system continuously checks for this also and will indicate '**FHR1 = FHR2**' if it detects the same data on both channels. In this event, simply reposition one of the ultrasound transducers to ensure that both twins are being separately monitored.

A marker ⌊? (or ⌈? on standard width paper) will also be printed on the paper.

Audio

When using ultrasound, separate audio sounds will be heard from each main unit. Adjust volume on each unit as required. Note that if one of the units is operating in FECG (scalp electrode) mode, electronic beeps will replace the Doppler heart sound in that unit.

6. Care of your BD4000

Handling

Although the **BD4000** is robust and designed to withstand normal clinical use, the unit does contain delicate components and should be treated with care. This applies especially to the transducers and the FECG interface module, which contain sensitive electronics and should not be dropped or knocked.

Maintenance

Other than careful cleaning, the **BD4000** does not require routine maintenance. If any parts of the system appear damaged, in any way, the system should be returned to your local service center for repair.

Ultrasound and ECG Coupling Gel

The use of water based gels supplied by Huntleigh Healthcare Inc. is strongly recommended. Oil based gels can damage the transducer and must not be used. The use of oil based gels will invalidate your warranty. The gels supplied are carefully designed for optimum performance in their intended uses. It is important to use the correct gels for each application to ensure best performance.

⚠ CAUTION

Switch the unit off and disconnect from the electrical outlet before cleaning.

⚠ WARNING

The BD4000 and its range of options and accessories are not designed to be sterilized.

FECG scalp electrodes are normally supplied sterile for single use only.

Cleaning

Main Unit

If required, this can be wiped with a soft cloth dampened with a mild detergent solution, avoiding the connectors. Do not allow any fluid to seep into the unit. Ensure the unit is completely dry before reconnecting to the electrical outlet.

Ultrasound Transducer	This should be cleaned by immersing in warm (50°C max.), mild detergent solution, using a bottle brush if necessary. Do not soak or run under a tap. Rinse with clean water and dry thoroughly before use.

⚠ WARNING

Do <u>NOT</u> immerse connectors

FECG interface module, legplate interface cable and Contractions Transducer (TOCO)	Wipe with a soft cloth dampened with a mild detergent solution, avoiding the connector. Do not allow any fluid to seep into the transducer. Dry thoroughly before use.
Transducer Belts	These should be hand-washed at 40°C max., using a mild detergent solution. Rinse with clean water and dry thoroughly (without using heat) before use.

Disinfection

Transducers and Leg Plate interface cable.

To assist with disinfection, wipe the transducers and leg plate with a soft cloth dampened with a sodium hypochlorite 1000ppm solution (2oz bleach per each gallon of water), and wipe dry.

Please be sure to check your local infection control policies or equipment cleaning procedures.

⚠ CAUTION

Phenolic, detergent based disinfectants containing cationic surfactants, ammonia based compounds, or antiseptic solutions such as Steriscol or Hibiscrub should never be used on any part of the system as permanent damage will result.

7. Troubleshooting

If you encounter difficulties in operating your **BD4000** fetal monitor, the following table lists some possible causes and solutions.

Problem	Cause	Solution
Poor signal (U/S)	Fetus moved or transducer incorrectly positioned.	Reposition transducer.
	Insufficient gel.	Apply gel.
Poor signal (FECG)	Poor scalp electrode attachment.	Re-apply or replace scalp electrode.
	Poor leg plate maternal contact	Check/re-apply leg plate.
	Poor connections.	Check connections.
UA display shows 'L' or 'H'	Toco transducer too loose ('L') or tight ('H').	Check and adjust belt. Re-zero using control panel zero button.
Paper feeds but no printing	Paper installed upside down.	Re-install paper pack with sensitive side up.
Paper not feeding	Paper tray not fully shut.	Push firmly in at both ends of tray - ensure both latches are locked in.
	Out of paper.	Check paper.
	Paper jammed.	Check correct pack installed. Ensure top and bottom packing cards are removed.
Print quality poor	Paper tray not latched shut at one end or both ends.	Push firmly in at both ends of tray - ensure both latches are locked in.

If trouble persists, consult your service center.

⚠ CAUTION

This product contains sensitive electronics, therefore strong radiated radio frequency signals could possibly interfere with it. This will be indicated by unusual sounds from the loudspeaker.

