Patient monitoring system - problem statement

1. PURPOSE

A patient monitoring system is required for the intensive care unit of a hospital. The main functions of the system are to display information on the patients' vital signs, and to generate alarms when unsafe conditions occur. In addition the system provides a number of auxiliary functions, such as setting up monitoring parameters and alarm limits, patient admission and discharge, alarm histories, event recording. The users of the system are nurses and doctors.

2. PHYSICAL STRUCTURE

2.1 BEDS
The system must be able to support a variable number of beds, up to a maximum of 16.

2.2 MONITOR
Each bed has a separate monitor that collects patient data, sends information to the display, and responds to user commands and queries.

2.3 DISPLAY
Patient vital signs are displayed on a screen situated next to each bed.

2.4 STAFF INTERFACE
Users operate the monitor via an input device, situated next to each screen.

2.5 INPUT SIGNALS
Cables from the patient are connected to the monitor. See the section on vital signs for the kind and number of signals that must be supported.

2.6 PRINT
Each monitor is equipped with a strip-chart printing device on which waveforms and other patient information can be printed.

2.7 CENTRAL STATION
A central station must be situated in the unit reception area. The functions available at this station must be limited to viewing patient information and receiving alarms. No monitor set up nor patient admission or discharge can be carried out from the central station. The central station has a display, a keyboard, a mouse and a printing device.

3. BEDSIDE MONITOR FUNCTIONS

3.1 VITAL SIGNS MONITORING

The monitor must read, check, display and store the patient's vital signs at regular intervals.

3.1.1 WAVEFORM DISPLAY
Some vital signs require a continuous waveform to be displayed on the screen.

3.1.2 VALUE DISPLAY
The current reading of each vital sign must be displayed on the screen at all times. If a cable is not connected, the displayed reading will not be physiologically valid - this is normally an indication that the cable is not connected, or that the sensing device is malfunctioning.

3.1.3 VITAL SIGNS SAMPLING RATE

A time interval between successive readings applies to each vital sign. The user must be able to change this value. A default time interval applies to each vital sign and is reverted to when the patient is discharged. A minimum and maximum value for the time interval applies to each vital sign. The different vital signs are described below.

3.1.4 ECG AND HEART RATE (HRT)

The ECG signal is carried by cables connected to electrodes attached to the patient's skin. Three different electrodes, with associated cables, can be attached to the patient. The three electrodes and cables are coded RA (Right Arm), LA(Left Arm) and C (Chest).

The user can select which of the three electrical signal s should appear as a waveform on the monitor screen. Only one of the three signals can appear on the screen as a waveform at any one time.

In addition, the system must display the current heart rate and the safe range in effect for heart rate. The current heart rate can be determined from the ECG signal.

The safe range can be set by the user. A default value of 50-150 applies if no values are entered for the patient.

The time interval for taking successive readings can be varied in one second steps, between a minimum of 2 seconds and a maximum of 30 seconds. A default of 5 seconds applies.

3.1.5 TEMPERATURE (TMP)

Temperature monitoring provides numerical information only—no waveform. The patient body temperature is measured via a probe and the signal carried to the monitor via a cable.

The current temperature must be displayed on the monitor screen. It must be possible to select either Celsius or Fahrenheit as the unit of measure. In addition, the current safe range for the temperature must be displayed, and can be set by the user. A default value of 30-42 (C) applies.

The time interval for taking successive readings can be varied in one second steps, between a minimum of 5 seconds and a maximum of 2 minutes. A default of 20 seconds applies.

3.1.6 INVASIVE BLOOD PRESSURE (IBP)

This involves a transducer being inserted into the patient's blood stream, and is the most accurate method for measuring blood pressure. The signal is carried via a cable from the transducer to the system.

Blood pressure is recorded as three values, the systolic pressure (when the heart is in contraction), diastolic pressure (when the heart is in expansion), and the mean of the systolic and diastolic pressures. All three values must be displayed on the screen. In addition, the signal waveform must be displayed on the screen.

