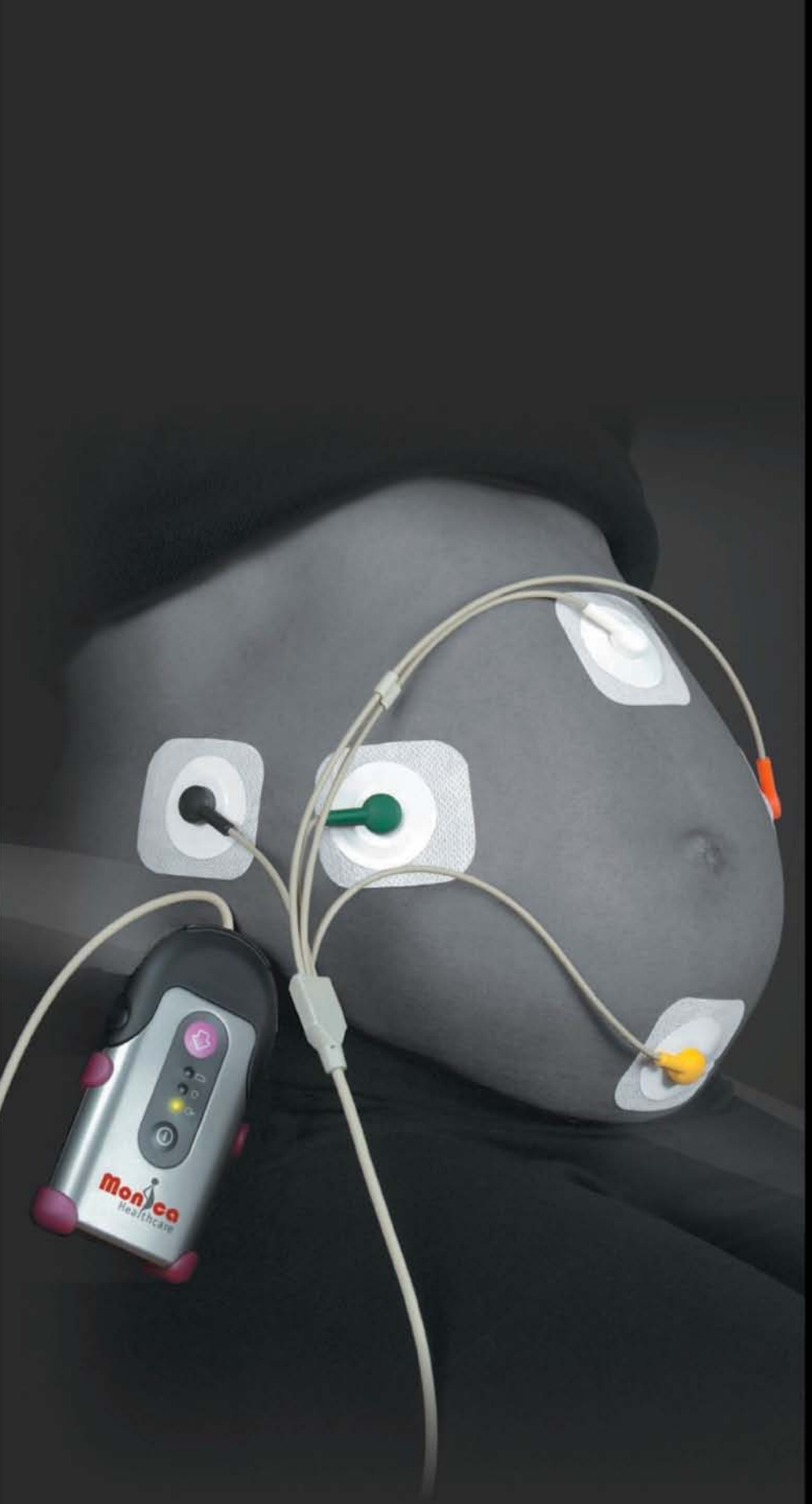

Monica AN24™

Reference Operator Manual

100-TF-006 Revision F

CE
00843

US law restricts this device to sale by, or on the order of, a physician.

Declaration

Information in this manual is believed to be accurate and reliable. However, Monica Healthcare Ltd assumes no responsibility for its use, or any infringements of patents or other rights of third parties that may result from its use. No license is granted by implication or otherwise under any patent or patent rights of Monica Healthcare.
This Operator's Manual is intended for trained medical personnel (including obstetricians, midwives, nurses, and physicians) who are familiar with obstetric procedures. Keep this operator's manual with the unit for use by the operator.

Conventions Used in This Operator Manual

Warning: A warning alerts you to a potential serious outcome, adverse event, or safety hazard. Failure to observe a warning may result in death or serious injury to the user or patient.

Caution: A caution alerts you to situations where special care is necessary for the safe and effective use of the product. Failure to observe a caution may result in minor or moderate personal injury or damage to the product or other property, and possibly in a remote risk of more serious injury.

On your monitor, this sign indicates that there is detailed information in this book, which you must read before proceeding with your task.

Numbers in brackets ( ) refer to the key number in Figure 1 or the index of Table 1

Contents

Section 1 - Unpacking the AN24™

Table 1 - The Monica AN24™ case should contain the following items

	Description
10	Monica AN24™ recorder/monitor [Item1, Figure 1]
11	Electrode lead connector [Item 2, Figure 1]
12	AN24™™ neck strap
13	Battery Charger and lead
14	AN24™™ monitor connector/computer USB cable
15	Monica installation CD (Monica VR installation program, AN24™ Reference & Concise Operator Manuals, Monica VR Operator Manual)
16	10 Electrodes
17	Roll of abrasive skin tape
18	AN24™ protective cover
19	Bluetooth® USB dongle
20	Quick Start Guide

Please confirm that you can identify all the items in the case.

Figure 1 Monica AN24™ Controls and Indicators

Section 2 - Product Description

2.1 General description

The Monica AN24™ is a wearable, battery-powered device for antenatal surveillance of fetal and maternal well-being. The AN24™ is designed to passively monitor Fetal Heart Rate (FHR), Maternal Heart Rate (MHR), and Uterine Activity (UA) from the Electro Hysterogram (EHG) during pregnancy[1] and can be used at any time from 20 weeks gestation to the end of first stage labour. Excessive vernix formation in the 26-34 week gestation period may result in a significant reduction in FHR detection in some patients. The AN24™ is currently suitable for singleton pregnancies only[2]. The AN24™ is suitable for extended monitoring sessions of up to 16 hours.

2.2 Patient attachment

The Monica AN24™ is attached via a detachable lead assembly that in turn attaches to 5 disposable ECG electrodes placed on the abdomen of a pregnant woman to generate 3 signal channels. The AN24™ then records the electrical signals present at these electrodes (the Electrocardiogram or ECG) that contains information relating to the maternal heart, fetal heart and other sources of electrical energy inside the body.

2.3 Data processing

The acquired signals are then converted by the AN24™ into a digital format and processed in real-time to extract clinically relevant information, such as the Fetal Heart Rate (FHR), Maternal Heart Rate (MHR) and Uterine Activity from the Electro Hysterogram (EHG).

2.4 Data viewing and storage

The processed data can either be stored by the AN24™ and downloaded to a computer at the end of the monitoring session, or wirelessly transmitted in real-time for viewing on a computer. The computer (installed with Monica VR software) enables the data to be viewed, stored, and printed.

2.5 Heart rate calculation

The time between the R-wave of consecutive fetal QRS complexes in the ECG signal is used to calculate the FHR. This is called the fetal RR interval. Similarly, the time between the R-wave of consecutive maternal QRS complexes in the ECG signal is used to calculate the MHR. This is called the maternal RR interval. See Figure 2.

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[1] Other Fetal/Maternal parameters will be available at a later date.

[2] Multiple pregnancy monitoring will be available at a later date.

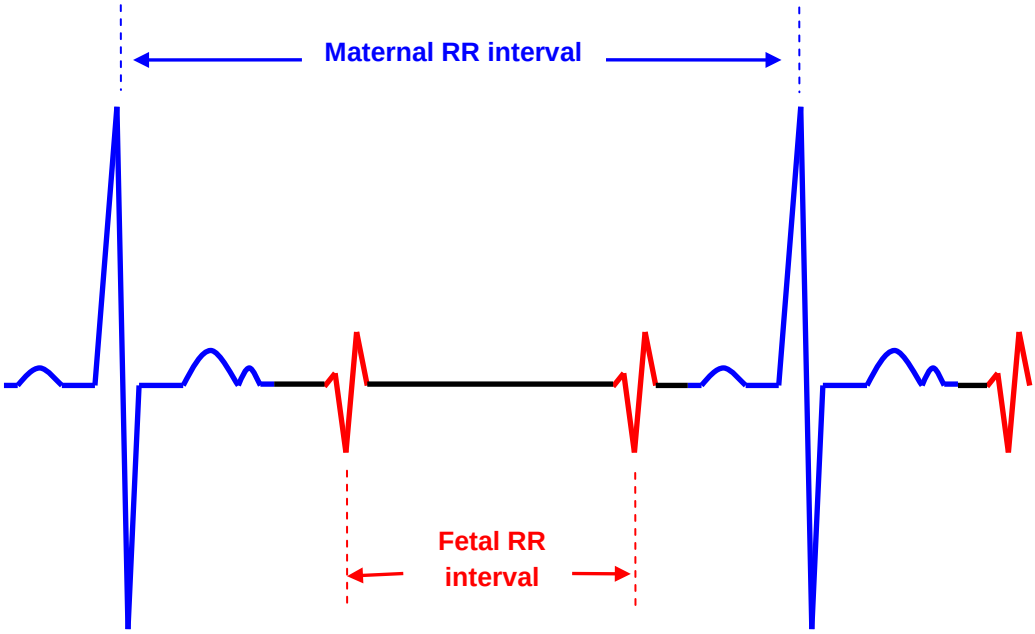


Figure 2 Calculation of FHR & MHR from ECG

The FHR and MHR are also '2-second averaged'. The 2-second averaged heart rates are calculated by firstly dividing the ECG into 2-second epochs. Each 2-second epoch is then checked for a minimum of two consecutive fetal ECG complexes and two consecutive maternal ECG complexes. If present, these complexes enable a heart rate to be calculated for that epoch. When more than two consecutive ECG complexes are available in a single epoch, the heart rates are averaged.

