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Title: # System Design Specification for Generation III Nexystem

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CHANGE HISTORY

Issue	Date	Author	Amendments
Draft A	27-1-00	P. Howard	First Draft
Draft B	2-2-00	P. Howard	Updates following first informal review
Draft C	16-2-00	P. Howard	Updates following 2nd informal review
Draft D	1-3-00	P. Howard	Updates following SDIT meeting of 29-2-00
Draft E	10-3-00	P. Howard	Updates following review of 9-3-00
Issue 1	14-3-00	P. Howard	Updated for Issue
Issue 1.1	03-July-2000	M.Llewellyn	Respiration analysis detail

INCOMPLETENESS RECORD

1. Protocol and transmission rate of PDL to BSU interface is undefined.
2. PDL battery recharge time is undefined.
3. Compression methods for PDL to BSU and BSU to TMS data transfers are undefined.

TABLE OF CONTENTS

1 Introduction

1.1. Purpose

The Nexystem is intended as a system for measuring, recording and, in some cases, transferring physiological data from patients in the home environment to a Health Care Professional.

The purpose of this System Design Specification is to define the top-level architecture of the Generation III Nexystem, the product elements and interfaces (including as applicable references to inter product protocols). It includes a functional description of each product element sufficient to specify the lower level operation of the product to each team.

It acts to define additional design requirements on the individual products in order to provide the system functionality.

The air interface protocol is defined in [4] and specifies the layer 1 to layer 3 structure of the air interface in line with normal protocol practice. The document includes the receiver diversity algorithm.

The interfaces between the PDL and BSU, and between the BSU and TMS, are defined in [5] and [6] respectively.

1.2. Scope

The document's scope includes on-body sensor, the E-patch, the Portable Data Logger, the Base Station Unit, and the TeleMonitoring System.

It also includes, either directly or as appendices, the interfaces between the components.

1.3. Amendment

Nil

1.4. Related Documents

Throughout this document, references in square brackets are to the documents specified below.

[1] System Requirements Specification for Generation III Nexystem (300-REQ-001)
[2] Nexisensor Product Design Specification (301-PDS-001)
[3] E-Patch Product Design Specification (301-PDS-002)
[4] Generation III Air Interface Protocol (302-DES-001)
[5] Generation III PDL to BSU Interface Protocol (302-DES-002)
[6] Generation III BSU to TMS Interface Protocol (302-DES-003)
[7] Nexan Technical Memo "868MHz Receiver - Initial Study" (J.D. Speake)
[8] PDL Product Design Specification (303-PDS-001)
[9] Hardware Recommendations - Generation 3 Software (305-REQ-002)

1.5. Abbreviations

The following abbreviations are used in this document.

AHA	American Heart Association
BER	Bit Error Rate
BMI	Body Mass Index
BSU	Base Station Unit
CPAP	Continuous Positive Airways Pressure
ECG	Electrocardiogram
FEC	Forward Error Control
FEV1	Forced Expiratory Volume in the first second
FSK	Frequency Shift Keying
FVC	Forced Vital Capacity
HCP	Health Care Professional

HR	Heart Rate
HRV	Heart Rate Variability
LCD	Liquid Crystal Display
MIT	Massachusetts Institute of Technology
PDL	Portable Data Logger
PEF	Peak Expiratory Flow
PER	Packet Error Rate
PSTN	Public Switched Telephone Network
QT	Interval between the Q and T complexes
RR	Respiration Rate
RSSI	Received Signal Strength Indication
SpO2	Saturation of haemoglobin with oxygen
SVT	Supraventricular tachycardia
TMS	Tele-Monitoring Station
VT	Ventricular Tachycardia

2 System Architecture

The system consists of the following components:

a) The on-body equipment, comprising the Nexisensor and the E-patch processing electronics. The Nexisensor is a disposable element, containing ECG electrodes, bioelectric impedance electrodes for respiration measurement, and a connector for an additional ECG electrode. It is a disposable item, designed to be worn for up to 24 hours. The E-patch takes measurements via the electrodes and also from an oxygen saturation sensor, and transmits them to the PDL. The E-patch is non-disposable, and is detachable from the Nexisensor.
b) The Portable Data Logger (PDL) which stores up to 24 hours worth of data received from the on-body equipment.
c) The Base Station Unit (BSU) which stores up to 14 days worth of data received from the PDL and performs ECG and respiration analysis to create summary reports.
d) The Tele-Monitoring Station (TMS) which is used to interrogate the BSU, and to interpret and display the data.

These components, and their interconnections, are illustrated in Figure 1.

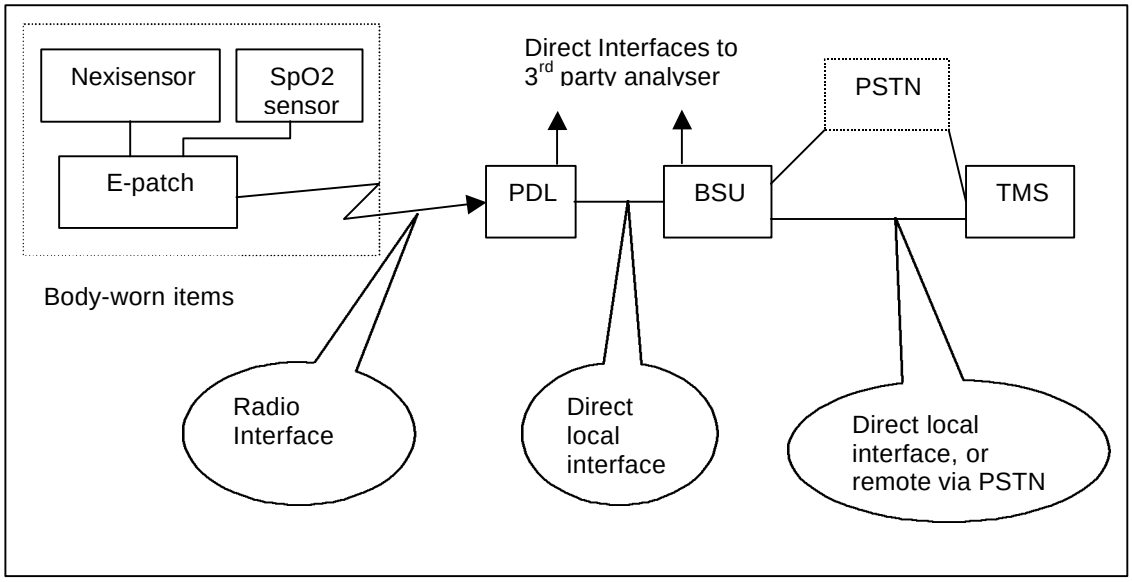


Figure 1

3 Functional Distribution

This section of the document describes how the functions are distributed between the elements of the system.

3.1. Nexisensor and Oxygen Saturation Sensor

a) The Nexisensor is responsible for:
   i. providing signals to the E-patch to permit ECG and respiratory measurements to be made
   ii. [removed]
   iii. providing power to the E-patch and to the oxygen saturation sensor

b) The oxygen saturation sensor is responsible for measuring blood oxygen saturation and passing the measurements to the E-patch.

These functional responsibilities are defined in more detail in the following subsections.

