MonitorMe

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.

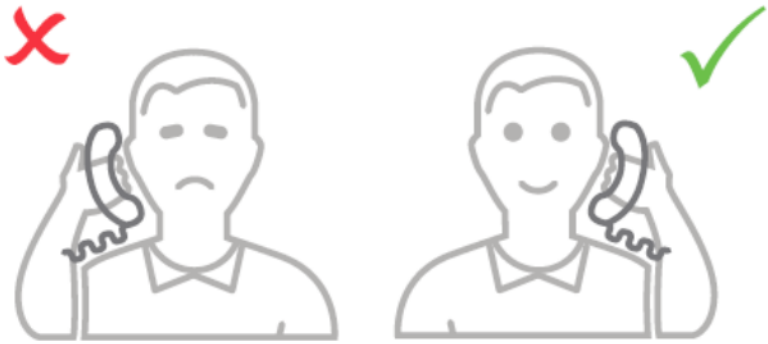
MonitorMe is most effective if the user follows a similar relaxation routine for a period of around 5 minutes in advance of the call. Similarly, the length of the automated call may be adjusted to allow the users vital signs to stabilise in the first few minutes. Only stable vital signs readings will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

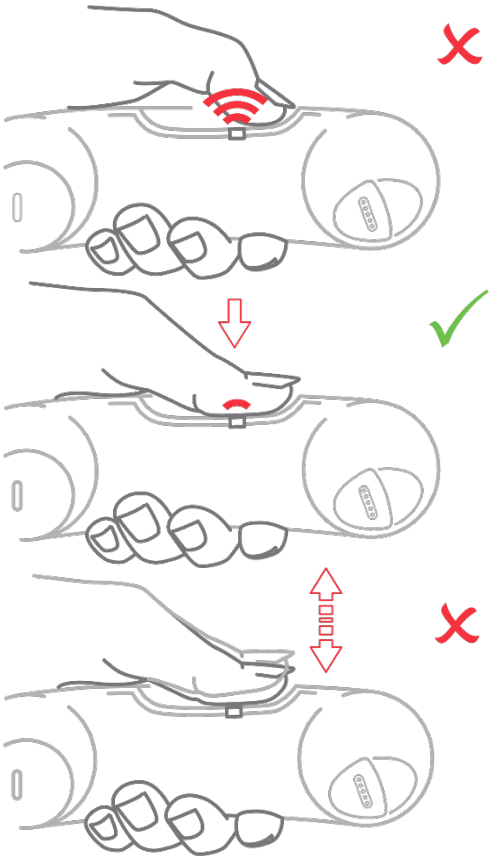
During the call MonitorMe collects vital signs information and sends it to a secure electronic patient record.

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

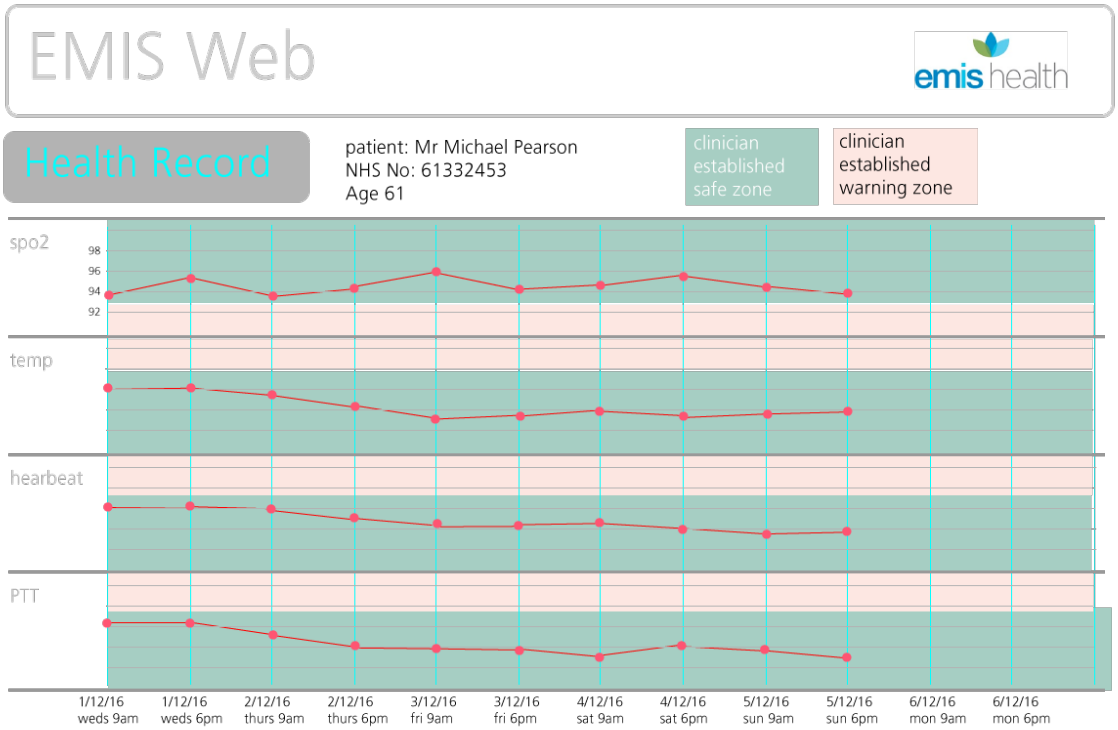
Sanandco have partnered with Egton Medical Information Systems Limited, part of the EMIS Group, to provide secure data hosting.