2.6 Heart rate data accuracy

The FHR and MHR data is only made available for viewing when the AN24™ is confident that this data is accurate. Confidence is based upon the general noise in the recorded data and characteristic shape of the ECG complex. In the event that the AN24™ is not confident of the accuracy of either the FHR or MHR, they will not be made available; the AN24™ will not 'fill in' any data. This method of providing a 2-second average is very different to the complex autocorrelation and rule-based methods used to calculate the FHR on Doppler based recorders.

2.7 Uterine Activity from EHG

The Uterine Activity is extracted from the slow-wave of the EHG, i.e. its envelope. The envelope is obtained by low-pass filtering the rectified fast-wave of the EHG. The UA is updated every 2 seconds as a number between 0 and 255, representing an EHG envelope from 0 to 500 microvolts.

Section 3 - Installation

3.1 Battery Charging

The Monica AN24™ (Figure 1) is dispatched with a non-removable rechargeable battery which, for shipping, is not fully charged.

The battery must be fully charged prior to use as described below.

Please refer to Figure 1

A. Connect the lead on the supplied battery charger into the socket inside the top of the AN24™ body (**1**). Plug the battery charger into a mains outlet and switch on the mains outlet. The amber battery status LED (**6**) will flash until the device is charged, when it will be constantly lit. This should take no more than 2½ hrs.
B. When the electrode leads connector (**2**) is connected to the Monica AN24™ Recorder (**1**) disconnect the lead connector (**2**) from the AN24™ body (**1**) by pressing the two buttons (**7**) on either side of the recorder, and gently pulling apart the AN24™ body (**1**) from the lead connector (**2**).

3.2 Software Install

The Monica VR viewing and reporting software must be installed on a suitable PC or notebook by following this process:

A. If your PC or notebook is part of a network, please make sure you have administrative rights and/or contact your network administrator.
B. Insert the Monica Installation CD into your CD drive.
C. The Monica VR Set-up program should launch automatically, displaying the welcome dialog box. If it does not launch automatically, use Windows explorer to manually select the CD drive, and open 'MonicaVR_setup.exe'

Follow the on-screen instructions. If further details are required, please contact your Distributor or refer to the AN24™ Reference VR Operator Manual.

3.3 Instructions

Please fully read these instructions before using the AN24™.

Section 4 - Operating the AN24™

4.1 Set-up procedure

4.1.1 Select mode.

The Monica AN24™ can be operated in two modes, namely:

Mode 1 - Retrospective mode
The Monica AN24™ records fetal heart rate (FHR), maternal heart rate (MHR) and Uterine Activity (UA) for retrospective upload and viewing on a computer running the Monica VR software or on the VR Monitor.

Mode 2 - Real time mode
The Monica AN24™ transfers FHR, MHR and UA using Bluetooth® wireless transmission in 'real-time' to the VR Monitor or to a Bluetooth® enabled computer running the Monica VR software for real-time viewing of the data.

The default mode when the Monica AN24™ is turned on for the first time is Mode 1 (Retrospective mode). Connection to a PC is required to set the time for the first recording.

The AN24™ already running in Mode 1 can be set up to run in Mode 2 by making a wireless Bluetooth® connection using the Monica VR software (see 4.5 Wireless configuration).

Alternatively, a Real-Time recording can be configured before starting a recording by connecting it to a PC running the Monica VR program (see 4.4 Connecting to a computer and 4.5 Wireless Configuration).

4.1.2 Electrode attachment

Prior to applying the electrodes, the skin must be prepared correctly using abrasive skin tape (**17**) as described in Appendix B.

Additionally, the electrodes (**16**) must be positioned correctly on the prospective mother's abdomen.

For skin preparation and electrode positions please refer to Appendix B –

4.1.3 Lead connection

Attach the electrode leads connector (**2**) to the electrodes (**16**) following the colour code guide in Appendix B. Ensure that the electrode leads connector (**2**) is securely attached to the AN24™ (**1**), by pushing the two sections firmly together such that the two buttons (**7**) are engaged.

4.1.4 Turn on

Turn on the AN24™ on by pressing the on/off button (3). All three LEDs (4, 5 and 6) will flash 3 times to indicate that the AN24™ has been turned on.

4.1.5 Memory status self-check

If the Orange memory status LED (**4**) begins to flash when the AN24™ has been turned on, this indicates there is data from a previous patient stored in the memory of the AN24™.

The stored data can be a) downloaded using Monica VR via USB or b) deleted remotely via Bluetooth® connection to the Monica VR software.

a) To download the data via USB, turn off the recorder (see 'Turn Off' section below), and connect the AN24™ to the computer running VR with the USB cable provided (please refer to the Monica VR Reference Manual for detailed instructions). Once the data has been downloaded, the recorder can be used for a new recording.

b) To delete the data via Bluetooth®, use Monica VR to connect to the recorder. The VR software will automatically recognise that there is data stored on the AN24™ and offer to delete the data or allow the user to disconnect it from VR to download as per a) above (please refer to the Monica VR reference Manual for detailed instructions). Once the data is deleted the recorder can be used for Real Time mode recording.

4.1.6 Battery status self-check

If the Yellow battery status LED (6) begins to flash when the AN24™ has been turned on, this means that the battery charge is too low for recording to begin. The LED will flash 10 times and then the AN24™ will be automatically turned off. See 'Recharging the batteries later in this section.

N.B. If there is data on the recorder, the Memory Status led will flash alongside the battery status LED.

4.1.7 Electrode attachment self-check

After turn on, the AN24™ will check the electrodes are attached correctly. The green signal quality LED (**5**) will go into one of three states:

- GREEN LED FLICKERS

The green LED flickers rapidly when the electrodes are not correctly attached. To solve this problem please refer to Section 10 - Troubleshooting. The AN24™ will continue this self-check until the problem has been resolved and recording will not begin until it has.

- GREEN LED ON

The green LED is constantly on to indicate that all electrodes are correctly attached to the skin. Once the AN24™ is satisfied that the electrodes are correctly attached the recording will begin. The AN24™ will then look for the maternal ECG.

- GREEN LED SLOWLY FLASHES

The green LED will flash (once every 2 seconds) when the AN24™ is satisfied that the electrodes are correctly attached and that the maternal ECG has been located (note – maternal ECG location may take up to 30 seconds once the correct electrode attachment has been confirmed). If the LED remains constantly on, please refer to Section 10 - Troubleshooting. If the problem persists please contact your distributor.

4.1.8 Secure the AN24™

If the patient wishes to carry the AN24™ it can either be held in their clothing (e.g. a pocket) or carried around the neck using the supplied neck strap (12). If the patient wishes to use the neck strap, attach it to the AN24™ main body (1) using the neck strap connection (9) and hang the neck strap around the patient's neck. Adjust the length of the neck strap so that the lowest part of the AN24™ is above the sternum and not touching the electrodes.

4.1.9 Secure Cables

If the ECG cable(s) are loose or hanging, secure them with hypoallergenic tape (not supplied) to the patient's abdomen to prevent the cables from pulling on or detaching from the ECG electrodes.

4.2 During monitoring

Self checks during a recording

During recording the AN24™ will regularly perform self-checks. The AN24™ can only be in one of the following four states:

MONITORING OK – GREEN LED FLASHES
The green signal quality LED (**5**) will continue to flash once every 2 seconds to indicate that the electrodes remain attached correctly and that the maternal heart beat has been located.

MATERNAL SIGNAL LOST – GREEN LED ON
The green signal quality LED (**13**) will remain constantly illuminated to indicate that the electrodes remain attached correctly but that the maternal heart beat cannot be located. This is not a cause for alarm and may be temporary and due to interference from other sources, for example the noise generated by maternal muscle/movement. Section 10 - Troubleshooting

ELECTRODE DETACHED – GREEN LED FLICKERS
The green signal quality LED (**5**) will flicker rapidly to indicate that one of the electrodes has become detached. The recording will not be stopped at this point, if suitably trained staff are available the electrodes should be re attached to resolve the problem, see Section 10 - Troubleshooting.