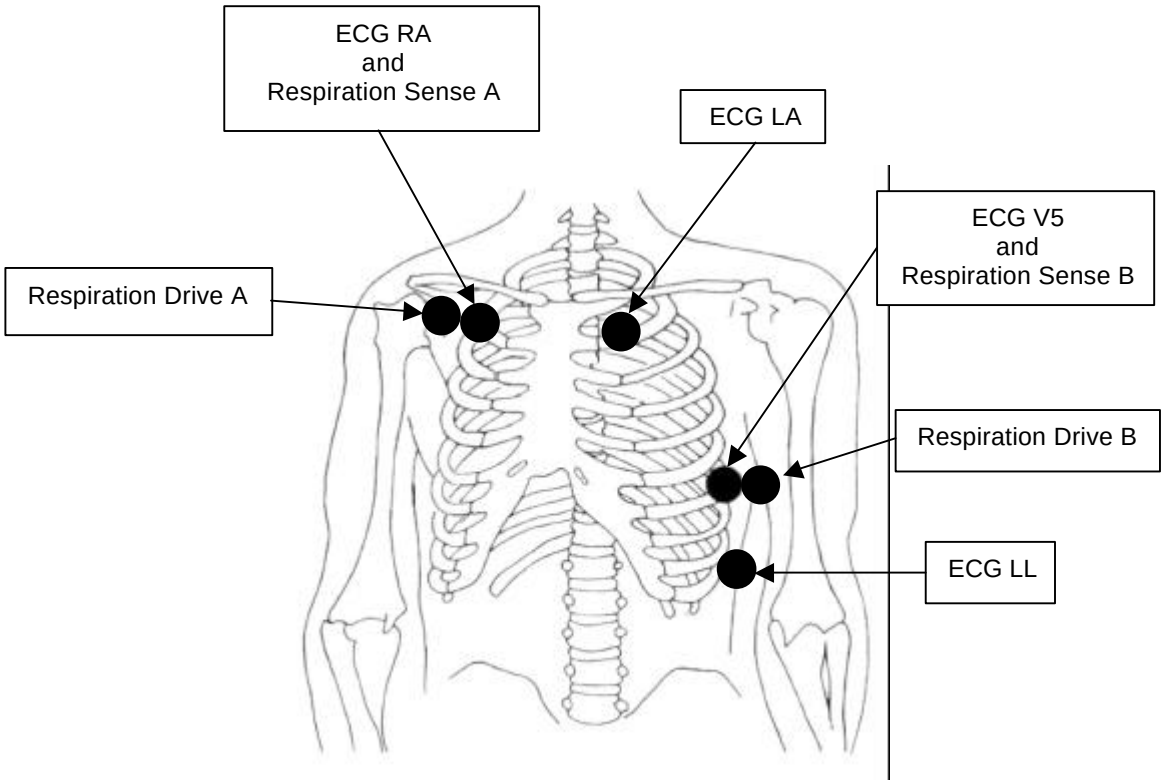
3.1.1. Physiological Measurements

a) The Nexisensor is a passive device, providing signals to permit:
   i. three leads (views of the heart) of continuous ECG, corresponding to a chest modified lead II, chest modified V5 and a flying lead.
   ii. a continuous measure of respiration rate and full respiration waveform, by impedance.

b) The oxygen saturation sensor is an active device, providing a measure of blood oxygen saturation, to enable an averaged result to be provided at least every 5 seconds.

The distribution of the electrodes is shown in Figure 2

Figure 2- Arrangement of Sensors



3.1.2. Transfer of Measurement

Signals shall be continuously available to the E-patch, once the latter is connected.

3.1.3. Provision of Power for E-patch

The Nexisensor shall contain a battery suitable for powering the E-patch and the oxygen saturation sensor for a minimum of 24 hours. The specification of the battery is part of the OBS PDS [2]

3.1.4. Non-functional requirements

a) It shall be possible for a normally-abled patient with average dexterity and visual acuity to be able to apply a Nexisensor (plus the E-patch), without the intervention of a healthcare professional.
b) The Nexisensor shall be a disposable element, detachable from an E-patch, for 24-hour use only.
c) Any adhesive elements shall be less aggressive than the existing Generation I Nexisensor adhesive, but must adhere for 24 hours.
d) The combined weight of the Nexisensor, the oxygen saturation sensor and the E-patch shall be less than 75g. The weight of the Nexisensor alone is specified in [2]
e) The Nexisensor shall meet IP52 (splash proof)
f) The sensor shall be provided in sufficient sizes to encompass body sizes up to an under the arm chest measurement of 55 inches. Signal quality shall be consistent over the various sizes. It is accepted that patients with very high BMI may suffer from degraded signal quality and any performance limitations in this area shall be identified and documented as part of the project.

3.2. E-patch

The E-patch is responsible for:
a) sampling the data provided by the Nexisensor and the oxygen saturation sensor

b) encoding the measurements into digital form
c) attaching an identifier of the source of the data
d) temporarily storing the encoded data
e) converting the data into a form suitable for transmission
f) transmitting the data and identifier
g) performing self-test on power-up, and transmitting the result
h) transmitting a predetermined bit sequence when configured to do so, to enable BER measurements to be made

These functional responsibilities are defined in more detail in the following subsections.

3.2.1. Sampling the Data

a) The E-patch samples each ECG lead 250 times per second. Each measurement is converted to a 10 bit digital value.

b) The impedance sensor is sampled 25 times per second. Each measurement is converted to an 8 bit digital value.

c) Oximetry measurements are taken from the external oximetry sensor once per second, each being stored as an 8 bit digital value.

3.2.2. Encoding of Measurements

a) The E-patch attempts to measure, encode and transmit data whenever it is connected to a Nexisensor and powered.

b) As well as the measurements specified in the previous section, the E-patch shall have the capability to encode two further eight bit values at a rate of 25 per second. These will be available for future expansion. One of them may be used to provide respiration data via a bend sensor.

c) Each E-patch shall have an identifier to assist traceability of the equipment and correct identification of patient data. This identifier shall be included in the data to be transmitted. The identifier shall consist of a number in the range 0 to 255, which will be transmitted in eight bits as part of each data packet sent. The main aim of this identifier is to distinguish between a number of local E-patches; it is not intended to define the E-patch uniquely over the whole population. The identifier is configured during manufacture of the E-patch.

d) The total amount of data to be encoded is therefore as shown in Table 1.

Table 1 - Data Rates

Data Type	No. of fields	Data field size	Measurement Rate	Data Rate	Data/24 hrs
ECG	3	10 bits	250/s	7500 b/s	648×10^6 bits
SpO2	1	8 bits	25/s	200 b/s	17.28×10^6 bits
Respiratory	1	8 bits	25/s	200 b/s	17.28×10^6 bits
Spare	2	8 bits	25/s	400 b/s	34.56×10^6 bits
Identification	1	8 bits	25/s	200 b/s	17.28×10^6 bits
Total				8500 b/s	734.4×10^6 bits

e) This data shall be sent in data packets at a rate of 25/s. Each packet therefore contains 340 bits of useful data. Note that, for simplicity of encoding, each packet contains a field for an oximetry reading, even though this value changes only once every five seconds.

3.2.3. Local storage of Encoded Data

The E-patch shall provide sufficient local storage to allow for conversion and transmission delays. The amount of memory needed is largely determined by the interleaving depth. The interleaving of ten packets specified in [4] results in the need to store up to 20 packets worth of data, 6800 bits. (This could be reduced

a little because the Identification and SpO2 information remains the same for many different transmitted packets.

3.2.4. Conversion of Data For Transmission

a) The encoding shall include appropriate Forward Error Control, interleaving and scrambling to ensure reliable transmission, and resilience against fading and interference. Forward Error Control allows errors in the received data to be detected, and in some cases, corrected. Interleaving separates adjacent measurements or adjacent bits, making it less likely that an error burst will affect consecutive measurements or bits when they are re-assembled. The ECG analyser is more resilient to errors or missing measurements if they are spaced apart, than if they occur close consecutively. Similarly, FEC mechanisms are more effective at correcting errors if they are spaced apart. Scrambling is used to eliminate long sequences of 1's or 0's from the final data stream, as such sequences can be problematic to decode.

b) Details of the conversion techniques used are given in [4]. Using the interleaving process specified means that there is a delay of up to 20 packets (800ms) between making a measurement and its being transmitted. The precise delay (which is needed for time-stamping purposes) can be calculated from the sequence number of the packet. See [4] for further details.

3.2.5. Transmission of Data

a) The E-patch sends the data in packets of approximately 500 bits, representing 40 ms worth of data. The data is transmitted using FSK modulation, and each packet has synchronisation information added to it, to enable the receiver to decode it correctly. Details are given in [4].

b) A patient wearing a working Nexisensor shall be able to move to up to, typically, 15 metres within a domestic environment from the rest of the system without any loss of data. The system shall provide an unobstructed free-space range of greater than 15 metres. This is considered in more detail in [4]

c) The transmitter shall meet the requirements of ETS 300-220-1 and FCC Regulations CFR47 Part 15

3.2.6. Transmission of Predetermined Bit Sequence

The E-patch may be configured to transmit packets containing a predetermined bit sequence instead of acquired data. The bit sequence has a pattern similar to that of a typical data packet, but shall contain an indication that it is not a normal packet. These packets may be used for Bit Error Rate measurements.

3.2.7. Self-test

a) It shall be possible to determine the correct operation of the E-patch before it is applied to a patient, in order to avoid unnecessary applications of the sensor due to hardware failure. To achieve this, when it is powered up, the E-patch sends packets indicating the results of self-tests. These packets have the same length as normal data packets and are sent as frequently. The E-patch continues to send the self-test packets for ten seconds. It then starts to send normal data packets.

b) This mechanism will allow the system to detect hardware failures before the E-patch is applied to a patient, provided that the E-patch is connected to the Nexisensor (and therefore powered) before the Nexisensor is applied to the patient. This will have to be a matter of operational discipline on the part of the patient. (Although the consequences of doing it in the wrong order are just that the patient will have needlessly put on the sensor, and that's their own fault.)