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.

Application Specification

Medical Purpose;

Measure and report the following vital signs of a user who is sufficiently well to be in a home environment (i.e. no severe immediate condition):

a. User skin temperature – inner ear
b. Blood oxygenation
c. Pulse rate (from pulse oximeter)
d. Heart rate (from ECG)
e. Pulse transit time (PTT)

Patient Population;

a. Age: Adult, including geriatric
b. Weight: >40kg, <160kg (i.e. not malnourished or outside typical adult mass)
c. Health: no condition that prevents self-sufficiency in the home
d. Nationality: multiple
e. Patient state: alert, cognitive, mentally competent. No significant disability in hearing (left ear), corrected vision. Left hand/arm has no significant disability or motion impairment. Ability to use normal phone. No left ear obstruction (e.g. cotton wool, excessive wax). Able to simultaneously hold phone to ear in left hand and comfortably push phone buttons.

Interaction with User Body;

a. Measurement site: Left hand thumb, index and middle finger, left ear
b. Measurement Condition: intact and uncovered skin at measurement sites. User in relaxed state (not post or mid exercise, agitated state).
c. Light energy in infrared and red frequencies applied at outer surface of left thumb for pulse oximetry function.
d. Left hand finger(s) conductively connected to electrical ground reference.

Intended User;

a. Education (minimum): grade 7 reading competence
b. Knowledge (minimum):
    i. comprehension to understand and respond to simple audio questions
    ii. read and identify westernised numerals and characters including * (star) and # (hash)
    iii. understands left and right
    iv. understands basic principles of telephone operation
c. Language: able to understand language of questionnaire voice – initially English.
d. Experience: no experience necessary provided pictorial instructions understood
e. Permissible impairments:
    i. Mild vision impairment – still able to identify keypad numerals and key features of phone.
    ii. Average degree of age-related short term memory impairment
    iii. Mild hearing impairment which can be compensated by higher volume
    iv. Loss of dexterity or function in lower body

Application;

a. Environment General:
    i. Used in a domestic/home environment
    ii. Indoor use only
    iii. Installed by user, not professional
    iv. Not used in wet environment
    v. Intended to exist in a static location save for occasional repositioning in location cleaning.
    vi. Survives 1m drop to wood floor over concrete; no functional impairment.
b. Environment Physical:
    i. Ambient operating temperature range: normal room temperature
    ii. Relative humidity range: normal room humidity
    iii. Ambient pressure range: normal room air pressure
c. Frequency of Use:
    i. No restrictions.
d. Mobility:
    i. Exists in a static, consistent location to be used on a resting patient

Lifecycle

The handset is considered a line replaceable unit and will not be maintained in the field. This includes any software or firmware maintenance.

The handset shall be designed for a minimum lifetime of 3 years when subject to a typical use case profile.

Shelf life of the handset shall exceed 5 years.

MonitorMe should be periodically cleaned with non-abrasive cleaning products such as alcoholic wipes.

Weight

Weight excluding packaging is 1000g. (734g hand and base set, 66g cables and 200g psu)

MonitorMe Technical Specification of Sensors and Components

All sensors and components operate simultaneously, and the data generated is processed simultaneously.

With the handset held correctly, all sensors determine a reading within 90 seconds of being enabled. The target is 60 seconds.

The handset is powered down when it is on the hook. The firmware shall commence sampling the sensor data within 1 second of the handset being lifted.

Power

MonitorMe is powered from a domestic AC mains source.

The mains source is converted to 5VDC nominal via an AC-to-DC power converter. The supply is EN60601-1 compliant including isolation equivalent to 2 Means of Patient Protection (MOPPs).

Phone Line

A Public switched telephone network (PSTN) compatible interface is provided via an RJ11 6P2C socket connector on the base unit.

The PSTN interface is implemented to maintain DC isolation from the remainder of the system.

The PSTN interface supports Dual-tone multi-frequency signalling (DTMF).