BATTERY LOW – YELLOW LED FLASHES
If the Yellow battery status LED (**6**) begins to flash, this indicates that the battery is running low. A short while after this occurs; the AN24™ will automatically turn off. If the device is in Mode 1 (recording mode) the recorded data will be retained until it is uploaded, see Mode 1 - USB upload later in this section.

4.3 Turn off

When the recording session is completed, turn the AN24™ off by pressing the on/off button (**3**) followed by the event button (**8**) followed by the event button (**8**) again.

This sequence of button presses must be completed within 4 seconds to turn the device off. When the AN24™ is switched off all three LED's (**4, 5** and **6**) will flash three times.

Data Upload - If the AN24™ was used in Mode 1 (recording mode), the recorded data must be uploaded to a computer running the Monica VR software, see 'USB Upload' later in this section.

Clean the AN24™ - Clean the AN24™ (**1**) and electrode lead connector (**2**) as described in Section 6 - Cleaning and Maintenance

Battery Charging - recharge the AN24™ (**1**) as described in 3.1 Battery Charging.

4.4 Connecting to a computer

Monica devices are an integral part of a personal computer based diagnostic system. The user must adhere to warnings in order to ensure safe and reliable performance of the system.

- The personal computer (non-medical electrical equipment) must be situated outside the patient environment (patient environment according to IEC 60601-1-1: radius 1.5m around the patient).
- The personal computer used should be approved to the appropriate safety standard for non-medical electrical equipment (IEC 60950, or its national variants).
- If there is a requirement for the personal computer to be situated within the patient environment it is the responsibility of the user to ensure the system provides a level of safety that ensures compliance with IEC 60601-1.
- The Monica VR Monitor (PT-100-040) fully complies with the above and is recommended when using the Monica AN24™™ to monitor in real-time within the patient environment (as defined by IEC 60601-1-1).

When connecting to a computer in either mode it is firstly necessary to ensure that the Monica VR software is successfully installed onto a suitable computer, see Section 8 - Monica VR Software to connect the Monica AN24™ to this computer:

A. Disconnect ECG leads - Disconnect the electrode lead connector (**2**) from the AN24™ (**1**) as described in 3.1 Battery Charging.
B. Launch software – Start the Monica VR software application on your computer.
C. Connect USB lead - Connect the AN24™-to-USB lead (**14**) into the socket inside the top of the AN24™ (**1**). Plug the USB end of the lead into a free USB port on the computer. The Monica AN24™ device will be automatically recognised by the computer and will provide status information.

From this point the Monica VR software will know if there is data stored on the device ready for upload (Mode 1 operation), or, no data stored on the device (Mode 2 operation). Whatever the status the program will guide you through the correct process to upload the stored data or configure the AN24™ for wireless operation, see below.

4.5 Wireless configuration

If there is no data available for upload, the Monica VR program will provide the option to set-up a wireless real-time monitoring session and will ask you to identify the patient, by providing the patient's name and hospital number. Monica VR will then take you through the set-up process. Alternatively an ad hoc connection can be made using the Monica VR software. Detailed information on these procedures is available in the Monica VR Reference Manual.

4.6 USB upload

If data is available for upload, the Monica VR program will give you the option to either delete the data, or upload it to the computer. If you chose to upload the data you will be asked to first identify the data, by entering the patient's name and hospital number. Monica VR will then take you through the set-up process. Detailed information on this procedure is available in the Monica VR Reference Manual.

Section 5 - Safety and Standards

5.1 General

This section describes safety precautions that may appear within the manual and those that appear as symbols labels on the AN24™ itself. Furthermore, this section describes a group of precautions that are applicable, in general, when using the AN24™.

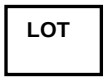
The Monica AN24™ is intended for trained medical personnel (including midwives, nurses, and physicians) who are familiar with obstetric procedures. Keep this operator's manual with the unit for use by the operator.

5.2 Symbols


Attention - Refer to manual


Class II Medical Device


Type BF



Batch number


Manufacture date


Bluetooth® approved device


ESD - Static sensitive device


CE approved


WEEE logo

5.3 Intended use

The Monica AN24™™ is a monitoring device for non-invasively measuring the

- Fetal Heart Rate (FHR)
- Maternal Heart Rate (MHR)
- Uterine Activity (UA)
- Maternal Movement (MMov)

The Monica VR software, which accompanies the AN24™, enables the measured parameters to be reviewed graphically using a PC or notebook computer, supports the user in recognising a non-reassuring trace using a FHR analysis decision support algorithm based on a method published by G A Dawes and C Redman and to generate hard copy traces and reports in a 'standard' user defined format. This data is intended to aid in assessment of the wellbeing of the fetus and mother from 20 weeks gestation to the end of first stage labour in singleton pregnancies.

Application of the device must be by trained personnel, but monitoring sessions can be carried out in hospitals, clinics, doctors' offices and in the patient's home.

Clinical indications for use of monitoring in high risk singleton pregnancies include:

- Ante partum haemorrhage
- Obese mothers
- Reduced Fetal Movements
- Pre-eclampsia
- Hypertension
- Poor Obstetric History
- Abnormal umbilical artery Doppler velocimetry
- Preterm Labour
- Post fetal surgery
- Known fetal abnormality which requires monitoring
- Suspected or confirmed intrauterine growth restriction
- Induction of labour
- Maternal Diabetes
- Home monitoring
- Early labour

This list is not exhaustive.

5.4 Standards

The Monica AN24™ complies with the following safety standards

Standard	Description
IEC EN 60601-1: 1990 UL60601-1:2003 CSA C22.2 No 60601.1	Medical Electrical Equipment Part 1: General requirements for safety
EN 60601-1-2: 2002 IEC 60601-1-2: 2001	Medical Electrical Equipment Part 1-2: General requirements for safety – Collateral Standard: Electromagnetic Compatibility – requirements and tests
EN 60601-2-47: 2001 IEC 60601-2-47: 2001	Medical Electrical Equipment Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
IEC EN 60601-1-4: 1996	Medical electrical equipment Collateral standard: Programmable Electrical Medical Systems
EN 980: 1996	Graphical symbols for use in the labelling of medical devices
EN 1041: 1998	Information supplied by the manufacturer with medical devices

5.5 Interpreting Results

Monica Healthcare recommend that a repeat test is undertaken, using either the AN24™ or an alternative device to confirm the results from the initial test. The repeat test should be carried out in the case of either normal or abnormal results generated by the AN24™.

5.6 Safety

WARNING: The Monica AN24™ is splash proof but is not designed for submersion in water. Patients must be warned not to immerse the AN24™ or any of its accessories in water, or to take a shower or bath whilst being monitored.

WARNING: The Monica AN24™ is not explosion-proof and must not be used in the presence of flammable anaesthetics.

WARNING: SHOCK HAZARD — Do not attempt to connect the battery charger with wet hands. Make certain that your hands are clean and dry before touching a power lead or plug.

WARNING: Use only the electrode lead cables supplied with the device. Use of any other cables may result in out-of-specification performance and possible safety hazards.

WARNING: Unplug the AN24™ from the AC power source (battery charger and detach all accessories before cleaning. Do not immerse the unit in water or allow liquids to enter the case.

WARNING: Examine the AN24™ and any accessories periodically to ensure that the leads, connectors and the device itself do not have visible evidence of damage that may affect patient safety or monitoring performance. The recommended inspection interval is once per week or less. Do not use the device if there is any visible sign of damage.

WARNING: Only the Battery Charger and mains plug supplied with the Monica AN24™, or its equivalent, is approved for use with the AN24™.

WARNING: Do not attempt to service the Monica AN24™. Only Monica approved and qualified service personnel should attempt any necessary internal servicing.

WARNING: The Monica AN24™ 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.

WARNING: Since the Monica AN24™ detects the electrical signals generated from the fetal heart, if other equipment which introduces electrical energy in to the mother is used (e.g. TENS machine, diathermy, impedance meter), then the AN24™ will not be able to detect the fetal heart rate.

WARNING: Do not operate the Monica AN24™ if it fails to pass the power on self-test procedure, see Section 4.

WARNING: Any unexpected data generated by the Monica AN24™ must result in further examination of the mother and fetus in a hospital environment. The data generated by the AN24™ must be backed up by alternative monitoring technologies.

WARNING: For Electromagnetic Compatibility (EMC). Use of accessories, electrodes and leads other than those specified in this manual may result in increased EMC emissions and/or decreased immunity of the Monica AN24™ to other electrical equipment.

WARNING: For Electromagnetic Compatibility (EMC). The Monica AN24™ has been tested for to IEC EN 60601-1-2 for EMC. However, the Monica AN24™ picks up very small electrophysiological signals and so occasionally if other electrical equipment is in the immediate vicinity of monitoring the AN24™ may produce spurious results. The operator should ensure that any such interfering electrical equipment is not in close proximity to the AN24™ during monitoring.