This should not affect the CTG.
However, we recommend that the source of interference is identified and eliminated.

8. Warranty and Service

a) **HUNTLEIGH HEALTHCARE INC. HEREBY DISCLAIMS ALL EXPRESS OR IMPLIED WARRANTIES (INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE) AND ANY AGREEMENTS, REPRESENTATIONS, AFFIRMATIONS, OR WARRANTIES, WHETHER ORAL OR WRITTEN, MADE BY ANY AGENT, EMPLOYEE OR REPRESENTATIVE OF HUNTLEIGH HEALTHCARE INC., UNLESS SPECIFICALLY SET FORTH IN THIS PARAGRAPH. HUNTLEIGH HEALTHCARE INC. SHALL NOT BE LIABLE FOR BREACH OF CONTRACT ARISING FROM ANY DEFECT IN MATERIAL OR WORKMANSHIP OF THE GOODS. ALL LEGISLATION RELATING TO EXPRESS AND IMPLIED WARRANTIES OR OTHER OBLIGATIONS ON THE PART OF HUNTLEIGH HEALTHCARE INC. THAT MAY BE LAWFULLY EXCLUDED ARE HEREBY EXCLUDED.**

b) Notwithstanding the foregoing, Huntleigh Healthcare Inc.'s sole warranty is that the Goods shall be free from defects in material and workmanship for a period, of twenty four (24) months for the BD4000 and twelve (12) months for the transducers, following delivery of such Goods to the original purchaser; provided that the Goods were used in an appropriate and reasonable manner during such period and provided further that Huntleigh Healthcare Inc. shall in no event be liable to Customer for defective Goods if: (i) the Goods are damaged in the course of shipping; (ii) any defect is caused wholly or to any material extent by Customer's negligence, misuse, failure to use the Goods properly or use of the Goods in conjunction with any accessory not approved for use with the Goods by Huntleigh Healthcare Inc.; (iii) the Goods are damaged as a result of improper maintenance, failure to follow manufacturer's instructions, including without limitation those on washing and cleaning,or failure to follow necessary routine maintenance procedures; or (iv) the Goods are altered, repaired or dismantled other than with manufacturer's written authorization using its approved procedures or by any party other than manufacturer's properly qualified and trained technicians.

c) Customer must provide written notice to Huntleigh Healthcare Inc. within said period, twenty four (24) months for unit or twelve (12) months for transducers, of any defect in the Goods. Upon Huntleigh Healthcare Inc.'s written request, Customer must return such Goods adequately packed (in their original packing) and fully insured to Huntleigh Healthcare Inc.'s place of business and shall be responsible for all shipping costs incurred therein.

Customer's exclusive remedy and Huntleigh Healthcare Inc.'s exclusive liability for any claim for loss, damage or destruction resulting from any defects in materials and workmanship shall be limited to repair, service, adjustment or replacement (at Huntleigh Healthcare Inc.'s option) of any nonconforming or defective Goods. Huntleigh Healthcare Inc. will have a reasonable time to repair, service or replace such Goods. Any Goods returned to Huntleigh Healthcare Inc. which are found not to be defective in breach of the warranty in Subsection (b) above, shall be returned to Customer in the manner described in this subsection.

d) IN NO EVENT SHALL HUNTLEIGH HEALTHCARE INC. BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSSES OR DAMAGES (INCLUDING BUT NOT LIMITED TO ECONOMIC LOSS, LOSS OF PROFITS OR SPECIAL DAMAGES) ARISING OUT OF OR INCURRED BY CUSTOMER IN CONNECTION WITH THE PURCHASE OF HUNTLEIGH HEALTHCARE INC.'S GOODS EVEN IF HUNTLEIGH HEALTHCARE INC. HAS BEEN ADVISED OR HAS KNOWLEDGE OF THE POSSIBILITY OR EXTENT OF SUCH DAMAGES SUFFERED OR INCURRED BY CUSTOMER OR ANY END USER AS A RESULT OF OR IN CONNECTION WITH ANY BREACH OF THESE TERMS AND CONDITIONS BY HUNTLEIGH HEALTHCARE INC. OR ANY TORT (INCLUDING BUT NOT LIMITED TO STRICT LIABILITY OR NEGLIGENCE) COMMITTED BY HUNTLEIGH HEALTHCARE INC., ITS AGENTS OR REPRESENTATIVES IN CONNECTION WITH THESE TERMS AND CONDITIONS OR ANY CONTRACT WITH CUSTOMER FOR THE SUPPLY OF GOODS.

