Operator's Manual

V1000 Foetal Heart Simulator

VIAMED

CE

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Introduction

The V1000 Foetal Heart Simulator allows the operation of foetal heart monitors to be verified and the accuracy of displayed foetal heart rate assessed.

It is a hand held, portable unit for use in any environment where foetal heart monitors need to be tested: before use, when suspected faulty or after routine servicing.

The V1000 simulates heart rates in the range of 30 BPM to 210 BPM.

Altering the intensity control on the front panel alters the amplitude, allowing the sensitivity of the transducer and monitor combination to be assessed.

The V1000 can simulate continuously in excess of 2 weeks at maximum intensity, using 4 x 1.5V AA/MN1500/LR6 alkaline batteries.

Areas of Application for the V1000

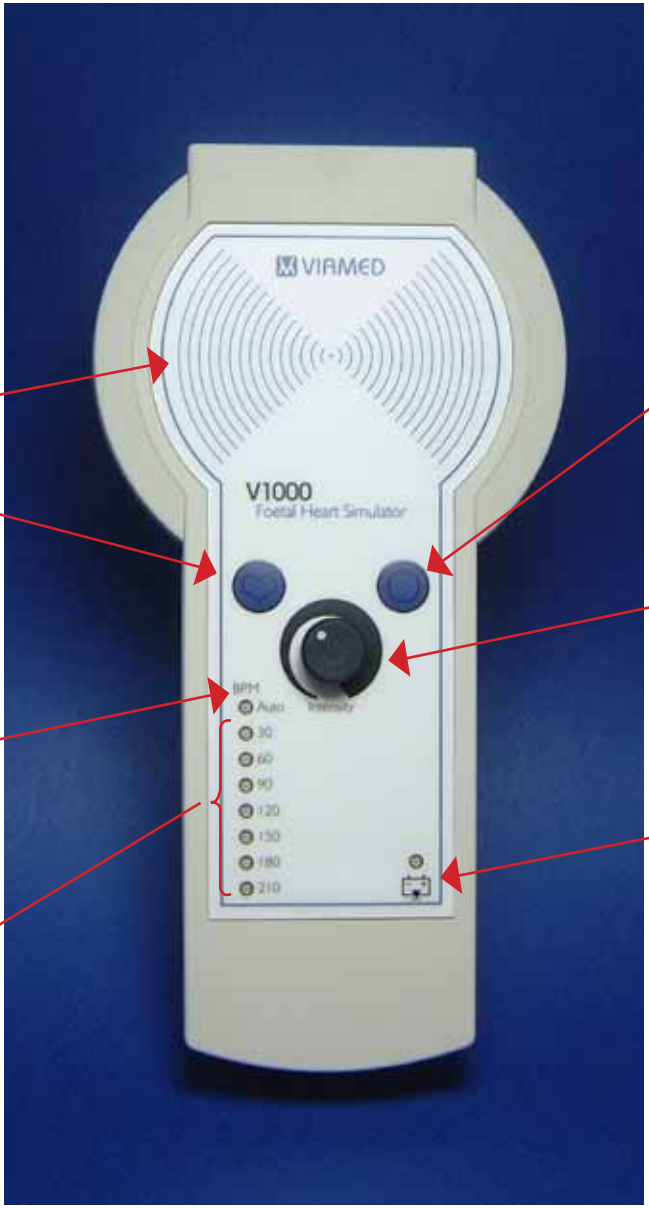
The following is a breakdown of when the V1000 can be used:

By Engineers for:
Fault finding and diagnosis of the monitor
Soak testing of the monitor
As part of a Planned Preventative Maintenance procedure
Verification of correct chart paper installed

By Midwives & Clinicians for:
Testing the foetal heart monitors and transducers prior to use
Verification of correct chart paper installed

For Teaching purposes:
Simulation of the foetal heart and training in the use of monitoring equipment

Controls and Indicators



Operating the V1000

The V1000 can simulate at fixed heart rates between 30 BPM and 210 BPM at 30 BPM intervals. It can also run an automatic test routine of 30 seconds at 30 BPM followed by the same duration at 60, 90, 120, 150, 180 & 210 BPM. This test routine is continuous until auto test is deselected or the simulator is switched off.