3.2.8. Non-functional requirements

a) The E-patch shall be re-useable in order to minimise the costs of the disposable elements of the system.
b) The combined weight of the Nexisensor, the E-patch and the oxygen saturation sensor shall be less than 75g. The weight of the E-patch alone is specified in [3]
c) The E-patch shall meet IP52 (splash proof).

3.3. Portable Data Logger

The Portable Data Logger is responsible for:

a) receiving the transmissions from the on-body sensor
b) recovering the data from the received signals
c) compression of the recovered data for internal storage
d) storing the data, together with time-stamp information in a local database
e) accepting inputs from user buttons and storing button events in the local database
f) transmitting the accumulated data via the PDL-Base Unit interface on demand
g) displaying sensor views on the dot-matrix display on demand
h) detection of alert statuses such as low battery and low database capacity
i) displaying status information on the dot-matrix display
j) displaying date and time of day on the dot-matrix display

These functional responsibilities are defined in more detail in the following subsections.

3.3.1. Data Capture and Transfer

3.3.1.1. Reception of Transmissions

a) The PDL receiver shall have sufficient sensitivity to receive signals from the E-patch at a distance of up to 15 metres within a domestic environment with a received BER of no greater than 10^{-3}.

b) The PDL has an option for diversity reception, and is capable of receiving signals from the E-patch via two separate antennas. The method of determining which signal to use is defined in [4].

c) Note that, because at present only one radio frequency is available, it is not possible to operate two Nexystems in close proximity, or there will be a danger of interference. If such interference does occur, the differing E-patch identities make it unlikely that the the wrong data will be logged.

d) While the PDL is expecting to receive information, it shall monitor the RSSI of the signals from the E-patch. If the RSSI from both antennas remains below a configurable value averaged over 4 seconds (the start RSSI warning value), the PDL shall generate an audible warning. This warning shall start at a low volume level and gradually increase over a period of several seconds. The audible warning shall then stop. Once an audible warning has been sounded, it will not be repeated until either:

   i. the averaged RSSI rises above the stop RSSI warning value and then once again falls below the start RSSI warning value, or

   ii. collection of data by the PDL is stopped, then restarted and the RSSI falls below the start RSSI warning value

e) So that the alarm doesn't go off every time the E-patch is disconnected from the sensor, it shall be possible manually to turn off the collection of data. Once data collection has been stopped, if the PDL receives self-test packets from the E-patch, it shall automatically resume the collection of data.

f) On receipt of self-test packets from the E-patch, the PDL shall log a "Start of Nexisession" event. Only one such event shall be logged for each burst of self-test packets.

3.3.1.2. Manual and Automatic Configuration of E-patch Identity

The PDL examines received packets to ensure that they contain the correct E-patch identifier. The recognised identifier is configurable manually or automatically. Automatic configuration is achieved as follows. If the recognised identifier is unconfigured, and the PDL receives self-test packets from an E-patch (indicating that the E-patch has just been turned on) then the PDL notes the identifier contained in the packets. If it receives three consecutive packets with the same identifier, it displays that identifier and asks for confirmation that this should be the recognised one. If the confirmation is made, then the identifier is set as the recognised E-patch identifier. Note that the manual or automatic configuration of E-patch identity is intended to be performed by a HCP. It is not anticipated that this would be a patient-invoked function.

3.3.1.3. Configuration of Patient Identification Information

The PDL shall be able to store a patient identification number. This number shall be configurable via the BSU, and shall be reported to the BSU when requested. The patient identifications number shall consist of four bytes.

3.3.1.4. Recovery of Data

This is described in [4]

3.3.1.5. Compression of Data

The recovered data is compressed to reduce the amount of internal storage required and to minimise data transfer times. The compression algorithm will be described in [8]. It is likely to be based on polynomial interpolation and Huffman encoding of the ECG values. Whichever algorithm is chosen must provide lossless compression.

3.3.1.6. Storage of Data

a) The PDL shall contain sufficient memory to be able to store 24 hours worth of logged and compressed data. In addition to physiological measurements, the PDL shall be capable of storing a schedule of auxiliary measurements to be taken by the patient. This schedule shall be received from the BSU. It shall be possible to determine the acquisition time of any data to a resolution of 10ms. (Note that a time can be specified to this resolution within 24 hours using three bytes.) Not every measurement needs to be individually timestamped, since the time of part of a sequence of regular measurements can be derived from the start of the sequence and the position within the sequence.

b) If more than a configurable amount of PDL memory has been filled, a warning shall be issued, instructing the patient to dock the PDL. If the PDL memory is completely filled, a further warning shall be issued, and the PDL shall stop logging data until it has been docked and stored data transferred to the BSU.

3.3.1.7. Transmission of Data to BSU

a) Data is transmitted to the BSU via a bi-directional interface. Details are given in [5]. The transmission rate is TBD. Approximate transmission times for various data transfer rates are given in Table 2. Values are given assuming no overhead, and assuming a 50% overhead for framing, etc. Neither value assumes any compression of the data.

Table 2 - PDL to BSU data transfer times

Transfer Rate	Transmission time for 24 hrs of data	
	No overhead	**50% overhead**
115200 bps	6375s = 1h 46m 15s	9562s = 2h 39m 22s
1.152 Mbps	638s = 10m 38s	957s = 15m 57s
4 Mbps	184s = 3m 4s	276s = 4m 36s

b) Each PDL shall have an identifier to assist traceability of the equipment and correct identification of patient data. This identifier consists of an 32-bit value, and shall be included in the data transmitted to the BSU, as well as the E-patch identifier, and the patient identification number.

c) On request from the BSU the PDL shall transfer acquired physiological data. The format of the information is specified in [5].

d) While the PDL remains docked with the BSU it shall be capable of transferring 'live' data to the BSU. When requested to send live data, the PDL shall temporarily suspend the transfer of previously acquired and stored data, or shall transfer it in parallel.

e) Data transfer from PDL to BSU shall be in the compressed form in which the data is stored within the PDL.

3.3.2. User Interface

3.3.2.1. Display of Date and Time of Day

During normal operation, when not displaying alerts, status messages, or patient data, the PDL shall provide a display of the current date and time. (Note: if date is to be displayed, it must be possible to configure this for UK or US format.)

3.3.2.2. Local Display of ECG and Respiratory Information

The system shall support the ability for a healthcare professional to view the raw data at any time the Nexi is applied to the patient and while the patient is within range of the PDL. The ability for patients to observe these views independently shall be configurable. It shall be possible to configure the PDL to display the data on a scale representing between one and three seconds, and to choose from any of the three ECG leads, or the respiratory information. When displaying ECG or respiratory information, the PDL shall simultaneously indicate heart rate, respiration rate, and SpO2 level.

3.3.2.3. Display of Patient Summary Information

The HCP shall be able to view a summary of the patient physiological data, including current HR, RR and SpO2 values.

3.3.2.4. Display of Status Information

a) Text labels and prompts on the PDL shall be configurable so that they may be displayed in various European languages. This shall include the capability of displaying accents and diaereses used in these languages.

b) While the PDL is receiving data from the E-patch, and is not docked in the BSU, it shall display a legend indicating that it is collecting data.

c) The HCP shall be able to view PDL status information, including: identity; percentage of free memory; date and time the PDL was last turned on; radio signal strength; and battery capacity.

3.3.2.5. Button Events

a) Two patient-activated event buttons shall be provided on the PDL for subjective data capture. The PDL shall log button events, timestamping them within one second of their occurrence. The time stamp shall have a resolution of 10ms. Note that these buttons will have other uses, depending on the mode of operation of the PDL.

b) [removed]

3.3.2.6. Detection of Alert Statuses

a) The PDL shall detect low battery charge condition, low memory availability, and internal self-test failure conditions, and shall provide appropriate alerts. These shall include both visual and audible indication.

b) The PDL shall be able to alert a patient to the need to take an auxiliary sensor reading. The alert shall be both audible and visual.

c) The charge status of the PDL batteries shall be indicated to the patient.

d) All PDL alerts shall be suppressed when the PDL is docked with the BSU, during which time only the BSU generates alerts.

3.3.2.7. Display of Auxiliary Sensor Measurement Schedule

The HCP shall be able to view the schedule of auxiliary sensor measurements held by the PDL, including: measurement number; total number of measurements; measurement type; window number; window start time; window end time.

