MonitorMe

Short Specification

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Sanandco

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MonitorMe Description

MonitorMe is a landline telephone complete with vital sign sensors. In the handset are sensors for the measurement of:

- heart rate by electro-cardiogram (ECG);
- pulse rate and peripheral capillary oxygen saturation (SpO2) by photoplythmosographic sensor (PPG);
- pulse transit time (PTT);
- and skin temperature.

Designed to be comfortably held only in the left hand, MonitorMe takes advantage of the physiological sweet spot created by sensor contacts to the left ear, left thumb and left fingers, enabling clinically accurate vital signs measurements to be captured.

MonitorMe Intended Use

MonitorMe is used for the non-critical monitoring of vital signs in a domestic environment with the ability to automatically transmit data to a remote location via basic telephone connectivity.

MonitorMe's low cost, call automation and simple to use technology make it appropriate for a wide number of care pathways. Typical use scenarios are:

- Monitoring of critical vital signs post operatively allowing earlier discharge from hospital. The clinician will set warning thresholds that allow elective readmission in case of complication.
- Remote monitoring of individual or multiple chronic disease states such as COPD to improve outcomes, prevent emergency admissions and allow people to remain in their domestic setting for longer.
- Remote low cost long term care of the elderly and vulnerable recognised as at risk of developing health conditions.
- Supporting residents and staff in the care home setting enabling early identification of poor health episodes, reducing hospital admissions and extending the length of stay in a care home setting.

MonitorMe is as simple to use and reliable as an ordinary plug-in telephone. It eliminates the need for a modem or broadband and avoids the challenges of less reliable smart phone technology.

Data captured is combined with responses to an automated telephonic health questionnaire and transmitted to appear on a patient record.

Data generated at prearranged intervals builds a vital sign trends graphs that can be observed by privileged users, typically a health care professional, who will use the graphs as part of a decision-making process to determine the need for a full clinical assessment. MonitorMe is not intended for direct diagnosis or determination of treatment, it does not screen, monitor, treat or diagnose a specific condition or disease. The collated data presents a means to determine rapid or prolonged variation in the user's vital signs, and therefore indicate a possible change in the patient's health.

MonitorMe can be used in conjunction with other devices such as a blood pressure cuff or spirometer and the automated call tailored to request the input of data generated by these additional devices.

MonitorMe Functionality

Handset General

- Molded in white high gloss plastics (ABS) with metallic sensors and clear polycarbonate thumb clip. Case parts are wipe clean with mild alcohol with minimal dirt traps.
- Ergonomics tailored to 5th percentile female and 95th percentile male hands and ears.
- Shaped to support easy prehensile grip when dexterity might be reducing.
- Location of sound outlet positioned to ensure the handset is raised to reduce the risk of the lobule (flap of skin below the outer ear) occluding the temperature sensor. The orientation of the temperature sensor is designed to point towards the ear canal for repeatable measurements. This is optimized when the user can hear sound from the ear piece most clearly.
- The arrangement of sensors helps to prevent use in the right hand whilst the design of the base encourages lifting the handset in the left hand only. Base/handset cable exit is on the left. Appropriate contact with all the sensors is assured when held in the left hand.
- Uses the left thumb to capture SPO2 via reflectance at a repeatable location. The addition of a sprung clip over the thumb helps improve thumb stability during measurement. SPO2 sensor software calculates the pulse at the thumb when held in this repeatable location. Clip adjusts height automatically to suit varying thumb thickness.
- A single lead ECG signal is captured utilizing a sensor within the ear piece which connects with the right side of the equipotential line and a sensor and earth via the fingers and thumb of the left hand which are on the left side of the equipotential line.
- Each sensor data value reported has a corresponding ‘confidence level’ value. This confidence will communicate the quality and consistency of the data used to generate the sensor value being reported. The confidence value is generated by a software validation and collation process.

Base General

- 0-9 keys plus * (star) and # (hash). Two keys allow user control of earphone volume, typically for those wishing to remove hearing aids when using MonitorMe.
- The ringer volume can be switched between two preset volumes.
- Handset and power cables are preconnected and cannot be removed to avoid user interference or accidental disconnection.
- Base is weighted and has non-slip feet to prevent sliding during use.
- A user feedback LED is located within the lower handset recess, directly in line of sight for the user. LED illumination varies between off, flashing and solid according to the calculated confidence measure. This LED offers the user an immediate feedback of the quality of grip whilst also allowing remote identification of user errors.