1. Place ultrasound gel on the centre of the transducer placement markings on the front panel of the V1000.

2. Obtain a good contact between the transducer and the V1000, with the transducer remaining central, using the concentric markings as a guide.

3. Press the On/Off button and ensure that each of the LED indicators illuminates during the self-test routine.

4. When the self-test routine is complete, the 120 BPM indicator begins to flash. If the low battery indicator is illuminated, replace the batteries.

5. Adjust the intensity control until the foetal heart monitor under test begins to respond, then set the intensity control as necessary.

6. Pressing the BPM selector button adjusts the output rate of the V1000, pressing the button whilst at 210 BPM sets the V1000 into the automatic test routine.

7. To switch off the V1000, press the On/Off button. Ensure that all rate indicators extinguish, detach the transducer and remove any residual gel using a damp cloth.

Low Battery Indication

When the V1000 detects that the batteries are nearing depletion, the low battery indicator will begin to flash. The
V1000 can still be used, but the user should consider that simulation may cease at any time without further warning.

When the battery voltage reduces to a level where the performance of the V1000 may be compromised, simulation will cease and the low battery indicator will remain illuminated.
When the low battery indicator is constantly illuminated, the batteries must be replaced.

Replacing the Batteries

The V1000 operates using 4 x 1.5V AA/MN1500/LR6 alkaline batteries.

To replace the batteries, remove the battery door on the rear panel, remove the existing batteries and insert new ones, observing the polarity indications inside the battery compartment.

Depleted batteries should be disposed of as per local regulations.

Caution: only use batteries of the type specified.

Note: If the V1000 is to be removed from service or stored, the batteries must be removed.

Cleaning

With reference to the Medical Devices Agency document "Sterilization, disinfection and cleaning of medical equipment: guidance on decontamination from the Microbiology Advisory Committee to Department of Health Medical Devices Agency" (known as the MAC Manual), "Introduction to Part 1 - Table 1: Classification of infection risk associated with the decontamination of medical devices"; the V1000 Foetal Heart
Simulator is classified as low risk, due to being "In contact with healthy skin, or not in contact with the patient".

The recommended decontamination method for low risk items is to clean in accordance with the guidelines in the MAC
Manual "Part 2; Cleaning (manual) - non-immersion".

Protection Rating

The V1000 is manufactured to an ingress protection rating of IP41.

Routine Maintenance

It is recommended that the V1000 be checked at least annually to ensure correct performance.

Perform functionality checks as detailed on the Performance Evaluation Sheet overleaf. There are no user serviceable parts inside: if the device does not meet the specification or if performance is suspect, please return it to Viamed for evaluation or repair.

Note: The output BPM is governed by the firmware and the microcontroller - there is no adjustable calibration control.

The V1000 is a simulator and is to not be used as a calibration device.

Optional Accessories

Part Number	Description
1420000	Wall mount for Foetal Heart Simulator
1420001	Case protector for use with Foetal Heart Simulator, model V1000. Colour: Grey
0013110	Carrying case Colour: Blue

Warranty

Viamed warranty ensures that goods are free from defects of manufacture for a period of one year from the date of shipment from Viamed.

Notes

Version: 1.1

V1000 Foetal Heart Simulator Performance Evaluation Sheet

Hospital/Organisation:	
Location (department, room no.):	
Engineer (print):	
Service Date:	

Action	Pass	Fail
Serial Number:		
Batteries replaced Comments:		
Check for overall signs of damage Comments:		
Check Power - Good Green LED Comments:		
Check Power - Low Green LED Comments:		
Check all LEDs function Comments:		
Check BPM Control Comments:		
Check BPM 120 Comments:		
Check BPM 150 Comments:		
Check BPM 180 Comments:		
Check BPM 210 Comments:		
Check BPM Auto Comments:		
Check BPM 30 (if applicable) Comments:		
Check BPM 60 Comments:		
Check BPM 90 Comments:		
Check Intensity Control Functionality Comments:		

Additional notes or comments:

Notes

ISO 13485:2003

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Specifications Subject to Change

Operator's Manual Part Number: 1490001
V1000 Part Number: 1410000