3.3.2.8. E-patch Identifier Configuration

The HCP shall be able to view and configure the E-patch identifier recognised by the PDL. The HCP shall be able to clear the recognised identity, so that no identity is configured.

3.3.2.9. Engineering Display and Configuration

a) An engineer shall be able to view:
   i. the PDL identity;
   ii. the current BER;

iii. the current PER.

b) An engineer shall be able to view and configure:
 i. the RSSI level below which the PDL will alert the patient to low signal level;
 ii. the RSSI level above which the PDL will cease alerting the patient to low signal level.

Configuration of values will require that the PDL is docked, and be performed via the BSU interface.

c) An engineer or HCP shall be able to:
 i. clear the memory of the PDL
 ii. reset the PDL.

Configurations of values will require that the PDL is docked, and be performed via the BSU interface.

3.3.3. Power supply

The PDL shall be powered using rechargeable batteries with sufficient capacity to enable continuous operation of the PDL for 24 hours between charges. The batteries shall automatically be recharged when the PDL is docked with the BSU. The required recharge time is TBD

3.3.4. Non-functional requirements

a) It shall be possible for a normally-abled patient with average dexterity and visual acuity to be able to operate the PDL without the intervention of a healthcare professional.

b) The system shall be simple to install in the home so that, in most cases, patients can set it up unaided.

c) The LCD panel shall be easy to read (even for someone with limited vision) and easy to understand. It shall be based on a 128 x 64 pixel display.

d) The system elements shall meet IP52 (splash proof)

3.4. Base Station Unit

The BSU is responsible for:
a) receiving data from the PDL
b) decompressing the received data
c) storing the data
d) producing ECG and respiration analysis/summary reports
e) [removed]
f) taking point-in-time measurements from auxiliary sensors and maintaining a readings schedule
g) sending analyses, summaries or raw data via modem or to a locally connected TMS on request
h) sending live data to a TMS on request
i) accepting instructions from the touchscreen
j) displaying information locally via the LCD touchscreen

These functional responsibilities are defined in more detail in the following subsections.

3.4.1. Reception of PDL data

When the PDL is connected to the BSU, the BSU shall request the PDL to transfer stored physiological data. Once the transfer is complete, the BSU shall accept further data from the PDL while the PDL is docked. Data received from the PDL is tagged with both the E-patch identifier and that of the PDL. The BSU shall check the E-patch and PDL identifiers to ensure that the data originates from the intended source. If either of the identifiers is not the expected one, the BSU shall generate an alert, and shall not transfer the data.

3.4.2. Decompression of received data

The BSU decompresses the data when it has been received, and stores it in uncompressed form.

3.4.3. Storage of data

a) The BSU shall be capable of locally storing at the patient's location a minimum of 14 days worth of continuously acquired raw data. Each session is tagged with both the E-patch identifier and that of the PDL.

b) The BSU automatically deletes data older than a configurable length of time. It shall not be possible to configure the storage time such that there is insufficient BSU memory to store the required amount of data.

3.4.4. Physiological analysis/summary reports

a) The BSU shall prepare summary reports, which are subsequently transferred to the TMS. One report is prepared for each session.

b) A session is defined as the period during which data is gathered while the patient wears a single Nexisensor. A session may last up to 24 hours, but may be less than this, for example if it is only required to collect data while the patient is asleep.

c) A session start is defined by the reception of Self-Test messages at the PDL. On receipt of these, the PDL records a time-stamped 'Start of Session' flag. A session end is defined by either the start of a new session, or the expiry of the predefined session duration, whichever is the earlier.

d) In order to produce the reports, the BSU needs to perform signal analysis on the physiological data, and so contains an ECG analyser and a respiration analyser. As the TMS also contains similar analysers, they are described separately, in sections 3.6 and 3.7 respectively. There are some differences between the analysers implemented in the BSU and those in the TMS; these are highlighted in the descriptions. The analysers shall have the ability to monitor the data to detect certain event conditions e.g. heart rate, outside pre-set bands defined by the HCP.

e) Summary reports shall typically be transferred in 5 minutes or less.

Commentary:

The fixed summary part of a 24 hour summary report will contain 67 bytes of data (See [6] for further details)
The trace part will contain 362904 bytes.
A three second raw data disclosure will contain 3078 bytes.
A 30 second raw data disclosure will contain 30780 bytes.

A "typical" heart disease patient may display 100 events in 24 hours. Suppose 90 of these result in a three second disclosure, and the remaining ten result in a 30 second disclosure.

Therefore the amount of raw data included in the report is:

90 * 3078 + 10 * 30780 = 584820 bytes.

The total length of the report is therefore about 950 000 bytes.

Transferring this at 5000 bytes per second will take 190 seconds or 3 minutes 10 seconds.

(Note: respiratory patient figures are not calculated, since it is clear that either the number of events (500) or the amount of data displayed for each event (15 minutes) is too high to be practicable.)

Note that the above figures are indicative, and serve only to illustrate the feasibility of the transfer times.

f) The measurement of blood oxygen saturation shall use a technique suitable for an ambulatory patient. It is a known restriction that artefact removal is not supported.

g) The summary report for a session will provide the following information:
   i. Trace of Heart Rate over the session time (1 sample per second)
   ii. Trace of Respiration rate over the session time (1 sample per second)
   iii. Trace of SpO2 level over the session time (1 sample per 5 seconds)
   iv. Analysis statistics (total monitoring time, time analysed, ECG artefact time respiration artefact time, gap time)
   v. ECG Beat counts (Total beats, total normal beats, total aberrant beats, Premature Normals and total dropped beats)
   vi. ECG Rhythm counts (tachycardia, bradycardia, bigeminy, trigeminy (US & EU definitions), VT, SVT, couplets short runs & long runs)
   vii. Respiration rhythm counts (user-defined apnoea, hypopnoea and periodic event).
   viii. Heart rate variability (SDNN & SMRR) over the entire session.
   ix. Heart rate and respiration rate statistics over the entire session (minimum, mean and maximum)
   x. An events list with optionally a 3 second waveform disclosure of "raw data" centred on the following events:
      (a) Non-normal beats detected
   xi. Trace of QT interval and QT_c (1 point per second, where calculated)
   xii. Information to generate a NN histogram
   xiii. An events list with optionally a 30 second waveform disclosure of "raw data" views centred on the following events:
      (a) Start and end of an ECG rhythm (tachycardia, bradycardia, bigeminy, trigeminy, VT, SVT, short runs and long runs)
      (b) Change of average respiration rate by a pre-defined percentage
      (c) Change of average respiration amplitude by a pre-defined percentage
      (d) Reduction in SpO2 level average by a predefined percentage (with the default being set to a drop of 3% over 10 seconds)
      (e) A user defined Apnoea event
   xiv. An events list with optional "raw data" waveform disclosure of configurable duration centred on the following events:
      (a) Patient event button activation
   xv. An events list with optional 15 minutes respiration and SpO2 "raw data" waveform disclosure for the following events:
      (a) A user defined Hypopnoea event
      (b) A user defined periodic breathing event.

h) The resolution of the waveform data disclosures in summary reports shall be configurable via instruction from the TMS. This enables sufficient data to be included for satisfactory viewing without transmitting unnecessarily large amounts of data.

i) These user-defined events shall be specified independently using terms of percentage change in respiration rate and/or respiration depth and/or blood oxygen level over a configurable time. Defaults shall be chosen to minimise the chances of the system generating large volumes of events in the absence of any user input.

j) The report will also contain summaries for each hour of data analysed (in accordance with EC38/EC57). Each hourly summary consists of:

   i. Beat counts
   ii. Minimum, maximum and mean HR
   iii. Number of episodes of each ECG rhythm type experienced within that hour
   iv. Total number of seconds of ECG artefact encountered in that hour
   v. Breath counts
   vi. Minimum, maximum and mean RR
   vii. Number of episodes of each respiration rhythm type experienced within that hour
   viii. Total number of seconds of respiration artefact encountered in that hour.

k) The analyser will produce statistical data of N-N interval for all normal beats, suitable for inclusion in an N-N interval histogram.

l) Summary reports are transferred in compressed form. The compression used is TBD.

3.4.5. Transfer of Raw Data

a) On instruction from the TMS, the BSU shall transfer raw data, logged between times defined in the TMS request. It shall be possible for the TMS to specify which raw data is transferred, i.e any or all ECG leads, respiratory, or SpO2 raw data.

b) Raw data is transferred in compressed form. The compression used is TBD.