Setting up the MonitorMe Remote Monitoring System

The MonitorMe remote monitoring system relies on an electronic back office populated with data for each patient and details of the automated telephone call. It is recommended that the following information be collected, but this can be tailored to suit specific circumstances:

Basic Data:

Carer Data	**Patient Data**	**Family/loved one data**
Name	Name	Name
Address	Telephone Number	Address
Phone Number	Address	Phone Number
email address	email address	email address
	National Health Number	

Physical Data for Patient:

Date of birth	Height
Sex	Weight
Ethnic Origin	Left arm measurement finger to ear
Device reference number	Date device specified

Health data for patient which then triggers inclusion of scripts from a standard menu:

Description of Condition	
Has the patient had an operation?	
Medication being taken	If none then Q6 disabled.
Has the patient COPD?	If yes triggers COPD questionnaire
Expand for other conditions	Tailor scripts accordingly as required.
Is temperature required as a report?	If yes trigger temperature triage and report
Is heart beat required as a report?	If yes trigger heart beat triage and report
Is SPO2 required as a report?	If yes trigger SPO2 triage and report
Is ECG variance required as a report?	If yes trigger ECG triage and report
Is questionnaire output required as a report?	If yes trigger questionnaire triage and report

Is blood pressure required as a report?	If yes include cuff with the device. Trigger blood pressure triage and report.
Any other signs to be monitored	Tailor as and when
Specify frequency of calls	Triggers automated calls to patient number

Technical Triage set up for each vital sign requested above:

Temperature	Amber limit – re do call in one hour Red limit or three ambers – raise clinical intervention
Heart beat	Amber limit – re do call in one hour Red limit or three ambers – raise clinical intervention
SPO2	Amber limit – re do call in one hour Red limit or three ambers – raise clinical intervention
Pulse Transit Time	Amber limit – re do call in one hour Red limit or three ambers – raise clinical intervention
Questionnaire output	If medication has not been taken or carer has not visited as anticipated raise clinical intervention.
Blood pressure	Amber limit – re do call in one hour Red limit or three ambers – raise clinical intervention

MonitorMe in the Home Use

MonitorMe does not need any special measures for installation, simply connect the power supply to a nearby plug socket and plug MonitorMe into a telephone socket or on-line filter using the cable supplied . MonitorMe is now ready to use by anyone as an ordinary telephone.

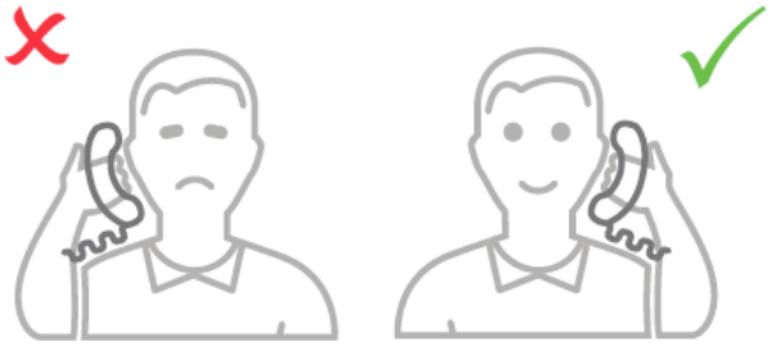
MonitorMe is most effective if the user follows a similar relaxation routine for a period of around 5 minutes in advance of the call. Similarly, the length of the automated call may be adjusted to allow the users vital signs to stabilise in the first few minutes. Only stable vital signs readings will be transmitted.

The automated call is initiated at times agreed with the clinician whereupon the system will ask security questions and wait for key pad responses. The automated call then follows a series of questions specific to the users care pathway.