WARNING: The lithium polymer battery pack used within this device has the potential for fire or burning. Do not disassemble, crush, heat or burn.

WARNING: The lithium polymer battery pack cannot be replaced by the user. Replacement may only be made with the battery pack specified by Monica Healthcare, and replacement can only be carried out by Monica Healthcare. Fire or burning may occur if the customer uses a battery pack other than specified by Monica Healthcare.

CAUTION: Keep the operating environment free of dust, vibrations, corrosive, or flammable materials, and extremes of temperature and humidity. The AN24™ and all lead connectors should be kept clean and free of electrode 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 two front-panel membrane switches.

CAUTION: General-purpose personal computers and modems are not designed to meet the electrical safety requirements of medical devices.

CAUTION: Do not autoclave the AN24™ or any accessories. Follow cleaning and disinfection instructions in Section 6 - Cleaning and Maintenance

CAUTION: Do not immerse AN24™, connector or leads in liquid. When using solutions, use sterile/clean wipes to avoid pouring fluids directly on to the AN24™ and connector. Follow cleaning and disinfection instructions in Section 6 - Cleaning and Maintenance

CAUTION: The water temperature must not exceed 40°C (104°F). Do not use chlorine bleach.

CAUTION: Take extra care when cleaning the membrane switches and LED surfaces, which are sensitive to rough handling.

CAUTION: Do not autoclave. Do not gas sterilize.

CAUTION: Only the Battery Charger supplied with the device is approved for use in recharging the internal batteries.

CAUTION: The Monica AN24™ is not specified or intended for operation during the use of defibrillators or during defibrillator discharge.

CAUTION: The Monica AN24™ is not specified or intended for operation in the presence of electrosurgical equipment.

CAUTION: There are minimum signal amplitudes under which the Monica AN24™ will not be able to measure physiological signals.

5.7 CE

CE The CE Mark on this product denotes conformity with the European Council Medical Device Directive 93/42/EEC.

00843

Section 6 - Cleaning and Maintenance

6.1 AN24™™ Device

To avoid damage to the AN24™, connector and leads, clean and disinfect only according to the following instructions. Care MUST be taken to preserve both the AN24™ label and the connector label.

***CAUTION*: Do not remove, conceal or deface the labels.**

CAUTION: **Do not autoclave. Do not gas sterilize.**

CAUTION: **Do not immerse the device or any accessories in liquid and do not expose the connector pins to the cleaning solution. Do not apply oil at any point.**

CAUTION: **Do not use undiluted bleach or any other cleaning solution other than those recommended here because permanent damage to the AN24™ and leads could occur.**

Clean - Wipe the AN24™ and leads with a soft non-abrasive cloth or disposable wipe soaked in aqueous detergent/ disinfectant or other solution such as 70% isopropyl alcohol. Do not use aerosol preparations since they might contain organic solvents. Do not pour fluids directly on the unit and its accessories. Wipe the exterior of the AN24™ and leads three times. Prepare the detergent according to the manufacturer's recommendations. If necessary scrub the AN24™, and leads with the solution using a soft bristled brush for five minutes.

Wash off & Dry - When using solutions, use sterile wipes or gauze to avoid pouring fluids directly on the unit and its accessories. Wipe the AN24™, and leads three times with sterile or distilled water to remove cleaning solution residue. Dry the AN24™, connector and leads thoroughly with a sterile soft towel or gauze surgical sponge.

Disinfect - If a low-level disinfection is required, use a 1:10 bleach solution after the AN24™ and leads have been cleaned following the same procedure described above. After the low level disinfections, wipe the AN24™ and leads three (3) times with sterile or distilled water to remove diluted bleach residue. Dry the AN24™, connector and leads thoroughly with a sterile soft towel or gauze surgical sponge.

Store the clean AN24™, connector, and leads in a clean bag, covered tray, or other suitable system when not in use.

6.2 Batteries

The 3.6V rechargeable lithium polymer battery pack should be stored at 0-35^{o}C. Typically the batteries will last for two years or more with regular use. If you need to replace the battery, contact Monica Healthcare directly or your Monica healthcare representative.

6.3 Firmware version

AN24™ Firmware
VR Software

Periodically there will be a need to release new versions of the Firmware and Software, please check with your local distributor to see if you have the latest version.

6.4 Calibration

Calibration of the Monica AN24™™ is not required

6.5 Servicing

Maintenance of the AN24™ is carried out by Monica Healthcare. The only routine maintenance which is necessary is battery replacement when failing to hold charge and cleaning as outlined earlier in this Section. Further information is available from:

Monica Healthcare Ltd
BioCity
Pennyfoot Street
Nottingham NG1 1GF
UK
Tel: +44 1159124540
Email: info@monicahealthcare.com
Web: www.monicahealthcare.com

Section 7 - Monica Accessories

Part No	Description	Included with standard AN24™
100-PT-001	Monica AN24™ Fetal/Maternal Monitor	1
100-PT-002*	ECG Lead Assembly - Standard; ~28weeks to term	1
100-PT-013	ECG Lead Assembly - Small; <28 weeks	
100-PT-014	ECG Lead Assembly - Research; all leads 500mm	
100-PT-003*	Soft silicon rubber protective skin sample	1
100-PT-015	Soft silicon rubber protective boot (x5)	
100-PT-004*	Battery Charger (UK\ EU\ USA type)	1
100-PT-005*	AN24™ – USB computer connection cable	1
100-PT-006*	Monica VR installation CD (including user manuals & video)	1
100-PT-007*	3M red Dot 2236 skin prep tape sample	1
100-PT-016	3M red Dot 2236 skin prep tape (x5)	
100-PT-008*	Monica approved electrodes – sample pouch (10 electrodes)	1
100-PT-017	Monica approved specific electrodes – 50 pouches x 5 electrodes (250 electrodes)	
100-PT-018	Monica specific electrodes – 6 boxes x 50 pouches (1500 electrodes)	
100-PT-009*	Monica AN24™ Neck Cord sample	1
100-PT-019	Monica AN24™ Neck Cord (x5)	
100-PT-010*	Monica Specific Bluetooth® Dongle	1
100-PT-011	Monica ‘Development Kit’ Collaboration/IP Agreement required	
100-PT-012*	Getting Started (with language variations)	1
100-PT-020	Glossy Sales Literature Folder x50	
100-PT-021	Sales Literature sheets (Fetal Holter, Fetal/Maternal Monitor, Research)	
100-PT-040	Monica VR Monitor -Monica All-In-One Medical Grade Touch screen Panel PC	
100-PT-041	Monica Cart - Monica Cart for Monica VR Monitor with Printer Shelf	
100-PT-042	Monica Wall Mount - Monica Wall Mount for Monica VR Monitor	
100-PT-050	Monica Quick View - PDA Setup Aid	

Section 8 - Monica VR Software

8.1 Overview

The Monica VR program allows the FHR, MHR, UA and maternal movement data to be viewed, stored and printed as a conventional CTG trace. It is also provides the Monica AN24™ set-up tools to configure the unit and label and store the monitoring sessions for easy identification and retrieval. The functionality of the Monica VR software is explained in detail in the Monica VR Operating Manual, though the system requirements and installation instructions are described below.

8.2 System Requirements

The Monica VR software has minimum system requirements as outlined below:

- Processor: X86 processor 300 MHz
- RAM: 512 MB
- CD reader: 4X or faster
- Free Disk Space: 1GB (enough for storage of 400 records)
- Graphics: Resolution of at least 1024x768
- Fetal Recorder Mode requires: 1 Free USB port (data download)
- Wireless mode requires: 1 Free USB port for Monica Bluetooth® ™ dongle, or, Bluetooth®-enabled computer with Microsoft Bluetooth® ™ Stack.
- Windows XP or Windows Vista
- Latest Windows Service Pack / update

Monica devices are an integral part of a personal computer based diagnostic system. The user must adhere to warnings in order to ensure safe and reliable performance of the system.

- The personal computer (non-medical electrical equipment) must be situated outside the patient environment (patient environment according to IEC 60601-1-1: radius 1.5m around the patient).
- The personal computer used should be approved to the appropriate safety standard for non-medical electrical equipment (IEC 60950, or its national variants).
- If there is a requirement for the personal computer to be situated within the patient environment it is the responsibility of the user to ensure the system provides a level of safety that ensures compliance with IEC 60601-1.

The Monica VR Monitor (PT-100-040) fully complies with the above and is recommended when using the Monica AN24™ to monitor in real-time within the patient environment (as defined by IEC 60601-1-1).