3.4.6. Transfer of Live Data

a) On instruction from the TMS, the BSU shall transfer "live data" as soon as it is acquired from the E-patch via the PDL. It is only possible to transfer live data if the PDL is docked with the BSU; if a live data request is received from the TMS at a time when the PDL is not docked, the BSU shall inform the TMS that the transfer is not possible. Transfer of live data shall continue until the connection between the BSU and TMS is lost, the TMS cancels the live data request, or the PDL is undocked from the BSU. The BSU shall indicate when live data is being transferred, to deter the patient from undocking the PDL.

b) Data that is transferred to the TMS during a live data session is also logged by the BSU, and may be subsequently included in a summary report or a response to a raw data request from the TMS.

c) The resolution of the live view data shall be configurable via instruction from the TMS. This enables sufficient data to be included for satisfactory viewing without transmitting unnecessarily large amounts of data.

d) Live data is transferred in compressed form. The compression used is TBD.

3.4.7. Auxiliary Measurements

a) The BSU shall contain ports for the connection of auxiliary sensors. The BSU shall be capable of detecting which sensor has been connected.

b) It shall be possible for the patient to initiate auxiliary sensor measurements at any time during system operation in the patient's house.

c) The system schedule of auxiliary sensor readings shall be transferable from the TMS or programmable via the BSU. The method of arbitrating between schedules entered locally or remotely is described in 3.5.4.

d) The BSU shall have the capability to transfer the schedule of auxiliary sensor readings to the PDL.

e) The BSU shall be able to alert a patient to the need to take an auxiliary sensor reading. The alert shall be both audible and visual.

f) It shall be possible to schedule auxiliary sensor readings in eight or more time windows. The start time and duration of the window shall be configurable. Within the time window, a patient is expected to make one or more auxiliary sensor measurements. The number and type of measurements per time window shall be configurable.

g) If the patient does not make a prescribed measurement within the time window in which it is scheduled, the alert is cancelled and the absence of a successful reading is indicated as a non-compliance event.

h) A user interface shall be provided to guide patients in making auxiliary sensor measurements. It shall be possible to re-prompt a user to make another measurement if the result of the previous measurement falls outside configurable limits.

i) Faulty or incorrect sensor connections shall be detected and highlighted to the user.

3.4.8. Communication via TMS

a) The BSU shall be able to be connected local to the TMS computer, or to a third party application, to allow direct transfer of data. The latter may require additional software to convert the data into a format suitable for the third party application. The production of such conversion software is outside the scope of the current document.

b) Each BSU shall have an identifier to assist traceability of the equipment and correct identification of patient data. This identifier consists of an four-byte number, configured during manufacture, and shall be attached to all data sent to the TMS. This is in addition to the E-patch and PDL identifiers already attached to the data.

c) The BSU software shall allow the scheduled transfer of selected historical data or real-time data on request by the TMS.

d) The BSU and TMS may be connected either locally or remotely, via the PSTN. For remote connection, the BSU shall support dial-in connection from the TMS. This ensures that patient telephone charges are not incurred when connected to the PSTN. Remote connection will require establishment via modems, but apart from this, communication is the same whether the connection is local or remote, and is described in [6].

e) Once a connection has been made, the BSU responds to requests from the TMS. Normally, the first request received by the BSU will be for a list of available summary reports. This list will contain the start and end times of each available report, and an indication if the report is very long. (The latter information is sent because a very long file may imply a large number of aberrant beats. This in turn may indicate that the sensor was not fitted properly, rendering the data useless.) The length which determines whether a file is considered very long is configurable from the TMS.

f) After sending the list of summary reports, the BSU may then receive requests for summary reports, raw data or live data from the TMS to which it responds accordingly. It may also receive new configuration data from the TMS, including auxiliary measurement schedule, summary report configuration, date and time, and recognised PDL and E-patch identities.

g) The BSU may also be interrogated for its current configuration.

3.4.9. Communication via LCD and touchscreen

a) Text labels and prompts shall be configurable, so that they may be displayed in various languages. These shall include American English, British English, French, German, Italian, Spanish and Swedish.

b) The system shall support the means to alert a patient to the need to take an auxiliary sensor reading.

c) The system shall have the ability to indicate to patients any system problems and to give instructions to aid them in the use of the system.

d) While the PDL is receiving data from the E-patch, and is docked in the BSU, the BSU shall display a legend indicating that data collection is in progress.

e) There are three perceived users of the LCD and touchscreen interface, and this interface shall have three corresponding modes of operation. The users are:
   i. Patient
   ii. HCP
   iii. Engineer

f) The default mode of operation shall offer Patient-related functions. From this mode, it shall be possible to enter either of the other modes, but entry to either HCP or Engineer modes shall be password protected. Passwords shall be configurable, and separate passwords may be defined for the two protected modes.

g) Functions available to the user in each of the three modes are described in the following subsections.

3.4.9.1. Functions available to the Patient

3.4.9.1.1. Auxiliary sensor measurements

The BSU shall be able to alert a patient to the need to take an auxiliary measurement. It shall guide the patient through the process of making the measurement, requesting the patient to re-take it if necessary. The time of the next due measurement shall be displayed as part of the normal patient view.

3.4.9.1.2. Cancel audible alerts

The BSU shall allow the patient to cancel any audible alerts that are being generated.

3.4.9.1.3. Start and stop session monitoring

a) The BSU shall indicate when the current monitoring session has ended, and instruct the patient to remove the Nexisensor.

b) The BSU shall indicate when a new session should be started, and instruct the patient to apply a new sensor. The BSU shall give instructions on how to apply the sensor. See section 5.1 for further details.

3.4.9.1.4. Data collection confirmation

The BSU shall display an icon indicating data collection is proceeding correctly when the PDL is docked.

3.4.9.2. Functions available to the HCP

3.4.9.2.1. Nexisession schedule

The HCP shall be able to define the planned start times and durations of the Nexi sessions. The default shall be for a session to start at the same time every day, and to last for 24 hours. Note that the actual start time of a session is when the patient applies the Nexisensor and the E-patch starts to transmit; the planned start time is the time at which the BSU instructs the patient to apply the sensor.

3.4.9.2.2. Auxiliary sensor measurement schedule

a) The HCP shall be able to define or modify the system schedule of auxiliary sensor measurements, including for each measurement:
   i. measurement type (i.e. sensor to be used)
   ii. window number

b) While setting up the measurement schedule, the HCP shall be able to display a screen identical to that shown when the patient is alerted to take a measurement. (This is so the HCP can demonstrate the screen while setting up the schedule.)

c) For each window number, the HCP shall be able to define:
   i. the window start time
   ii. the window end time

The HCP shall be able to view the total number of windows and measurements.

3.4.9.2.3. Status Information

The HCP shall be able to view the following status information:
a) identity of BSU and PDL
b) percentage of free memory in BSU and PDL (if PDL is docked)
c) date and time when PDL was last turned on (if PDL is docked)
d) PDL battery capacity (if PDL is docked)

3.4.9.2.4. Configuration

The HCP shall be able to configure the following parameters and to view them except where otherwise stated:
a) HCP password (not viewable)
b) whether PDL will display raw data to the patient
c) E-patch recognised by the PDL (including the possibility of clearing the E-patch identifier entirely)
d) PDL recognised by the BSU
e) Patient identification number stored in the PDL

The HCP shall also be able to clear the memory of the PDL and to reset the PDL.

3.4.9.3. Functions available to the Engineer

a) The engineer shall be able to view:
   i. the BSU identity
   ii. memory statistics for both BSU and PDL
   iii. error statistics

b) The engineer shall be able to configure the following parameters and to view them except where otherwise stated:
   i. engineering mode password (not viewable)
   ii. E-patch recognised by the PDL (including the possibility of clearing the E-patch identifier entirely)
   iii. PDL recognised by the BSU
   iv. Patient identification number stored in the PDL
   v. E-patch recognised by the BSU (this should be the same as that recognised by the PDL)
   vi. the RSSI level below which the PDL will alert the patient to low signal level
   vii. the RSSI level above which the PDL will cease alerting the patient to low signal level
   viii. language of text labels and prompts

c) The engineer shall be able to:
   i. clear the memory of the PDL
   ii. reset the PDL

d) The engineer shall be able to use a hard-coded password to reset both HCP and engineering passwords.