The safe ranges for the three values can be set separately. The default values are: SYS: 80-200; DIA: 20-120; MEAN: 40-140.

The time interval for taking successive readings can be varied in one second steps, between a minimum of 2 seconds and a maximum of 2 minutes. A default of 10 seconds applies.

3.1.7 NON-INVASIVE BLOOD PRESSURE (NBP)

This method of measuring blood pressure uses a cuff around a patient limb, which is periodically inflated (automatically, when requested by the patient monitoring system) so that a reading can be taken. The signal is carried via a cable to the system. No waveform is displayed as measurement is not continuous. The current value for the systolic pressure, diastolic pressure and mean pressure must be displayed.

The time interval between successive readings can vary between 1 minute and 30 minutes. The default value is ten minutes.

The safe ranges for the three values can be set separately. The default values are: SYS: 80-200; DIA: 20-120; MEAN: 40-140.

3.1.8 PATIENT ADMISSION AND DISCHARGE

In order to activate alarms and collect history data, the patient must be admitted. Patient admission consists of inputting the patient name and age range into the monitor and connecting the vital sign probe cables to the patient. The cables may be connected before the name and age range are input. Not all patient cables need to be connected: monitoring will start only for those which are connected.

When it is no longer necessary to monitor a patient, a discharge procedure must be followed to clear the monitor of all patient data collected. Monitor defaults are reinstated when a patient is discharged. Patient cables must be disconnected before the discharge procedure can be completed. After a patient has been discharged, reconnecting patient cables will restart data monitoring.

3.1.9 PAUSING AND REACTIVATING MONITORING

This function must be provided to enable a patient to be removed temporarily from the monitor, without having to discharge the patient. Pausing will stop the monitor collecting or displaying data or taking alarm actions. Reactivating monitoring reverts to normal monitoring.

3.2 ALARMS

3.2.1 SMART ALARMS

Alarm processing is not activated until the monitor has detected valid physiologic data from the patient. This allows a patient to be admitted and the necessary patient connections made without bothersome alarm tones.

If, during monitoring, a new vital sign is added, for example, invasive blood pressure, the alarm processing for that vital sign will not be active until valid physiologic data is detected.

3.2.2 ALARM STRUCTURE

There are two kinds of alarms:
• 	Patient Status Alarms and
• 	System Status Alarms.

The monitor responds differently to each category. Patient Status Alarms always take priority over System Status Alarms.

3.2.3 PATIENT STATUS ALARMS

Patient status alarms are triggered when a patient's vital sign is outside its safe range. Patient status alarms can be of two types: critical and message.

When a critical alarm occurs, the following actions are taken: a high-pitch alarm tone is sounded, the alarm is stored in the alarm history, and a flashing visual alert is displayed.

When a message alarm occurs, the following actions are taken: the alarm is stored in the alarm history, and a flashing visual alert is displayed.

Each alarm associated with a vital sign exceeding its limit (low and high) can be assigned to either of these two levels. The default assignment (see defaults) is reinstated upon discharge.

3.2.4 SYSTEM STATUS ALARMS
System Status Alarms are triggered by mechanical or electrical problems and are of lower priority than patient status alarms. An invalid physiologic reading for a vital sign will cause a system status alarm.

When a system status alarm occurs, a low-pitch alarm tone is sounded and a flashing visual alert is displayed.

3.2.5 SILENCING ALARMS
This function allows the current alarm to be silenced for 60 seconds. The message "SILENCED" is displayed on the screen. Any new alarm at an equal or greater level will sound and the silence command is canceled.

3.2.6 ALARM VOLUME ADJUSTMENT
The alarm tone volume can be set to a value within a 1 to 10 scale, with 10 being the loudest. The volume will revert to the default value of 5 when the patient is discharged.

3.2.7 SAFE RANGES
It must be possible to view the upper and lower limits of the safe ranges for all the vital signs, together with their unit of measure and their current alarm level, and whether they are being monitored or not.