Phone Base

The phone base shall consist of the following user accessible standard phone features:

a. Large push button 3x4 keypad
b. Handset cradle including hook switch
c. Adjustable ring volume
d. Adjustable earpiece volume
e. Audible ring

Ear Piece Speaker

The ear piece speaker has the following specification:

a. Impedance = 8 ohm +/-20%
b. Power rating nominal = 0.25W (min)
c. Power rating max = 0.5W (min)
d. Frequency response (typ) = 2-16kHz
e. Output SPL (min) = 60dB(1w/1m@2kHz)

f. Distortion = <5% max @2kHz, rated power

The speaker is mounted to permit sound output to the user with a quality comparable to a standard commercial POTS phone.

Microphone

The microphone has the following specification:

a. Omnidirectional

b. Output impedance (typ) = 2.2kohm

c. Frequency response (typ) = 0.2-16kHz

d. Sensitivity (typ) = -40dB

e. Minimum voltage (typ) = 2.0VDC

The microphone picks up audio from the user with sensitivity and quality comparable to that of a standard commercial POTS phone.

Temperature Sensor

The temperature sensor is a Melexis MLX90615 device which may read a resolution of 0.02 degrees Kelvin.

The firmware reads the temperature from the sensor twice per second.

The temperature is converted to degrees Celsius for subsequent processing. The resolution is better than 0.1 degrees Celsius.

The laboratory temperature measurement accuracy is +/-0.3 degrees Centigrade over an object temperature range of 32 to 42 degrees.

Accuracy is maintained in the range +15 to +35 degrees Celsius ambient temperature.

The temperature sensor operates in Direct Mode (80601-2-56).

Pulse Oximeter Sensor

The pulse oximeter interface consists of 2 LED's – one red (660nm) and one infra-red (940nm) – and a photodiode. This is connected to a Texas Instruments Analogue Front End (AFE chip) that provides the necessary drive electronics and connects to the processor via an analogue to digital converter (ADC) and a high speed synchronous serial interface (SPI interface). Visible, infra-red and ambient light samples are at 22bit resolution.

The firmware automatically adjusts the LED illumination level and AFE gain to maximise photodiode signal to noise ratio.

The PPG signal contains useful information up to approximately 120Hz. The sample rate therefore needs to be at least twice this frequency. The PPG interface is therefore sampled 300 times per second.

The ambient and infra-red (optionally and/or red) streams is used to detect finger presence. This is done by setting the LED brightly on and looking for a drop in ambient level detected and a corresponding rise in illuminated light detection.

The infra-red and visible samples are used for pulse detection and blood oxygen calculation. The sample data has the ambient light level removed prior to being read out from the AFE. This reduces the effect of changes in illumination during measurement. The sample streams are passed through a low pass filter with a 40Hz cut-off. The purpose of this filter is to remove any 50Hz interference that may have been picked up by the sensitive photodiode amplifier.

The pulse rate is calculated by measuring the time between rising edges of the infra-red pulse waveform. The infra-red waveform is used for this purpose as it will typically be greater in magnitude than the red waveform. The rising edge trigger point is also time-stamped to provide the end point for the PTT measurement.

The blood oxygen saturation is calculated using the Root-Mean-Square (RMS) values of the infra-red and red samples (i.e. the power of the AC component of the light signals).

The SpO2 accuracy of the sensor is within 4% A_{RMS}

(A_{RMS} is defined by 80601-2-61 (annex CC). It is the root-mean-square difference between measured values and reference values).

The pulse rate output requirements are:

i. Range: 30 to 200 bpm
ii. Accuracy: within 4% A_{RMS}

The handset shall determine and communicate the time period between the pulse detected by the ECG function and the pulse detected by the Pulse Oximeter function.

The measured time of arrival of the rising edge is recorded to an accuracy of 4 ms. Note the actual time of arrival of the rising edge at the ADC is the time it is detected by the pulse timestamping block minus the group delay of the filters. This is factored in to the pulse transit time calculation.

The firmware produces a pulse rate measurement provided the sample waveform is stable for at least 15 seconds.

The sensor-tissue interface shall not be raised above 41C during intended use, given an initial tissue temperature of 35C.

The amount of energy applied to the user is expected to be in the order of 5mW continuous. In actuality the LEDs are pulsed (above 30Hz) and so output power is significantly less than continuous power.

Electro-cardiogram (ECG) Sensor

The ECG is implemented using 2 Plessey EPIC PS25151 sensors. These are standard IC packages that electrically connect to custom sensor plates on the handset.

The sensor plates are metallic (alloy), but are electrically insulated from the user by a specialist coating. The sensors rely on this insulation to function correctly as the detection is via capacitive coupling of the users body potential field. An electrically conductive connection to the user would stop the ECG function performing. In addition to the anodised sensor plates, the user is required to contact a third plate to act as a common mode potential reference. This plate is electrically conductive and connects via a low impedance path (direct connection) to the ECG sensor ground.