3.4.10. Non-functional requirements

a) The BSU shall be small & light enough to be carried to a patient's home and shall take up as small an area in the patient's home as possible. It shall be silent in operation, except when generating audible alerts.

b) The system shall be simple to install in the home so that, in most cases, patients can set it up unaided.

c) The LCD panel shall be easy to read (even for someone with limited vision) and easy to understand. It shall be based on a 320 x 240 pixel display.

d) The BSU shall meet IP31

3.5. Tele-Monitoring Station

a) The Tele-Monitoring Station collects, stores, and presents information from BSUs. Typically, a TMS will handle data from many remote BSUs, communicating with them via the PSTN using modems. The TMS can only communicate with one BSU at a time. The maximum number of BSUs the TMS can handle is defined in [9]

b) The TMS is responsible for:

   i. Dialling in to each BSU (when remotely connected) on demand or according to a pre-established schedule and establishing a dialogue.
   ii. Transferring summary reports from the BSU
   iii. Transferring raw data from the BSU
   iv. Displaying summary reports and raw data
   v. Configuration of BSU
   vi. Maintenance of patient database

c) These functional responsibilities are defined in more detail in the following subsections. Note that the analysis of data is performed by the data analysers, which are treated as separate sub-systems, though physically located within the TMS and BSU.

3.5.1. Dialling BSU

a) The TMS shall be able to dial a BSU at configurable times for the transfer of acquired data and configuration of the BSU. In order to achieve this, the TMS maintains the transfer schedule and telephone number for each BSU as part of the patient database.

b) The TMS shall be able to dial a BSU on user request for the transfer of acquired data and configuration of the BSU

c) The TMS shall also be able, on user request, to establish communication with a BSU locally connected directly to a TMS serial port.

3.5.2. Transferring data from BSU

3.5.2.1. Summary Reports

a) On connection to the BSU (whether a scheduled connection or as a result of a user request), the TMS obtains a list of all summary reports available from the BSU. This list shall contain the length of each report. If the connection is scheduled, the TMS will request the transfer all summary reports generated by the BSU since the previous connection, except for ones longer than a configurable value. If the connection has been established as a result of a user request, the list of available reports is presented to the user, who is able to request the transfers of specific reports. The summary reports are tagged with the E-patch, PDL, and BSU identifiers.

b) If at the time of connection, the BSU has data for a partly completed session, it shall indicate to the TMS that this is the case. It shall be possible for the TMS to request a summary report for the partial session, though such report will obviously be incomplete.

3.5.2.2. Raw Data

a) The TMS can send requests to the BSU for the transfer of raw data to the TMS. The request shall specify the starting and finishing times for the data.

b) A likely method of requesting data is as follows.

i. The TMS receives summary reports from the BSU.
ii. These are examined at some later time by a HCP.
iii. The HCP finds part of the period covered by a report to warrant further analysis.
iv. The HCP requests the raw data for the period of interest from the TMS
v. The TMS contacts the BSU immediately and requests the raw data.
vi. The BSU provides the raw data for the requested period and the summary report.

3.5.2.3. Live Data

The TMS can send a request to the BSU for the transfer of live data to the TMS. The TMS will then start to receive live data, or an indication from the BSU that live data is currently not available.

3.5.3. Display of data

a) The TMS shall be able to present the acquired raw Nexisensor data to the user via a password-protected interface.

b) The TMS shall be able to present the results of signal analysis (performed either by the analyser in the TMS or the one in the BSU) to the user.

c) When connected to a BSU, the TMS shall be able to display live data, (real-time Nexisensor data: ECG, Respiration & SpO2) provided that the PDL is docked in the BSU.

d) ECG printouts shall be on a 25mm/sec or 50mm/sec scale when printed out on A4 or letter paper. The printout must display clearly what scale is in force.

e) Raw data waveforms (ECG, Respiration and SpO2) shall be displayed in the following scales

i. 50 mm/sec
ii. 25 mm/sec
iii. 5 mm/sec

and in a time window of 1, 2, 3, 5 or 15 minutes

f) All parameter traces shall be aligned relative to the same time window.

g) Display of raw data shall include any annotations produced by the ECG and respiration signal analysers. See section below for full details of analyser outputs.

h) Data defined as artefact must be underlined in black.

i) It shall be possible to scroll automatically through the raw data on screen at up to 12 times real time.

j) Playback ("live" or off-line) of raw data shall allow smooth scrolling and "page wipe" display options.

k) The TMS shall present a summary listing of patients and details of active and immediate future monitoring and transfer schedules.

l) The TMS shall be able to set up and transfer a schedule of auxiliary sensor readings to the BSU.

m) The TMS shall provide a trend view of patient auxiliary sensor measurements over the following timescales: 1 hour, 1 day, 1 week, 1 month, 3 months, 6 months. Measurements that fall outside a defined range of values shall be displayed distinctively (possibly by a change in colour) to indicate exceptional values.

n) It shall be possible to configure the high and low values of patient auxiliary sensor measurements that determine whether measurements are indicated as exceptional.

o) The TMS shall indicate to the user if there are summary reports that have not been transferred because they were deemed to be very long. The TMS shall provide the option for the user to request such reports to be transferred anyway.

p) The length above when a data session is deemed to be very long, and so not automatically transferred during scheduled connection is configurable by the user on a per patient basis.

3.5.4. Configuration of BSU

a) The system schedule of auxiliary sensor readings shall be programmable from a TMS. Because the schedule can be programmed either from the TMS or directly at the BSU, there needs to be a way of managing between them. When a TMS is connected to a BSU, it obtains the BSU's current schedule, and compares it with its own copy. If the TMS copy is flagged for update, then that copy is transferred to the BSU. If the TMS copy is not flagged for update, then both are stored in the TMS database. The TMS user is notified that the schedules are out of alignment, and can choose whether to use the BSU copy or the TMS copy. If the user chooses to use the BSU copy, this overwrites the TMS version in the TMS database. If the user chooses to use the TMS copy, that copy is marked for update, and so will be transferred next time the BSU is connected. If the user changes the schedule at the TMS, the changes are reflected in the TMS copy of the schedule, which is marked for update.

b) The summary report contents shall be configurable from a TMS. Configurable parameters shall include:
i. Whether raw data samples are included with reported events
ii. The duration of samples associated with event button pushes.
iii. Heart rate defining the onset of tachycardia
iv. Heart rate defining the onset of SVT
v. Heart rate defining the onset of VT
vi. Heart rate defining the onset of bradycardia
vii. Whether US or EU definition of trigeminy is used
viii. Length of absence of beats defining a reportable pause

ix. Threshold and baseline establishment time for reporting respiration rate change
x. Threshold and baseline establishment time for reporting respiration amplitude change
xi. Threshold and baseline establishment time for reporting SpO2 change.

c) Note that the first of the above is likely to be changed on a per patient, or even per report basis, while the remainder are likely to remain the same for all patients and reports, and be changed only occasionally.

d) The number of aberrant beats in a session, and the rate of aberrant beats above which the BSU indicates that the session has a large number of beats, is configurable from a TMS.

3.5.5. Maintenance of Patient Database

a) The patient database shall contain:
i. a record of the unique identifiers of the system elements (BSU, PDL, and E-patch) being used by a each patient
ii. the schedule of point-in-time auxiliary sensor measurements for each patient
iii. the schedule of transfers of summary reports from each patient's BSU
iv. records of patient information
v. records of acquired patient data
vi. the telephone number to dial to access the BSU
vii. the configuration of each patient's BSU

b) It shall be possible to delete the entire record of data for a patient, but safeguards shall prevent inadvertent or unauthorised deletion of records.

3.5.6. Non-functional requirements

a) It shall be possible to operate the TMS software on a HCP's existing PC (which meets a minimum specification requirement), without the need for it to be pre-loaded on a dedicated PC. The recommended minimum specification for the PC is defined in [9].

b) The TMS user interface shall be easy to learn and use.