8.3 Software Installation

If a Monica VR Monitor (part no. 100-PT-040) was ordered with a Monica AN24™™ it will arrive with the VR software preinstalled and this section can be skipped

A. Before beginning, please ensure the computer satisfies the system requirements. Please make sure the installer has administrative rights for the installation process and/or contact the network administrator.
B. During the installation, it may be necessary to restart the PC. Please save any open work and close any applications that may be running.
C. Insert the installation CD into the CD drive.
D. The Setup program should launch automatically, displaying the select language dialog box. If the Setup program does not launch automatically, use Windows explorer to manually select the CD drive, and open the file named 'MonicaVR_setup.exe'
E. Select the setup language from the drop-down list and click the 'OK' button
F. After reading the Welcome message, click the '*Next*' button to continue. The '*Cancel*' button can be used at any time to leave the installation.
G. The license agreement will be displayed. The terms of the license agreement must be accepted before clicking '*Next*' to continue, otherwise installation cannot continue. If the terms of the license agreement are not agreed to, the installation can be cancelled by clicking the '*Cancel*' button.
H. The Select Destination Location dialog will be displayed, showing the directory where Monica VR will be installed. To change this location, select browse.
I. Click '*Next*' to display the Select Start Menu Folder. This will be the location that the Monica VR launch icon will be placed under the Start Menu. Either a new location can be entered or an existing location used.
J. Click '*Next*' to display the Select Additional Tasks dialog. The following options are available:
    - 'Create a Desktop' icon
    - 'Create a Quick Launch' icon
K. Click '*Next*' then *'install'* to start copying the files to the PC.
L. From the finished dialog,
    - Select 'Setup pdf creator to enable pdf export' to install the PDF Creator software. This will enable the user to preview and print the patient reports as a pdf file for storage and transfer. If the 'Setup pdf creator to enable pdf export' is selected on the finish screen it will automatically start the setup program after the VR setup has finished – follow the on screen instructions to complete installation.
    - Click '*Finish*' to exit the installation. The PC may need to be rebooted to finalise the installation.
M. Open the Monica VR software from the start menu and click on the "Settings" button to setup the ID format for the patient.
N. Connect the AN24™ to the PC running Monica VR via a USB port to install the software drivers

Section 9 - Specifications

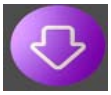
9.1	**Measured**	Time	Real-Time clock
		Maternal Movement	3 axis accelerometer
		Clinical Event Marker	Button
		Abdominal Electrophysiological Signal	3 different channels
9.2	**Calculated**	FHR	Range 60-240 beats per minute 2 second average
		MHR	Range 40-240 beats per minute 2 second average
		Maternal Movement	4 levels – (Inactive to very active)
		Uterine Activity	Range 0-500 microvolts (0-255 levels)
9.3	**Storage**	Internal Micro SD Card	
9.4	**Interfaces**	Download	USB – download stored data to computer Wireless – Real-Time data transfer using Bluetooth®
		User	LED indicator 1: Yellow – Battery status LED indicator 2: Green – Signal quality LED indicator 3: Orange – Memory status Button 1: On/Off Button Button 2: Event marker
9.5	**Data Format**	Series 50 Protocol via Bluetooth®	
9.6	**Battery**	Rechargeable lithium polymer 3.6V 2400mA-hours	
9.7	**Battery Charger**	Input	100-240V, 50-60Hz UK\EU\US adapter
		Output	DC 5V 1A USB PC connection
9.8	**Dimensions**	11.5 x 5.5 x 2.0 cm Including lead assembly	
9.9	**Weight**	105g excluding lead assembly	
9.10	**Operating Temperature**	0 to + 40°C	
9.11	**Storage Temperature**	0 to + 40°C	
9.12	**Approval**	CE approved (Directive 93/42/EEC)	

Section 10 - Troubleshooting

10.1 Signal Quality (Green LED flickers)

Electrodes are not attached correctly.

If green LED flickers, first check that the electrode lead connector cap is connected securely on both sides of the AN24™ (both buttons engaged). If this does not resolve the problem, put AN24™ into electrode check **'Phase 1'** by pressing event button twice within a 2-second period

 x2

The system will then 'display' the electrode/skin impedance for the electrodes connected to the yellow, green and orange leads.

The electrode/skin impedance will be communicated to the user as follows:

- LED on continuously – the electrode connected to the lead defined by the LED colour has a good connection / low skin impedance
- LED flickers - the electrode connected to the lead defined by the LED colour has a bad connection / high skin impedance

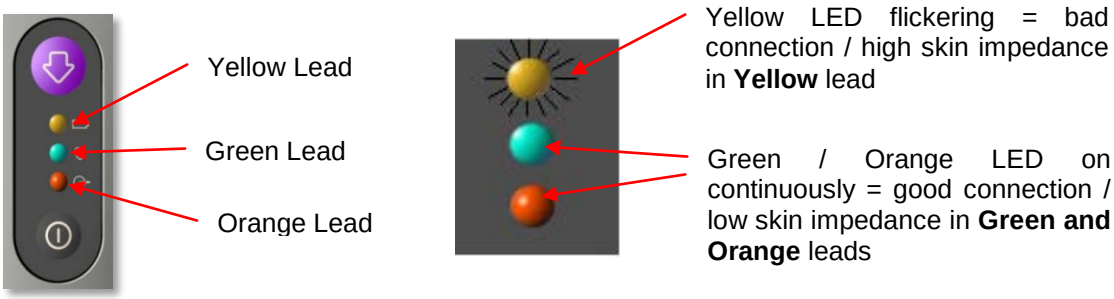
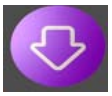


Figure 3 Phase 1 Lead check

If a bad connection is identified in the Yellow, Orange or Green leads, disconnect the lead from the electrode(s) that has a bad connection (leave AN24™ on), remove the electrode(s) and again prepare the skin as described in steps 2 -5 above. When all the electrode(s) have been replaced the leads should be reconnected.

If all the LED are on continuously (good connection), put the AN24™ into electrode check **'Phase 2'** by pressing event button twice within a 2 second period.

 x2

In 'mode 2' the electrode/skin impedance will be communicated to the user for the remaining two electrodes as follows:

- Yellow LED on continuously – the electrode connected to the **White** lead has a good connection / low skin impedance
- Yellow LED flickers - the electrode connected to the **White** lead has a bad connection / high skin impedance
- Green LED on continuously – the electrode connected to the **Black** lead has a good connection / low skin impedance
- Green LED flickers - the electrode connected to the **Black** lead has a bad connection / high skin impedance

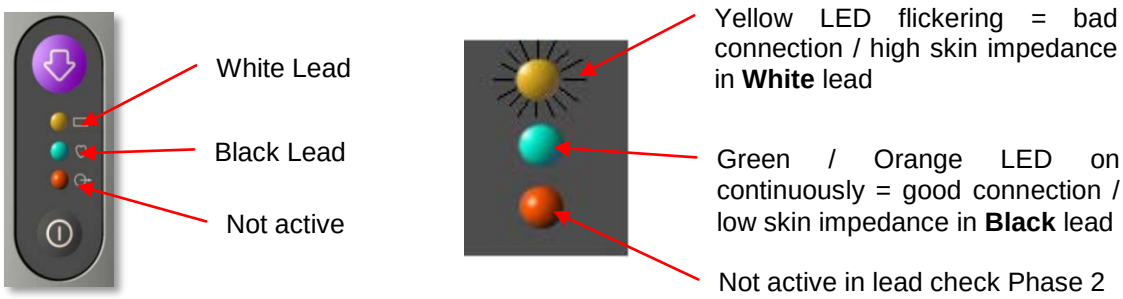
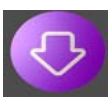


Figure 4 Phase 2 Lead check

If a bad connection is identified in the black or white leads, disconnect the lead from the electrode(s) that has a bad connection (leave AN24™ on), remove the electrode(s) and again prepare the skin as described in Step 2 above. When all the electrode(s) have been replaced the leads should be reconnected.

If the Green and Yellow LED's are on the user should start their monitoring session by pressing the event button twice within a 2-second period

 x2

In the unusual event that it is not possible with repeated skin preparation and correct electrode placement to bring the impedance down and gain a good connection; the test must be aborted.

To abort the electrode check phases (Phase1 or Phase2): switch off the AN24™ as usual (press ON button, then press pink Event button, then press pink Event button)

Alternatively, the lead may be broken. Turn the AN24™ off. Disconnect the lead from both the AN24™ and the electrodes. Attach a spare lead and retry.

If problem is not resolved, contact Monica Healthcare for advice.

Excessive vernix formation in the 26-34 week gestation period may result in a significant reduction in FHR detection in some patients.

10.2 Signal Quality (Green) LED constantly on

The maternal heartbeat cannot be picked up by the AN24™, though the electrodes are correctly connected. This is a common occurrence, which may be due to interference from other sources, for example the noise generated by maternal muscle/ movement. The mother should relax and remain in a supine position for as long as practicable during the recording for optimal results. If problem is not resolved, contact Monica Healthcare for advice.

10.3 Battery Status (Yellow) LED flashing when unit is not being charged

Battery is low. The AN24™ will shortly automatically turn off. Upload the data and recharge the batteries (see 3.1 Battery Charging). If problem is not resolved, contact Monica Healthcare for advice.

10.4 Memory Status (Orange) LED flashing

This indicator will only light just after the AN24™ has been turned on and indicates that there is > 1 minute of data on the device. Upload / delete the data currently stored on the device (see Section 4 -). Turn on the device and resume the monitoring session. If problem is not resolved, contact Monica Healthcare for advice.

10.5 AN24™ will not turn on

Recharge the AN24™. If after recharge the AN24™ still does not turn on, return to Monica Healthcare for service.

