

Instructions for Use

V1000 Foetal Heart Simulator



VIAMED

CE

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Introduction

The V1000 Foetal Heart Simulator allows the operation and functionality of foetal heart monitors to be 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. The V1000 is a simulator; it is not a calibration device, therefore should not be used to validate the accuracy of an individual monitor's displayed foetal heart rate.

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 with foetal heart monitors:

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:

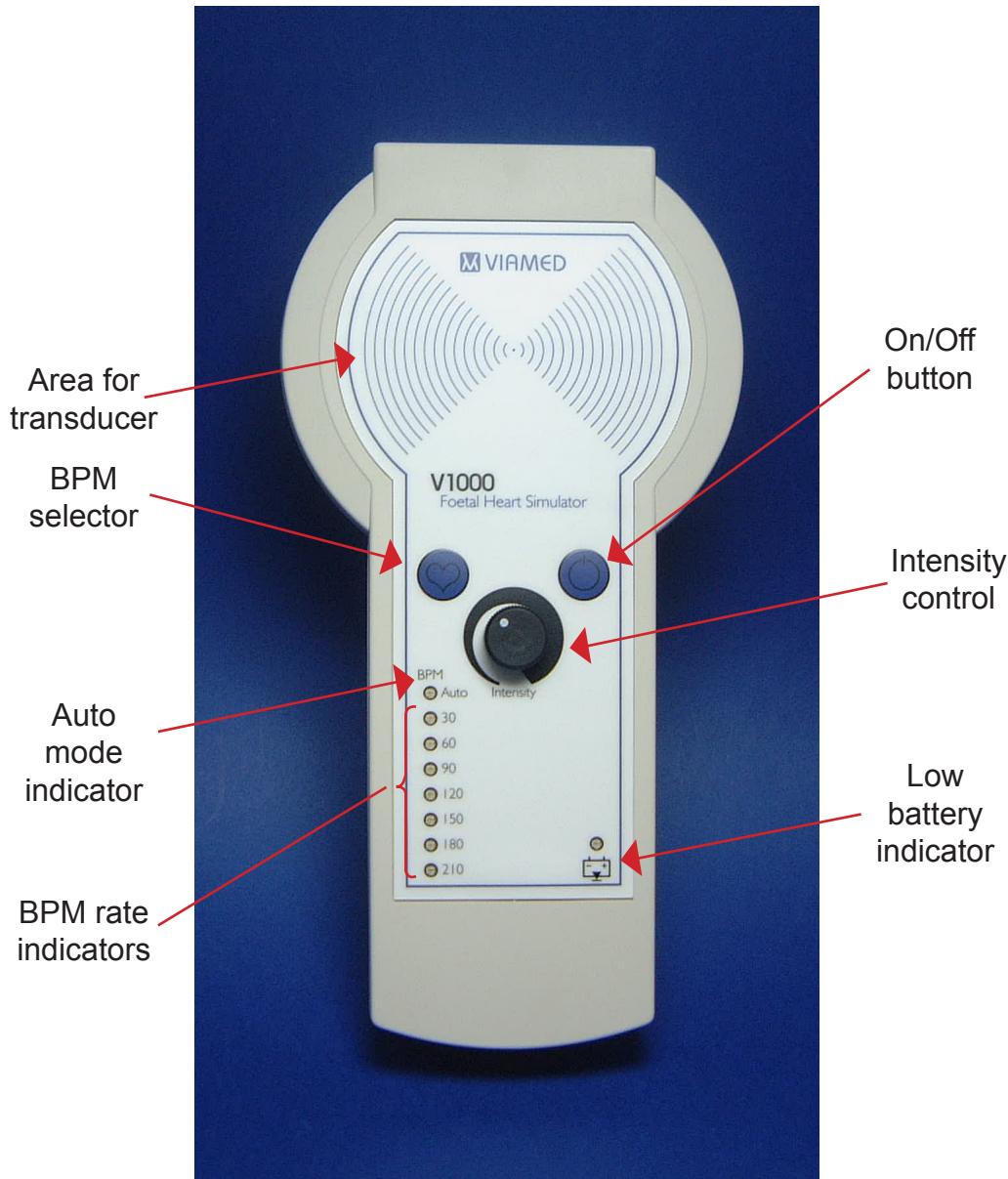
Testing monitors and transducers prior to use.

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 flashing or 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 red. The V1000 can still be used, but the user should consider that simulation may cease at any time without further warning.

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.

If required, units can be returned to Viamed for annual service and testing.

Part number 1480000: V1000 Service & Testing (includes Certificate of Calibration).

If a service is not deemed necessary, but a Certificate of Calibration is required in order to comply with local standards; then units may be returned to Viamed for testing and a Certificate of Calibration will be reissued.

Part number 1480001: V1000 Certificate of Calibration.

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.

Disposal

The V1000 should be disposed of as WEEE (Waste Electrical and Electronic Equipment) in accordance with local ordinances and regulations, or it can be returned to Viamed. You are responsible for the return packaging and carriage costs, but we will process the returned WEEE free of charge on your behalf.

Return address for WEEE:

Viamed Ltd. - WEEE Processing
15 Station Road, Cross Hills, Keighley
West Yorkshire BD20 7DT
United Kingdom



V1000 Foetal Heart Simulator Performance Evaluation Sheet

Date:		
Serial Number:		
Action	Pass	Fail
On control: Press on/off to switch on and activate the self test routine.		
Pass: If self test activated and completed		
Fail: If self test not activated, replace batteries.		
If low battery indicator is flashing red, then replace the batteries.		
BPM Control - sequentially press the rate button and verify operation of the associated LED indicator		
BPM 120	Yellow LED	
BPM 150	Yellow LED	
BPM 180	Yellow LED	
BPM 210	Yellow LED	
BPM Auto function	Green LED	
BPM 30	Yellow LED	
BPM 60	Yellow LED	
BPM 90	Yellow LED	
Connect the V1000 to a foetal heart monitor, select BPM auto function and verify the functionality of the heart rates		
Intensity Control Functionality		
Off control: Press on/off button to switch off		
Performance evaluation: PASS/FAIL		
Signed:		
Name:		

Notes



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