e) Customer shall not create, directly or indirectly, any warranty obligations on the part of Huntleigh Healthcare Inc. to the customers of Customer, and in particular, without limiting the foregoing, Customer agrees not to pass on to its customers any warranties beyond or in addition to those given by Huntleigh Healthcare Inc. to Customer hereunder. Where the Customer is a dealer in the Goods, it shall be responsible for the labor cost of all repairs and Huntleigh Healthcare Inc. shall be responsible for providing all repair parts during said twelve (12) month warranty period.
The dealer shall provide written verification of warranty repairs including the original invoice number, date of purchase, description of repairs,name of its customer and date of sale to such customer.

f) Customer shall be deemed to have full knowledge of the nature and properties of the Goods ordered and of any hazards they involve and the proper treatment, storage and handling thereof. Any technical advice furnished by Huntleigh Healthcare Inc. or its representatives or agents is given only on the basis that it is followed at the Customer's own risk.

Service Returns

A service manual is available for the **BD4000** series.

It contains relevant service information including block circuit diagrams, parts lists and fault finding guidelines. The service manual can be obtained by contacting your local supplier or the Customer Care Department.

For service, maintenance and any questions regarding this, or any other Huntleigh Healthcare Inc.'s Dopplex product, please contact:

Service Department
Huntleigh Healthcare Inc.
40 Christopher Way
Eatonton, NJ 07724-3327

Tel : (800) 223-1218

Or your local distributor.

CAUTION

In the unlikely event that you need to return this product, please adopt local decontamination procedures and provide documentation outlining the product's status.
Please ensure that this documentation is accessible without having to open the package.

No product return will be accepted without first obtaining a Return Goods Authorization number from a Huntleigh customer service agent.

Huntleigh Healthcare Inc. reserves the right to return, unopened, any shipment not complying with this requirement.

9. Technical Data

General

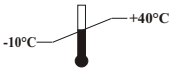
Product Name:	**Baby DOPPLEX® 4000**
Model No.:	**BD4000**

Physical

Size - Control Unit:	93mm (4”) x 380mm (15”) x 250mm (10”) (HxWxD)
Weight :	4.5Kg/8.8lbs

Environmental

Operating Temperature:	-10°C to +30°C (+50°F to +86°F)
Storage Temperature :	-10°C to +40°C (-50°F to +104°F)



Electrical

Power Supply:	100 to 250Va.c. 50/60Hz
Fuse Type :	T2A 250V
Audio Power:	1 Watt max.

Ultrasound Transducer

Transmitter Frequency:	US1 - 1.5MHz ± 1%
Acoustic Output:	Under the requirements laid down in IEC1157:1992, the peak negative acoustic pressure does not exceed 1MPa. The output beam intensity does not exceed 20mW/cm² and the spatial-peak temporal-average intensity does not exceed 100mW/cm².

Contractions Transducer

Range:	0 to 100% relative units.
Max. Load:	300g.

Regulatory Compliance/Standards

Complies with:	BS5724 : Part 1 : 1989 IEC601-1 : 1988 EN60601-1 : 1990 UL2601-1 CSA22.2 No. 601-1
EN60601-1 Classification:	Type of shock protection - Type B except Leg Plate (LP2) - Type BF

Degree of Protection Against Water Ingress:	Ordinary equipment
Degree of Safety in Presence of Flammable Gases:	Not suitable for use in the presence of flammable gases.
Mode of Operation:	Continuous

Performance

FHR Range:	U/S - 50 to 210 bpm FECG - 30 to 240 bpm
FHR Accuracy:	±1bpm over full range.
FHR Scale Options:	50 to 210 bpm at 20 bpm/cm, 30 to 240 bpm at 30 bpm/cm.

CE

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Medical Devices Directive 93/42/EEC

Manufactured in the UK by Huntleigh Healthcare, Diagnostic Products Division.
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As part of the ongoing development program the company reserves the right to modify specifications and materials of the Baby Dopplex® 4000 without notice.

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21/10/2004