10.6 AN24™ will not turn off

Return to Monica Healthcare for service

10.7 AN24™ will not recharge

Disconnect AN24™, reconnect battery charger and check charger is connected at both the wall socket and the device. Leave the recorder connected to the charger for half an hour. Then disconnect the AN24™ from the charger and reconnect it again. If problem is not resolved, contact Monica Healthcare for advice.

10.8 AN24™ will not connect via USB

Disconnect USB lead from both the AN24™ and computer. Reconnect USB lead and retry. If problem is not resolved, connect the AN24™ to the charger for half an hour and try connecting the recorder to the computer again. If the problem is not solved, contact Monica Healthcare for advice.

10.9 AN24™ will not connect via USB and will not recharge

If the AN24™ does not charge and is not recognised by the PC Disconnect AN24™, reconnect battery charger and check charger is connected at both the wall socket and the device. Leave the recorder connected to the charger for half an hour. Then disconnect the AN24™ from the charger and reconnect it again. If problem persists there may be an issue with the Bluetooth® module in the AN24™ - please contact Monica Healthcare for advice.

If the AN24™charges but is not recognised by the PC Disconnect USB lead from both the AN24™ and computer. Reconnect USB lead and retry. If the problem persists there may be an issue with the USB cable – please contact Monica healthcare for advice

10.10 AN24™ will not connect via Bluetooth®

Bring the AN24™ physically close (i.e. within 2 metres) of the computer and retry. If problem is not resolved, contact Monica Healthcare for advice.

Section 11 - Returns Procedure

11.1 Maintenance

There are no user serviceable parts in the Monica AN24™ or accessories. In the event of device failure or the battery needs to be changed, please contact Monica Healthcare or your local representative.

11.2 Returns

To return a defective product to Monica, you will need to obtain a Return Goods Authorization (RGA) number from the Monica Healthcare Support Group. Please contact a Service Coordinator at:

Telephone: +44 1159124540
Email: support@monicahealthcare.com

You will need to supply the Service Coordinator with the following information:

- The Model number(s) and Serial number(s) of the product, this information can be found on the label on the rear of the AN24™.
- The quantity of items you wish to return.
- Your "Bill to" address for invoice purposes.
- Your "Ship to" address.
- Your Purchase Order number.
- Details of the reported failure.

The Service Coordinator at Monica Healthcare will then inform you of:

- The Return Goods Authorization (RGA) number.
- The warranty or non-warranty status of the units being returned.
- Any repair charge.

All returned material must be shipped “PREPAID” to the address below for both warranty and non-warranty repairs. Please reference your RGA number on both your purchase order and the shipping label:

RGA reference number:
Tioga
St Thomas House
St Mary’s Wharf
Mansfield Road
Derby
DE1 3TN
UK

Appendix A - CE Approvals

UL International (UK) Ltd

An affiliate of Underwriters Laboratories Inc.

EC Certificate - Full Quality Assurance System Approval Certificate

(Annex II, section 3 of the Directive 93/42/EEC on Medical Devices)

Manufacturer	**Authorised Representative**
Monica Healthcare Ltd Biocity Pennyfoot Street Nottingham NG1 1GF	Not Applicable

Scope of Certificate:	Design and Manufacture of Fetal Monitoring Devices
Device Classifications:	Class IIb
Device Descriptions:	Portable, battery-powered device designed to monitor a pregnant mother and unborn baby in the antenatal period.
Model/Type :	Please refer to Attachment

We hereby declare that an examination of the full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex II (with the exemption of section 4) of Directive 93/42/EEC on Medical Devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

Certificate issued by:

Certification Manager
For UL International (UK) Ltd

UL International (UK) Ltd
Wonersh House
The Guildway
Old Portsmouth Road
Guildford, Surrey GU3 1LR
United Kingdom
+44 (0)1483 302130

Certificate no:	543
Original certificate:	10 October 2007
Current certificate:	16 December 2008
Certificate expiry:	10 October 2010

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UL International (UK) Ltd

An affiliate of Underwriters Laboratories Inc.

Attachment

The products detailed in the certificate below includes the following:

Products	Classification
Monica AN24 including uterine activity monitoring and accessories;	Class IIb

- ECG lead assy & connector
- AN24 Holster & belt clip
- Battery Charger
- Monitor connector/computer USB cable
- Monica VR s/ware and manual
- 30 Electrodes
- Abrasive skin tape
- Bluetooth Dongle

Certificate issued by:

Certification Manager
For UL International (UK) Ltd

UL International (UK) Ltd
Wonersh House
The Guildway
Old Portsmouth Road
Guildford, Surrey GU3 1LR
United Kingdom
+44 (0)1483 302130

Certificate no:	543
Original certificate:	10 October 2007
Current certificate:	16 December 2008

CE 0843

Appendix B – Electrode Placement

I. Patient Posture

It is very important that the patients' stomach muscles are relaxed and this is why **monitoring overnight during sleep is ideal**. If this is not possible then encouraging the patient to relax on a bed either on her back (recumbent or semi-recumbent) or on her side (left) for as long as practicable during the monitoring session. The patient should **avoid:**

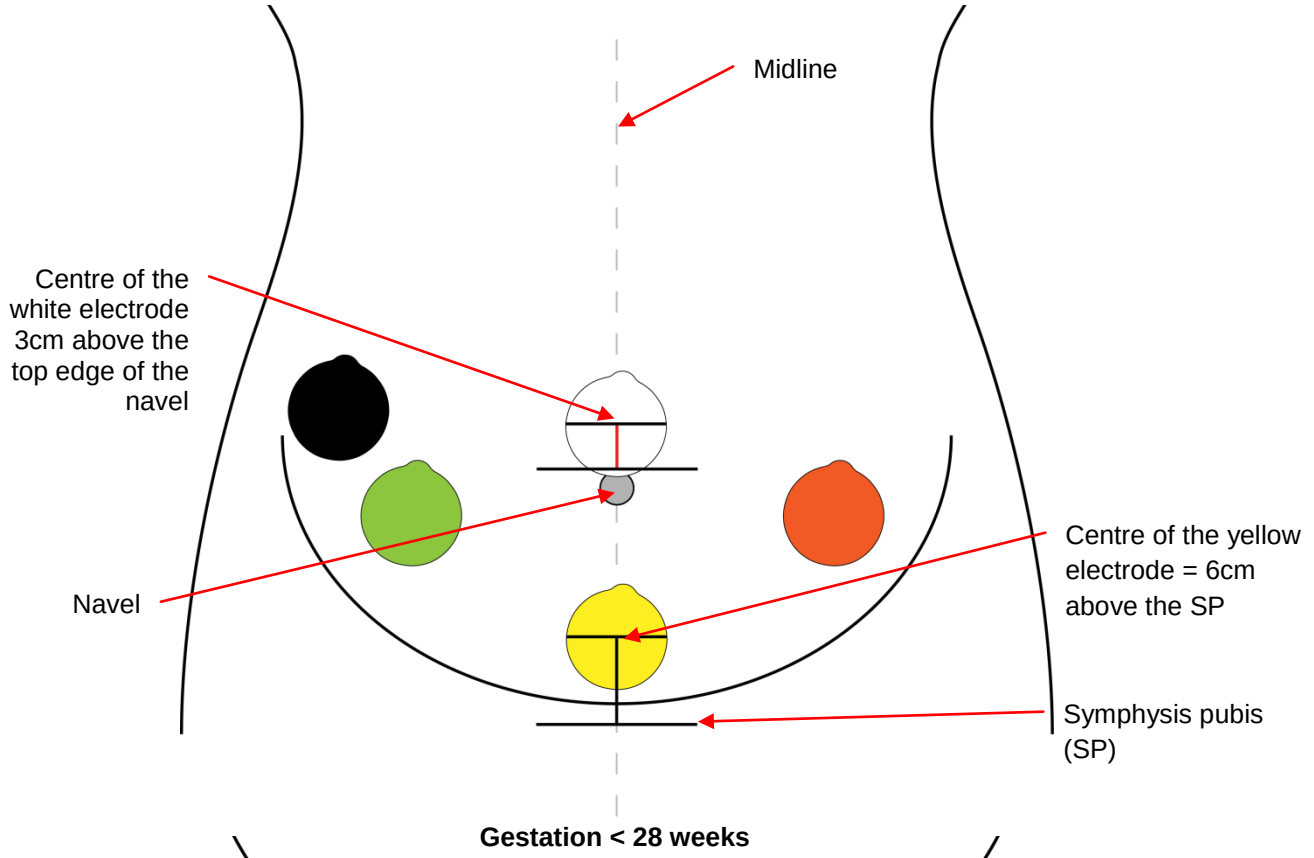
1. Any position or activity where the abdominal muscles are contracted e.g. sitting upright or lying down with her back raised from the hips at an angle of 45°. If this is unavoidable then using a cushion to support the back can help.
2. A tense stressful situation which will cause abdominal muscle tone to increase even though the patient is in a comfortable position e.g. When the room where the patient is being monitored is filled with Drs, Midwives, Family, Children and other onlookers. In this situation it is advisable to leave the Monica AN24 in place and return when the patient situation has changed.