3.6. ECG Analyser Performance

a) The ECG acquisition is intended to provide 22 hours of analysable data per 24 hours on 95% of patient population.

b) The ECG analyser will detect aberrant beats with at least 93% sensitivity and at least 93% positive predictivity (calculated as gross statistics) on all MIT and AHA database records. (Note that for the purpose of this definition, aberrant beats refers to beats in the MIT and AHA databases labelled as ventricular ectopic beats.)

c) The analyser will detect QRS complexes with 99.7% sensitivity and positive predictivity (calculated as gross statistics) on all MIT and AHA database records.

d) Any deficiencies in performance shall be documented (for example known poor performance on patients with atrial fibrillation would be documented).

e) The analyser will utilise the data corresponding to chest modified lead II and chest modified V5 when processing data.

f) Where data from the optional flying lead is available, use of this signal to improve artefact detection and beat classification may be made, but this implementation decision will be made during software development and will not affect the presentation of results to the user.

g) All analyser performance will be reported according to ANSI/AAMI EC57.

h) The analyser will include an artefact detector intended to exclude the following:

i. Excessive noise
ii. Distortion
iii. Signal saturation
iv. Muscle movement and myopotential
v. Data dropout

i) In addition, the analyser performance will not be adversely affected by baseline wander.

j) Periods of data excluded due to artefact shall be reported to the user.

k) The analyser will report the total duration of data supplied, the total duration of analysable data and the total duration of artefact (both due to noise and data gaps).

l) The analyser will automatically categorise beats into the following categories:
i. Normal sinus
ii. Aberrant
iii. Premature normal
iv. Unclassifiable

m) In the TMS analyser, each analysed beat will be assigned a template according to its similarity with other beats in the analysed session. User interaction will allow the re-classification of a particular template as any of the above automatically assigned type, plus any of the following additional types:
i. Normal type 1
ii. Normal type 2
iii. Aberrant type 1
iv. Artefact

n) These templates are not available in the BSU analyser.

o) The analyser will detect the following rhythms:

i. Tachycardia, defined as heart rate exceeding a threshold over 4 beats, with a default user customisable rate of 130 bpm
ii. Supraventricular tachycardia (SVT), defined as paroxysmal tachycardia, with a default user customisable rate of 130 bpm
iii. Ventricular tachycardia (VT), defined as paroxysmal VT based on aberrant beats, with a default user customisable rate of 130bpm
iv. Bradycardia, defined as HR falling below a user customisable threshold, with the default set to 60 bpm
v. Bigeminy, defined according to the MIT database standard (See EC38).
vi. Trigeminy, defined according to the MIT database standard (See EC38). Both US and European definitions shall be supported, with the user able to switch the current definition in force.
vii. Couplets, short and long runs of aberrant beats, defined according to the MIT database standard.
viii. Pauses, defined as a user defined absence of beats (excluding periods of artefact, or gaps).
ix. Irregularly irregular rhythm with constant morphology corresponding to Atrial fibrillation (to be further defined in a clinical sense.)

p) For all the above rhythms, start time, end time and duration shall be reported.

q) The analyser will calculate the QT interval and corrected QT interval using Bazzett's formula (QT_c) wherever such calculation is possible, and report it at a frequency of up to 1 Hz on one lead only of ECG data.

r) The analyser will calculate the heart rate variability (HRV) of the analysed session as the standard deviation of normal to normal intervals (SDNN), plus the statistical median of blocks of 5 mins of R-R intervals (SMRR).

3.7. Respiration analyser performance

a) The respiration acquisition is intended to provide data at least 80% of which acquired during sleep or prescribed rest shall be analysable.

b) The analyser will report the total duration of data supplied, the total duration of analysable data and the total duration of artefact (both due to noise and data gaps).

c) The analyser will include an artefact detector intended to exclude the following:
   i. Excessive noise
   ii. Signal saturation
   iii. Movement
   iv. Data dropout

d) In addition, the analyser performance will not be adversely affected by baseline wander.

e) Periods of data excluded due to artefact shall be reported to the user.

f) Any deficiencies in performance shall be documented.

g) The analyser will detect breaths in the signal, including the peaks of inspiration and expiration.

h) The analyser shall report the total number of breaths detected during the analysed period.

i) The analyser will detect and report the following respiratory events:
   - Increase or decrease in average respiration rate by a defined threshold (default 50%). Both the threshold value, and the time required to establish a baseline value should be user-configurable.
   - Impedance events, identified by the measurement of three parameters on the impedance trace;
     A The average value of stable non-artifactual breathing that establishes a baseline over a pre-defined period (default 2mins)
     B An increase/decrease by a set percentage (default 50%) in amplitude from the baseline set in A above
     C The change persists for a specified amount of time (default 10 secs)
   - SpO2 events identified by the measurement of parameters on the SpO2 trace;
     A A baseline established as an average over a set time period (default not specified)
     B A drop in value from this baseline of a set percentage value (default 3%)
     C Duration of drop for specified amount of time (default 10 secs)
   - When a respiration amplitude event occurs within a configurable time before an SpO2 event (both as defined above), these events will be reported as a single event with an appropriate name.
   - Periodic breathing over a specified period (default 10 mins).
   - All events listed above shall report the minimum and maximum HR values across the duration of the event, where such data is available.

j) The analyser will preferably report the following additional respiratory rhythms, according to established definitions: periodic breathing (reporting cycle length and frequency), apnoea (reporting the length of episodes) and hyponoea (reporting the length of episodes).

3.8. Auxiliary Point-in-time Sensors

a) The auxiliary point-in-time sensors are connected via the BSU. See section 3.4.7 for details of the BSU functionality associated with the sensors.

b) The auxiliary point-in-time sensors are responsible for:
   i. measurement of systolic and diastolic blood pressure, via a standard blood pressure unit with an arm cuff
   ii. measurement of PEF, FEV1 and FVC, via a standard hand-held spirometer
   iii. measurement of weight, via standard weigh scales
   iv. passing these measurements to the BSU

c) Consideration should be made in the equipment design to allow patients to be able to take auxiliary sensor measurements without the intervention of a healthcare professional.

4 Interface Specification

4.1. Nexisensor - E-patch

Any connectors which the patients have to use shall be very robust, easy to connect and it shall be obvious to the patient that they have made the connection properly

4.2. E-patch - PDL

The E-patch - PDL interface is a unidirectional FM radio interface. Layers 1 to 3 of the air interface protocol are defined in [4].

4.3. PDL - BSU

The PDL and BSU communicate using a serial interface. This is specified in [5].

4.4. BSU - TMS

The BSU and TMS communicate using a stream-based protocol, based on TCP/IP sockets. This permits either local connection of the subsystems, or remote connection via modems and the PSTN. The interface is specified in [6].

4.5. Auxiliary point-in-time sensors - BSU

a) Any connectors which the patients have to use shall be very robust, easy to connect and it shall be obvious to the patient that they have made the connection properly

b) The presence of auxiliary, point-in-time sensors shall be optional.

5 Usage Scenarios

This section contains some scenarios illustrating various ways in which the Nexystem might be used.

5.1. Patient instructed how to use Nexystem by experienced HCP

In this scenario, the patient is instructed in the use of the Nexystem by an experienced HCP, who also starts the first session. The patient is then left to change the sensor and start new sessions on their own.

1. The doctor interviews the patient and says the latter will be monitored in their own home. Explains briefly the process.
2. The doctor tells the HCP to monitor the patient for 3 days, and to collect blood pressure measurements and spirometer measurements twice a day.
3. The HCP arranges with the patient which 3 days will be suitable, and confirms that the patient has a suitable telephone connection at home.
4. The HCP sets up the TMS by entering patient details, but not the dates of the measurements.
5. The HCP turns on the PDL, and checks that it is clear of data and E-patch identity. (If it is not, it may mean that it still contains data from another patient, or just that someone has forgotten to clear it after its previous use. The procedure to be followed if the PDL is not clear is out of the scope of this scenario. Before proceding the HCP needs to have a clear PDL available.)
6. The HCP docks the PDL in the BSU.
7. The HCP selects the initialisation option on the BSU. This causes the PDL identity to be stored in the BSU, and requests the patient identity to be requested. *(It would be better if the patient identity had only to be entered once, and transferred between TMS, BSU, and PDL. However, I'm not sure this is possible.)*
8. The HCP enters the time of day at which the patient should be alerted to the need to change their Nexisensor, and the number of days for which the monitoring is to take place. By default, the BSU will assume that monitoring should begin immediately, and that a session should last for up to 24 hours. The HCP may, however, change the session start time and length.