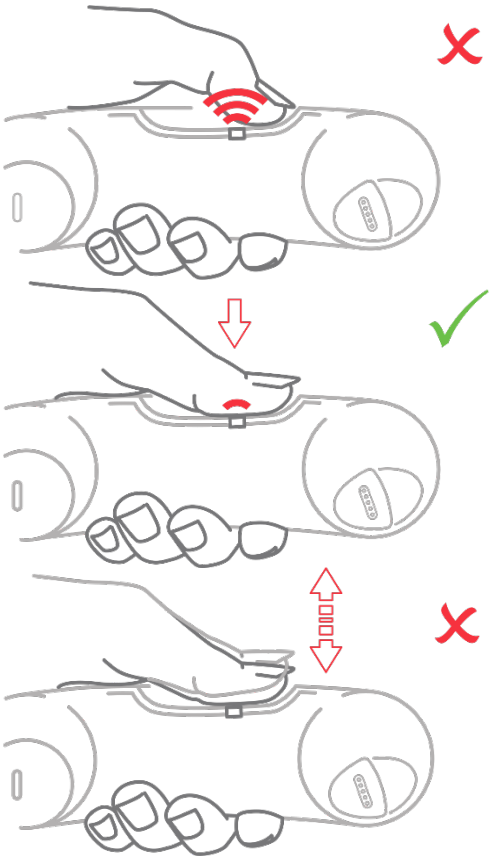
During the call MonitorMe collects vital signs information and sends it to a secure electronic patient record.

Accuracy of the readings is improved by the following user instructions:

1. Hold MonitorMe in the left hand.



2. The left thumb should be placed into the recess below the clip and the red light covered by the flat of the thumb. This should be a gentle relaxed contact, please do not squeeze.



3. The ear piece should be lifted to the left ear. The metal contact may feel cold. This will help guide the ear piece to the correct position. Listen carefully to the sound and adjust the position of the ear piece until the sound level is greatest. Ensure long hair does not obstruct the ear piece.
4. Fingers should contact the metal bar on the handset.
5. There is a red light on the telephone base located in the hand set recess. This red light indicates the quality of the connections with the MonitorMe sensors. When the connection is good the light will remain on, when not so good the light will flash.
6. The automated call will also advise if the data collected is not optimised and ask you to check how the handset is being held. The data collected will be securely transferred to your electronic patient record.

Retrieving Data from the MonitorMe Patient Record

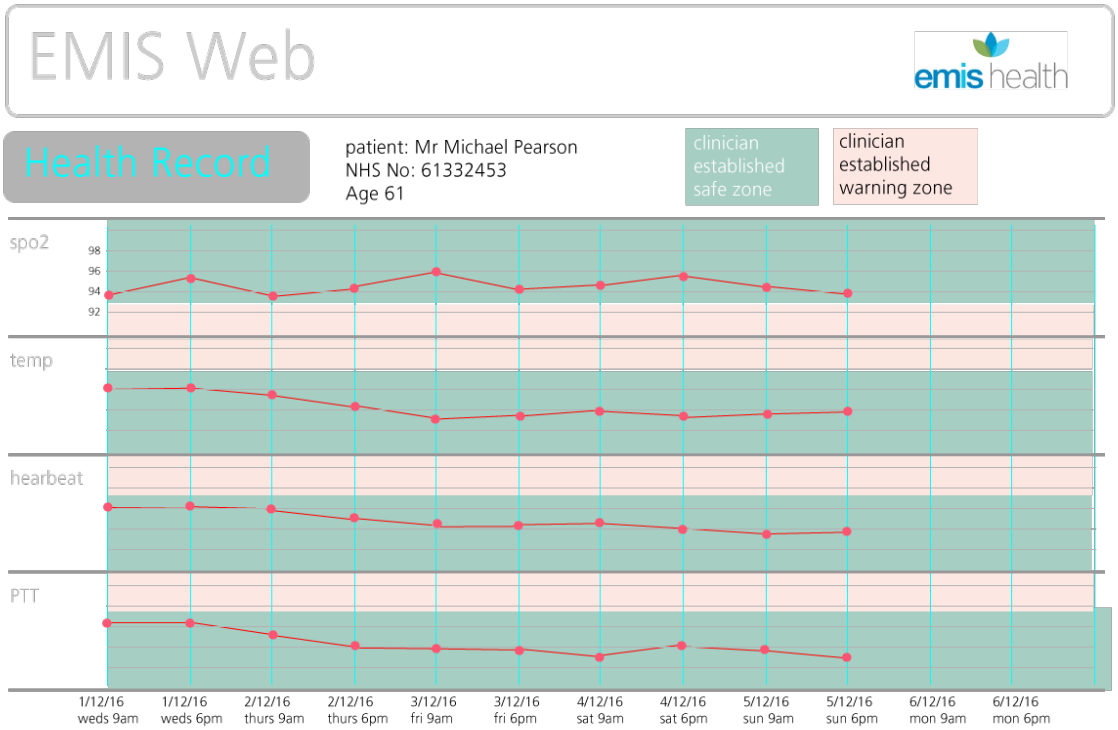
Sanandco have partnered with Egton Medical Information Systems Limited, part of the EMIS Group, to provide secure data hosting.