II. Electrode Location

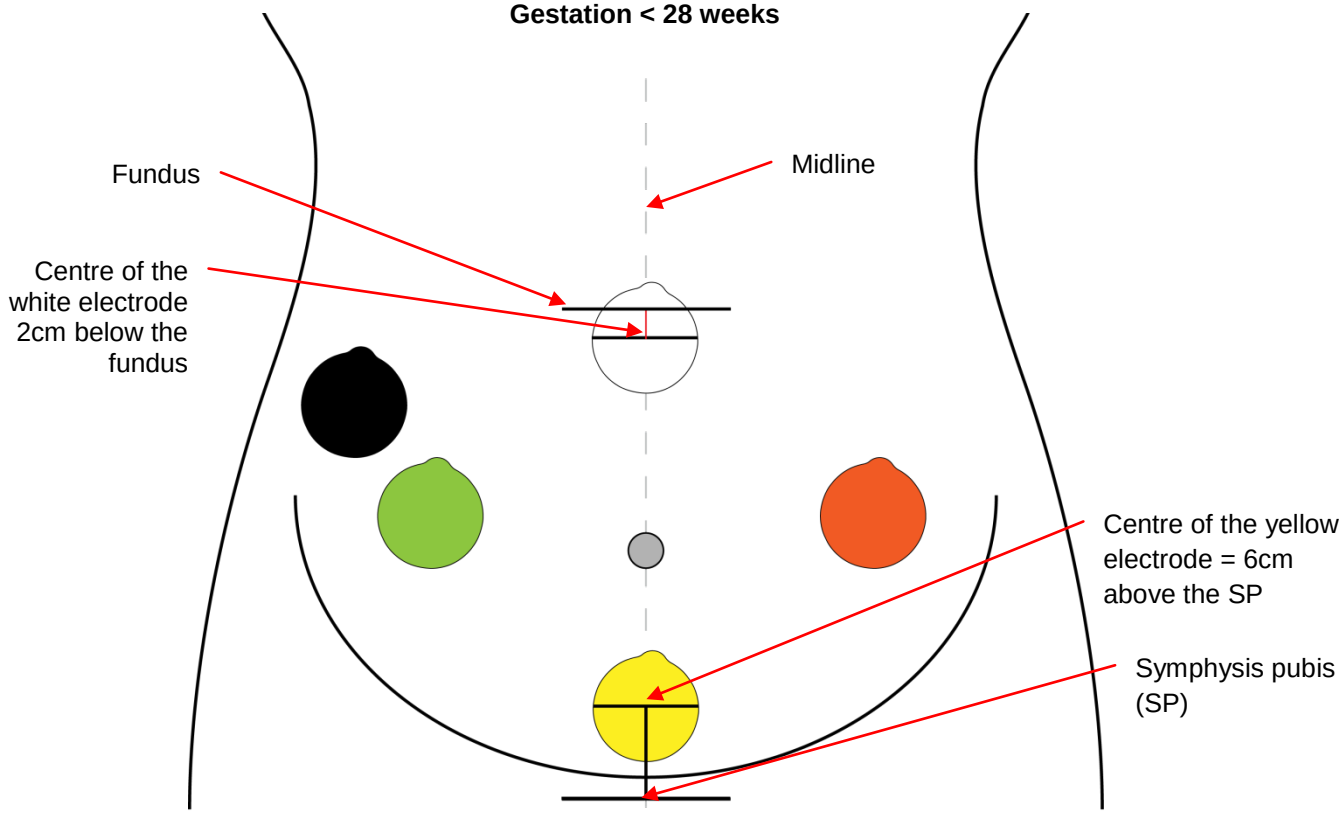
It is important to correctly prepare the skin before the application of the electrodes. You are advised to read all of this section before starting the procedure.

The instrument has three separate detection channel leads. The connectors on these leads are colour coded as **orange**, **white** and **green**. All three channels share a common connection point and this lead connector is coloured **yellow**. Finally, a ground lead with a **black** colour coded connector is also used. These leads are connected to 5 electrodes positioned on the maternal abdomen. Please refer to the table and figures below for guidance in positioning the electrodes.

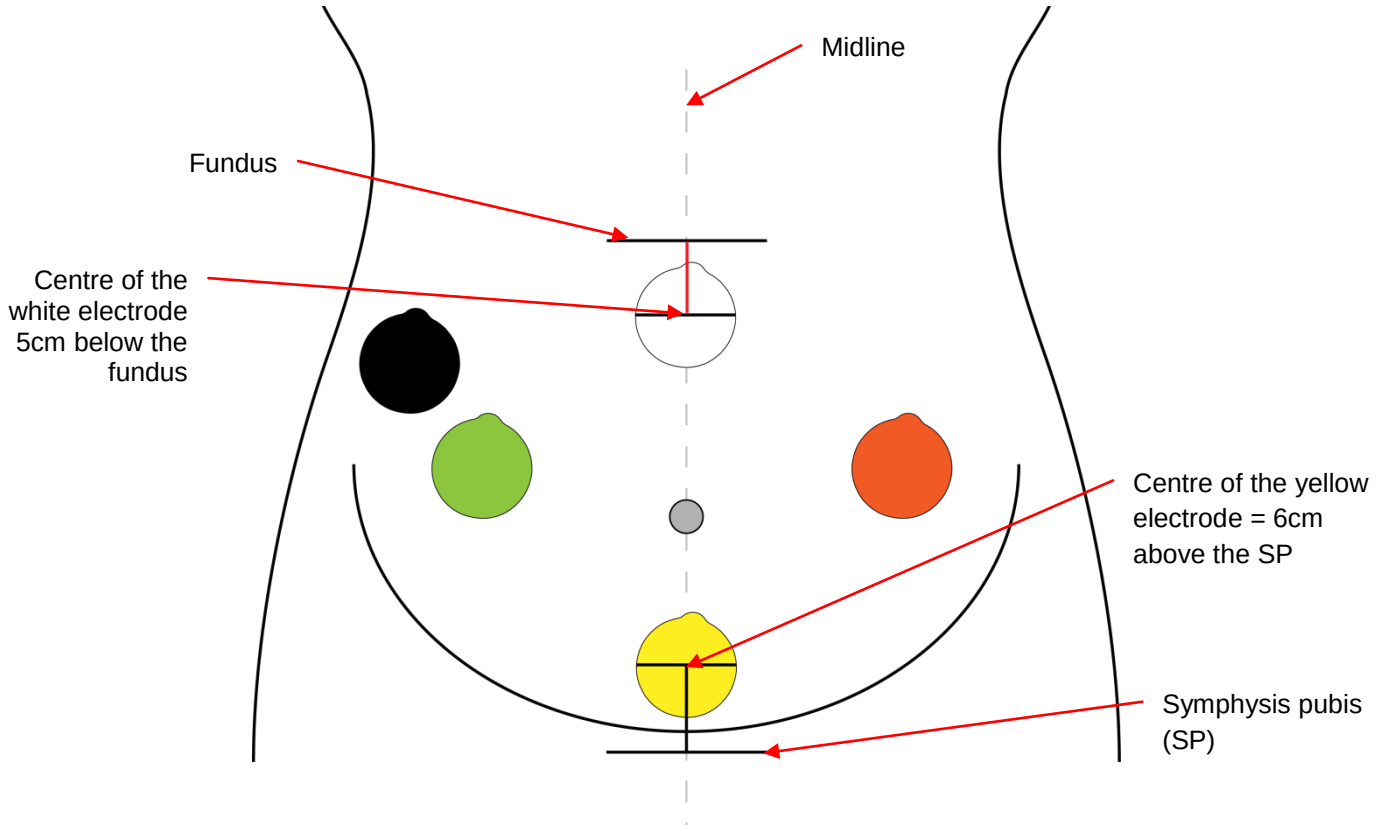
Electrode / Connector	Position
Yellow	Place the yellow electrode on the mid-line 6cm above the upper margin of the symphysis pubis or as close to 6cm above the upper margin of the symphysis pubis as you can achieve without requiring removal of the pubic hair.
White	**For gestations < 28 weeks** Place the white electrode on the mid-line so that the centre is *3cm above the navel*
	For gestations 28 to 33 weeks Place the white electrode on the mid-line so that the centre is *2cm below the fundus*
	For gestations > 33 weeks Place the white electrode on the mid-line so that the centre is *5cm below the fundus*
Green and Orange	The green and orange electrodes on the left and right of mother's abdomen are positioned to form a diamond as indicated in the examples shown in the figures below.
Black	The black electrode is the reference electrode and is positioned towards the back behind the green electrode. Its exact position is not critical.



Gestation < 28 weeks



Gestation 28 to 33 weeks



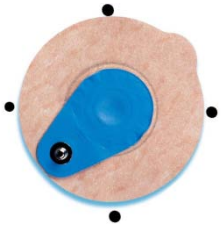
Gestation > 33 weeks

III. Preparation of the skin and electrode application

It has been found that if the electrodes are placed directly onto the skin then an unacceptable skin-to-electrode resistance can occur. This high resistance is caused by dead skin cells and other contaminates. These dead skin cells must be removed by using abrasive tape as supplied (**17**).