One sensor plate exists on the earpiece intended to contact the outer ear. One sensor plate is on the handset body intended to be contacted by the hand. The reference (conductive) plate is also on the handset body.

The EPIC devices have very high input impedance which permits them to amplify small changes in the electric field in the vicinity of the sensor plates to provide a useable signal, but one that is heavily corrupted with mains frequency interference. The use of a pair of plates and a differential amplifier removes most of the interference, but some will remain that must be filtered out in software. The output of the differential amplifier is passed through an anti-alias filter prior to connection to the ADC.

The ADC provides 12-bit unsigned samples.

The ECG signal contains useful information up to approximately 120Hz. The sample rate therefore is 300 times per second.

Because this application only requires measurement of the interval between adjacent QRS peaks no other features of the PQRST complex are required so the strategy adopted is to use a high pass filter to remove all features except the QRS peak. The detection algorithm then becomes a matter of simply looking for peaks.

The ECG output requirements are:

i. Range: 30 to 200 bpm
ii. Accuracy: within 4% A_{RMS}.

The detection time of the QRS peaks are recorded to provide the start time for the PTT measurement.

The firmware produces a heart rate measurement provided the sample waveform is stable for at least 15 seconds.

Pulse Transit Time (PTT)

The pulse transit time is derived within the validation module from valid ECG and PPG pulse and heart rate measurements – specifically the times of arrival of the relevant peaks in the waveforms. Because this is a time measurement it is important that the filters used in the signal chains for the ECG and PPG provide constant or bounded group delays.

The measured time of arrival of the ‘R’ peak is recorded to an accuracy of less than 5ms.

Quality of outputs and Confidence Levels

The software makes an estimate of the signal quality to be passed to the validation block along with each reading. The methods are reading dependant, but include stability, signal to noise ratio or correlation with other readings.

The software also determines if the handset is being held correctly and communicates this by illuminating an LED light in the base. The checks that may be performed are:

1. The optical sensor for the pulse oximeter may be used to determine if a finger is present or not. A finger present indication would be a high level of illumination detected when the IR LED is illuminated and a low level of ambient light.

2. The temperature sensor can be checked for a temperature within the valid human range (32-42 degrees Celsius).

3. The peak to mean ratio of the ECG signal is at least 4:1.

Any sensor data value reported out of the handset has a corresponding 'confidence level' value. This confidence communicates 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.

The confidence in the final value is produced from a combination of the standard deviation, signal quality, and number of readings, as shown in Table 1. The low standard deviation threshold is defined for each measurement type.

Table 1:

Confidence	**Conditions**
None	No readings
1 - Low	Total number of readings less than minimum threshold) OR High deviation (greater than 2 x low deviation) OR Only one reading at chosen value OR Poor / ok quality score
2 - Medium	Medium deviation (between 2 x and 1 x low deviation) OR Less than minimum threshold of readings at chosen value OR Good quality score
3 - High	Low deviation AND excellent quality score

Base Communications

The base and the handset microcontrollers communicate with each other via a serial inter-processor interface.

The handset shall communicate over the UART using ASCII characters of 0-9, * (star) and # (hash) only. Messages shall be a superset of the DTMF messages defined in a MonitorMe specific DTMF Protocol specification.

Applicable medical standards

BS EN 60601-1	Medical device safety: General standard
BS EN 60601-1-2	EMC collateral standard
BS EN 60601-1-6	Medical usability (calls BS EN62366))
BS EN 60601-1-11	Home health medical equipment collateral standard
BS EN 60601-2-27	Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment. The “ECG” function operates to monitor heart rate only and as such no direct compliance with any BS EN 60601 particular standard is mandated for this function.
BS EN 62471	Photo-biological safety of lamps and lamp systems.
BS EN ISO 80601-2-56	Safety and essential performance of clinical thermometers for body temperature measurement
BS EN ISO 80601-2-61	Safety and essential performance of pulse oximeter equipment
BS EN IEC 62304	Medical device software

The system does not (and is not required to) implement an alarm system or create alarm conditions; consequently BS EN60601-1-8 is not applicable.

Applicable Telephony standards

2014/53/EU	Radio Equipment Directive (RED)
TIA-968-A	PSTN connection
EN 55022 CISPR 22	ITE emissions
EN 55024 CISPR 24	ITE immunity
EN 60950	Safety of information technology equipment
TBR21	PSTN interface via DTMF
ETSI ES 203 038	PSTN terminal analogue handset performance (product level, performance in conjunction with handset) [supersedes TBR38]
ETSI ES 201 235	Specification of dual-tone multi-frequency (DTMF) transmitters and receivers
BS EN 62368-1	Audio/video, information and communication technology equipment. Safety requirements.

Software Class

The MonitorMe device provides trend measurements only and a bad measurement will not present an immediate danger to the user. The software is therefore Class A as defined in EN IEC62304.

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.