EMIS Group Plc and Egton Medical Information Systems Limited are registered with the Information Commissioners Office, Registration Number: Z5514037. The system is hosted securely via UK data centres in line with NHS and HSCIC recommendations, alongside other Egton Digital services. These data centres are PCI DSS, ISO27001:2005, ISO14001:2004 and ISAE 3402 Type II accredited.

The service utilises SSL (Secure Sockets Layer) for encrypted access and transmission of data. The SSL connection utilises 2048bit RSA encryption and the certificate is signed by a trusted CA (Certificate Authority). Inbound connections are controlled via dedicated load balancing and firewall solutions.

Privileged users can access the data generated via appropriate devices such as a Smart Phone, Tablet or PC. System access is authorised by secure username and password combinations.

Data will be presented either digitally or graphically. Typically, graphs will be presented and where data captured is outside prescribed thresholds then this will be flagged to the privileged user by a traffic light system.



The same data can be shared with other software providers via an appropriate API.

Example Use of MonitorMe – Early Discharge from Hospital:

Stage 1 – MonitorMe Set-up

Following major surgery Patient X is being prepared for discharge from hospital. He/She appears to be recovering well and normal body functions are working well. The care professional identifies Patient X as a suitable person to leave hospital with a MonitorMe device.

The care professional opens the professional portal of the patient record system and enter basic data for the patient (including phone number to be used for the call), carer and a specified loved one. Physical data of the patient is also included together with a description of the patient's condition.

At this stage the professional ticks boxes to indicate the type of reports to be generated to support the on-going care pathway. This is also linked to the health questionnaire and appropriate automated questions are established. The final part of the professional set up is to stipulate the frequency of call.

Patient X is then discharged from hospital with the MonitorMe device and any medication that has been prescribed.

Stage 2 Using MonitorMe:

Patient X plugs MonitorMe into a power socket and also the telephone line. No further set up is required. He/She can continue to use MonitorMe as an ordinary telephone.

At the specified time(s) of day the automated call will ring Patient X. The automated call will ask for Patient X's "password" (may be specific health authority reference number or just date of birth). Patient X will confirm this using the telephone keys.

This will start the health questionnaire and the vital signs sensors. Software in MonitorMe will check that readings from the sensors are stable and that the handset is therefore being held correctly. (Left hand, ear piece centred in the left ear, fingers connecting properly on the handset). In the event that this is not the case then the automated call will ask Patient X to adjust his/her grip.

The results of the health questionnaire will be stored together with the vital signs readings on the patient record.

The automated call will end with a confirmation the data has been captured accurately.

Stage 3 Evaluation of Data:

The care professional will have an icon on a PC or mobile device which when clicked will open up the MonitorMe Professional Portal. From this single entry point the care professional will be able to access all the data for their patients. They will be able to see trends for temperature, oxygen saturation, pulse and blood pressure, together with results from the health questionnaire to target which Patient's might be most in need of intervention.

Should automated triage of the results be selected then the professional portal page will highlight in amber those patients with occasional results outside the normal limits and therefore rapidly identify where care may be most required. In the event that readings are significantly outside the normal

limit or have been amber for three consecutive readings then the status will be raised to red identifying the need for urgent intervention.

Stage 4 Review by Loved Ones:

Patient X will be able to specify who can look at his/her patient record thus enabling a loved one or family member with access to the internet to be able to review the data. The report may include the time and date when the last data was received, and may also include the trend data or the time when interventions have been requested. This will serve to reassure and empower loved ones and family members and provide the greatest opportunity for all round positive outcomes.