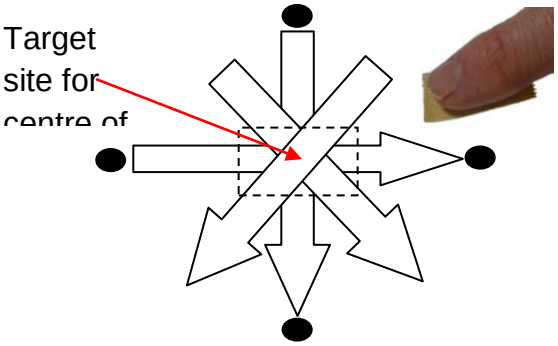
Using a **new Monica Specified Electrode**[3] as a guide, place the electrode (including protective back) on to the site to be monitored (see above), and using a Penflex skin marker pen place a dot on 4 opposite sides of the electrode as shown below.

[3] Once a pack of electrodes is open the moist conducting centre will dry out if the unused electrodes are not kept in the bag and if it is not re-sealed tightly. When using electrodes from a previously opened bag please confirm the electrode centre is still wet.



Note: *If unable to use a pen to mark the site an alternative* ***MUST*** *be used to mark the site. Example: patient's fingers or ultrasound gel as markers.*

Take a section of prep tape and stick it to the end of your index finger. Using a brushing action firmly stroke the area between two opposing dots in one direction only to remove the dead skin and other debris away from the electrode site. DO NOT BRUSH BACKWARDS AND FORWARDS At each site brush 5 times in a horizontal direction, 5 times in a vertical direction and then once on each diagonal, as the diagram below demonstrates.



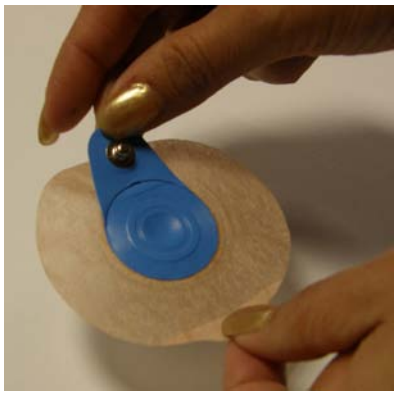
Use a 'wet-wipe' (Medline 'Ready Cleanse' ref MSC095280) to wipe away the dead cells and other debris. Ensure area is dry before placing the electrode.

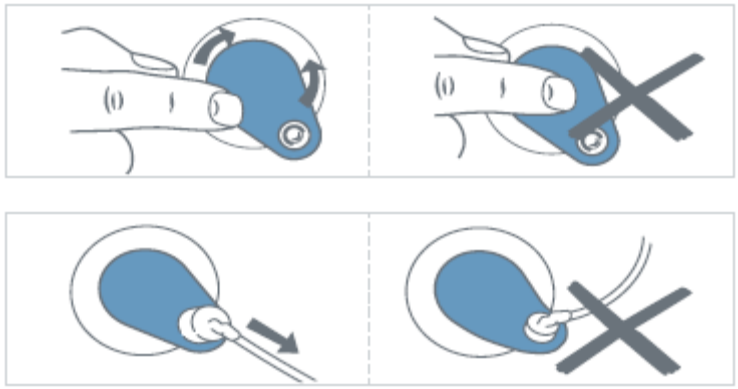
Caution: If the mother has been using oil, cream or lotion it is advisable to remove any residue in the area where the electrodes are to be placed with a soapy sponge or cloth - remove any soap with clean water and dry the area before starting preparing the skin as described above

Peel back the electrode by holding the adhesive free area and confirm the electrode centre is wet. Now hold the electrode by the metal stud connector tab as shown below so that it can be placed on the skin between the 4 markers. **The objective is to place the centre of the electrode on the intersection of all the vertical, horizontal and diagonal brush strokes.**

MISSING THIS INTERSECTION BY JUST 5mm CAN MAKE THE DIFFERENCE BETWEEN GOOD AND POOR QUALITY RECORDINGS.

Only press down on the adhesive outer edge of the electrode, to ensure it is well stuck down. Do not press on the central electrode area





When positioning the electrode ensure that the connection stud /tab is pointing to the right side of the patient, so that the cable connection tab on the electrode is aligned with the direction in which the cables are being pulled

Repeat the above until all five electrodes have been placed.

If the electrode skin impedance is not achieved for one or more of the electrodes as identified by the Monica AN24, QuickView or Monica VR, carefully peel back the problem electrode by holding the single strip of paper remaining so as not to touch the sticky part of the electrode as far as possible, so as to leave one edge in contact with the skin, and then rub the area with a 2% alcohol wipe before re-abrading applying firm pressure as described above.

Caution: Using an alcohol wipe on abraded skin may cause patient discomfort and skin irritation.

If after a second attempt of re-abrading the impedance is still too high, leave the electrodes in place for 15-30 minutes and then re-connect the Monica device. This will give time for the electrolyte in the electrode to permeate the skin pores and reduce the skin/electrode impedance.

It is recommended that users watch the short video on the Monica Installation CD. In addition, before attaching the electrodes on to a patient, the user should prepare the skin and place five electrodes on themselves or a volunteer, connect the Monica AN24™ and switch on. The positioning of the electrodes is not important, but this will provide an insight into the skin preparation needed in order to obtain a steady green LED (**5**) indicating that all the electrodes have been correctly attached to the skin.

Caution: Use only moderate force since excessive use of prep tape may cause patient discomfort and skin irritation. In some patients local skin reactions to the electrode adhesive\gel may occur causing slight reddening of the skin.

Caution: Do not use any electrodes which are dry or from a pack that has been opened by more than one month. When opening a fresh packet of electrodes, if all the electrodes are not used, write on the pack the date opened and make sure the pack is sealed to prevent the remaining electrodes from drying out.

Warning: Only use any electrodes specified by Monica healthcare (see Section 7 – Monica Accessories in the concise operating manual). Failure to use the specified electrode could result in unacceptable noise levels resulting in poor FHR detection.

Repeat the above steps for the remaining electrodes if more than one has been identified as having too high a skin/electrode impedance.

Caution: Do not use water to remove the electrodes

IV. Lead connection

The 'button' connector on the electrode is located on a 'flap' that is not stuck down. This means that, (a) the flap can be lifted and the correct colour coded lead connector can be pressed/snapped onto the button without pressing on the skin and disturbing the gel electrode contact with the skin and (b) no downward force is applied to the maternal abdomen.

V. Protective cover and neck strap

The protective silicone rubber cover (**18**) is designed to protect the Monica AN24™ during use, keep it clean and to keep it dry. Before connecting the electrode leads slip them though the hole at the back on the cover and push them one at a time through the small opening at the top of the cover. Pull the top of the cover down and stretch the bottom of the cover over the base so it creates a tight fit around the AN24™. Connect the electrode leads connector to the AN24™ as described in Section 4 of the concise operator manual. The buttons can still be operated and LEDs viewed once the cover has been fitted when the cover 'window' is positioned over the button/LED membrane. Finally, connect the neck strap to the base of the AN24™. The neck strap provides a convenient method for the patient to hold and 'wear' the Monica AN24™ during a recording.

VI. Lead security

It is important to secure and tidy the electrode leads to avoid lead or electrode detachment during operation. The electrode leads are of different lengths to aid in their correct placement and are fitted with two small plastic lead separators, which can be repositioned to avoid lead tangles and aid placement. The long single lead is fitted with a Velcro band so that it can be neatly coiled and secured when the patient is mobile.

VII. Electrostatic Discharge (ESD) precautions

Although precautions have been taken to ensure otherwise, static electricity could cause damage to the sensitive input circuits of the AN24™ and render the device inoperable. In the context of the AN24™, static is most likely to reach the AN24™ via a user\ patient touching static sensitive parts of the device.

ESD precautionary measures should be taken to minimise the risk of damage to the AN24™. More specifically:

- The connector which joins the AN24™ [18] and lead connector [17] together should not be touched by any part of the body, including the fingers
- The metallic (conducting) part of the electrode (press-stud) clips at the extremities of the electrode leads [17] should not be touched by any part of the body, including the fingers

All staff that use the AN24™ should receive an explanation of the ESD warning symbol and receive the following basic training\ instruction in ESD precautions before use of the AN24™:

- How to fit the AN24™ to the patient, and;
- How to attach the electrodes to the AN24™, and;
- How to attach the electrodes to the patient.

Monica Healthcare reserves the right to make changes in specification and/or discontinue any product or accessory at any time without notice or obligation and will not be liable for any consequences resulting from the use of this document.

Bluetooth® is a registered trade mark of Bluetooth SIG Inc.
Windows XP/Vista are registered trademarks of Microsoft Corporation.
All other trademarks are the property of their respective owners.

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The Monica AN24™™ complies with the requirements of the European Council Directives: 93/42/EEC concerning medical devices
ISO 13485 Monica Healthcare Ltd operates Quality Management Systems that have been approved and audited to ISO 13485.

Monica Healthcare Limited
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