9. The HCP connects the E-patch to a power supply. This causes the E-patch to start transmitting. The PDL notes the identity contained in the first packets to be transmitted. Because the PDL has no programmed E-patch ID, it sends a 'new E-patch identity' message to the BSU.
10. The BSU displays the identity and asks the HCP to confirm that it is the correct one.
11. The HCP checks the displayed ID with the marking on the E-patch, and confirms that they are the same. (If they are not the same it means either that: a) the E-patch is incorrectly marked, b) the E-patch or PDL is faulty, c) there has been interference in the radio signal, or d) there is another transmitting E-patch in the vicinity. The procedures to be adopted in these circumstances are out of the scope of this scenario.)
12. The HCP visits the patient at home, taking a BSU, a PDL, an E-patch, and a supply of Nexisensors of various sizes. Also a mobile phone.
13. The HCP connects the BSU to the telephone socket, and reassures the patient that the phone will still be usable, by making a call from the mobile phone, and getting the patient to make a call to the mobile phone. (This also confirms that the telephone connection is correct.)
14. Note that the HCP is experienced in the use of the Nexystem, and so does not need to be guided through the setting up process.
15. The HCP shows the patient how to operate the blood pressure monitor and/or the spirometer.
16. The HCP sets up the schedule of auxiliary measurements via the BSU interface, agreeing with the patient convenient times for these to be made. While doing so, the patient is shown the prompts that will appear when the readings are due.
17. The HCP turns on the PDL and docks it with the BSU.
18. The HCP shows the patient how to apply the Nexisensor. Since this involves the patient undressing, it is likely that it will take place away from the BSU. The HCP may take the PDL with them, in order to facilitate checking the ECG waveform when the sensor is attached, or leave the PDL docked in the BSU.
19. The HCP determines which size of Nexisensor is the correct one by holding the Nexisensor templates against the patient.
20. The HCP connects the E-patch to the sensor, and may check the PDL display to ensure that the E-patch and sensor are working correctly
21. The HCP applies the Nexisensor to the patient.
22. The HCP may refer to the ECG display on the PDL to check that the everything is working.
23. The patient tests the coverage by walking around their house or flat, while the HCP monitors the ECG waveform on the PDL to ensure that reception is satisfactory. Note that the patient should not be encouraged to go outdoors for this test, not even into the garden. The idea needs to be instilled that the PDL must accompany the patient on any journeys outdoors.
24. [removed]
25. The HCP tells the patient to take the PDL with them when they go out, and puts reminder notices on the exit doors.
26. The HCP re-runs through the procedures for taking the auxiliary measurements and tells the patient how to change the Nexisensor.
27. Unless the HCP re-configures the BSU at this point, the default Nexi session duration is taken to be 24 hours.
28. The HCP puts the BSU into patient display mode, and tells the patient to keep the PDL docked in the BSU when not away from the home. While in patient display mode, the BSU displays the time of the next auxiliary measurement, except when displaying other messages. The PDL displays ☺ when it is receiving signals from the E-patch and is not docked. The BSU displays the symbol when the PDL is docked and is receiving signals. The patient is told to check these symbols after applying a new Nexisensor, and to ring the HCP if they are not visible.
29. The HCP leaves.
30. The HCP rings the patient and explains that the readings are going to be examined, and that the PDL should therefore be docked, and the phone will be unavailable for a while.
31. The HCP monitors live data via the TMS to confirm that everything is working.
32. When the time comes to make an auxiliary measurement, the BSU displays a reminder message to the patient.
33. When a new Nexi session is due to start, the BSU displays a message telling the patient that it is time to change the Nexisensor, and to dock the PDL. Note that the BSU is configured with the time to indicate to the patient the need to change the Nexisensor. It will take a while for the patient to remove the old sensor and apply the new one. The next session will start when the new E-patch is connected.

The precise time that this occurs is not possible to control, and the BSU does not need to attempt to control it.

34. The patient acknowledges the message by touching a 'button' on the touchscreen of the BSU. This causes the BSU to put the PDL into a mode in which it will not generate an alert if it loses radio contact with the E-Patch. Note that if the patient fails to dock the PDL before changing the Nexisensor, the system will still start a new Nexi session.
35. The BSU gives the patient the instructions to:
    - remove Nexisensor
    - remove E-patch from Nexisensor
    - discard Nexisensor
    - wash (optional)
    - prepare skin
    - connect E-patch to new Nexisensor
    - apply new Nexi-sensor
    - check the ☺ on the PDL
36. [removed]
37. Once the E-patch is connected to the Nexisensor it starts to transmit. The first few seconds of transmission are test messages. The PDL recognises these as the start of a new session. It therefore records a marker for the new session. When the data is subsequently transferred to the BSU, the BSU notes the start of a new session, and cuts the first ten minutes of data, since this is likely to be garbage sent while the patient is applying the Nexisensor. Because the PDL is in patient display mode, and has the ID already programmed, it starts recording the next session immediately.
38. The patient uses the touch screen on the BSU to confirm that the sensor has been changed.
39. The BSU should ask the patient to dock the PDL if this has not already been done, and check for the ☺.

5.2. Patient fitted with Nexisensor and PDL at hospital and sent home without BSU

In this scenario, the patient visits the hospital and is fitted there with a sensor, E-patch and PDL and sent home. This would be done if the patient did not have a telephone, or was considered incapable of attaching the Nexisensor or operating the BSU. Note that in this scenario, it is not possible for auxiliary measurements to be made.

1. The doctor discusses the case with the HCP and they decide that the patient should be fitted with a sensor at the hospital.
2. The HCP makes an appointment with the patient to visit the hospital.
3. The HCP configures a PDL with the patient reference number and E-patch number, and makes sure the PDL is fully charged.
4. The patient arrives at the hospital. After the necessary skin preparation, the patient is fitted with the Nexisensor and E-patch.
5. The patient is given the PDL, which is preferably attached to their belt or similar. They are told to keep the PDL with them at all times, leaving it by the side of the bed at night. They are also instructed to post the PDL the following day back to the hospital. They are given a suitable mailer for this purpose.
6. The following morning, the patient removes the E-patch, and Nexisensor. They put everything into the mailer, including the PDL, and posts the package to the hospital.
7. On receipt of the package, the HCP discards the Nexisensor, and returns the E-patch to the store. Note that the HCP may have received several PDLs, and will not necessarily know from a visual inspection from whom they have been received. However, each PDL contains the patient reference number, and so can be identified by this.
8. The HCP docks the PDL into a modified BSU. This reads the patient identity, the PDL and E-patch identities, and the logged data and stores this information. Note that the BSU does not analyse the stored data. *(Why not?)*
9. Since the time needed to recover the data from the PDL is unlikely to be long enough to allow the PDL batteries to be re-charged, the HCP removes the PDL from the BSU and places it in a separate charging unit.
10. The HCP docks other PDLs into the BSU to recover the information. The BSU therefore holds information relating to several patients. Depending on numbers and operational procedures, it may be

necessary for the HCP to have access to several chargers, or a charger capable of charging several PDLs simultaneously.

11. The TMS initiates a communication session with the BSU.
12. The BSU reports the sessions it has stored and which have not been transferred to the TMS. It indicates that these sessions comprise raw data only, and have not been analysed.
13. The TMS requests the sessions to be transferred.

6 Regulatory Requirements.

6.1. General

a) The oxygen saturation sensor shall be an OEM supplied unit, with a proven medical history, modified to connect to the on-body electronics

b) All patient-contacting materials shall have a proven medical history.

6.2. Medical Standards

a) The Generation 3 shall meet the regulatory standards specified in Table 3. References to EN60601 shall also be taken to include the equivalent American standard UL2601-1

b) In addition, the project shall be conducted in a manner compliant with Nexan's quality system and the requirements of the EC Medical Devices Directive 93/42/EEC.

Table 3 - Applicable Regulatory Standards

Element/ Regulatory Aspect	System	Sensor	E-Patch	PDL	BSU	TMS
Safety	EN1441 EN60601-1-4	EN60601-1 EN60601-1-1	EN60601-1 EN60601-1-1	EN60601-1 EN60601-1-1	EN60601-1 EN60601-1-1	EN60601-1 EN60601-1-1 EN60601-1-4
Performance		EC38 EC12	EC38 EC12	EC38	EC38	EC38 EC57
Radio Approval			RTTE Directive *EN300-220-1[1]* FCC CFR47 Pt 15	RTTE Directive *EN300-220-1[1]* FCC CFR47 Pt 15	RTTE Directive *EN300-220-1 [2]* FCC CFR47 Pt 15	
Telecoms Approval					RTTE Directive *CFR21[1]* FCC 68	
EMC			EN300-683 FCC CFR47 Pt 15 EN60601-1-2	EN300-683 FCC CFR47 Pt 15 EN60601-1-2	EN55022-B EN55024 EN300-683 [2] FCC CFR47 Pt 15 EN60601-1-2	
Biocompatibilty		ISO10993				
Environmental			EC38	EC38	EC38	
Marking and Information		EN980 EN60780 EN1041	EN980 EN60780 EN1041	EN980 EN60780 EN1041	EN980 EN60780 EN1041	EN980 EN60780 EN1041

[1] To be used as part of the self declaration of compliance to the RTTE directive
[2] Only if diverse receiver fitted

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