It must also be possible to change the upper and lower limit for any vital sign, and the level they are assigned to.

All limits revert to their default values upon discharge.

3.3 EVENT RECORDING

The user must be able to input textual remarks on the patient condition. The name of the doctor/nurse and the time and day of the remark, as well as its text, are retained by the monitor, until the patient is discharged.

3.4 MONITOR SET UP

3.4.1 TURNING A VITAL SIGN ON OR OFF
Turning a vital sign off will remove the relevant waveform from the screen, if any. In addition, any display of information concerning that vital sign is removed. Alarms are off and data is not collected for that vital sign.

Turning a vital sign on will revert to normal display and alarm monitoring.

3.4.2 TURNING WAVEFORMS ON OR OFF
The user can ask for a waveform to be removed from the display. By default, waveforms are displayed. Once removed, a waveform can be reinstated.

3.4.3 SETTING MONITOR DEFAULTS
Monitor defaults can be changed only when the monitor is in a discharged state.

The following defaults can be changed:
• default safe ranges for each vital sign (HRT, TMP, NBP, IBP)
• default alarm levels for each vital sign. A different level may apply to the low and high limits.

3.4.4 RECALLING DEFAULTS
At any time during monitoring it must be possible to revert to default settings.

3.4.5 DEFAULTS

Vital sign	Unit of measure	Monitoring Interval	Safe range	Physiologic limits	Alarm level if sign too low	Alarm level if sign too high
HRT	BPM	5 secs	50-150	0 - 300	Critical	Critical
TMP	C (F)	20 secs	30-42	0 - 47	Critical	Critical
NBP	mmHg	10 mins	SYS 80-200 DIA 20-120 MEAN 40-140	SYS -99 - 350 DIA -99 - 350 MEAN -99 - 350	Message	Message
IBP	mmHg	10 secs	SYS 80-200 DIA 20-120 MEAN 40-140		Message	Message

3.5 PATIENT HISTORY DATA

3.5.1 ALARM HISTORY

It must be possible to view information concerning the 16 most recent patient status alarms.

For each alarm, the following information must be displayed:
• static waveform of the signal that caused the alarm, if applicable
• safe ranges in force at the time of the alarm
• value that triggered the alarm

3.5.2 VITAL SIGNS
It must be possible to view the vital signs collected in the last 24 hours in a tabular form. The user must be able to choose the time interval for the display. For each time interval, the maximum, minimum and average value must be displayed. The time interval cannot be less than the maximum monitoring rate for the vital sign concerned.

3.5.3 RECORDED EVENTS
The monitor must be able to display events (i.e. textual remarks) recorded by staff in the last 24 hours.

4 CENTRAL STATION FUNCTIONS

The functions of the central station are similar to those of the monitor, except that the set up functions are not available. The user must select a bed before patient information can be displayed. Only one patient's information is displayed at any one time. Display of data on the

central station is similar to the display on the monitor. For completeness, all the differences are described below.

4.1 VITAL SIGNS MONITORING

4.1.1 WAVEFORM DISPLAY
Waveforms do not have be displayed on the central station.

4.1.2 VALUE DISPLAY
When a bed is selected, vital signs values must be displayed on the central station screen, for the selected bed, in the same way in which they are displayed at the bedside monitor, except that no waveforms are displayed, and the bed number will appear on the display.

4.2 ALARMS

Alarms must be displayed and sounded on the central station. Alarms can be silenced and their volume adjusted.

4.2.1 SAFE RANGES
It must be possible to view the upper and lower limits of the safe ranges for all the vital signs, together with their unit of measure and their current alarm level, whether they are being monitored or not.

4.3 PATIENT HISTORY DATA

All patient history data must be available to the central station. The user must select a bed number before data can be displayed.
Alarm history, vital signs and recorded events can be displayed or printed on request.

5 SYSTEM FAILURES

A failure in central station hardware or software must not affect the functioning of any bedside monitor.
A software ot hardware failure of a bedside monitor must be reported as a system status alarm on the central station.