Model PAM™3000
Patient Assessment Monitor

WIRELESS2000
RF & UWB Technologies Ltd

PAM™3000 INSTRUCTIONS FOR USE

APPLICATION:	Patient Assessment Monitor
PRODUCT NAME	PAM™3000
PRODUCT P/N:	100.100.10.00

Revision's History

Originator	Approved	Rev	Date	Comments
E. Gavrilovich		00	08.03.2006	Preliminary draft
Eli A	E. Gavrilovich	01	07.04.2008	Rev history, Notes and FCC information added.
Eli A	E. Gavrilovich	02	14.07.2008	Table of contents added
Eli A	E. Gavrilovich	03	12.08.2008	FCC Regulatory Note added. CCS Note added (RA input).

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1 Preface

The *Instructions For Use* are for clinical professionals using the PAM™3000 system and provide basic operation overview of the system and its functions.
Familiarize yourself with all instructions including alerts and warnings before starting to monitor patients.

Read and keep the **Installation and Maintenance Guide** that comes with the system, as it contains important information about care and cleaning that is not repeated here.

In these ***Instructions For Use***:

• A flashing **alert (red)** alerts you to a potential serious outcome, adverse event or safety hazard.
• A **warning (yellow)** alerts you to where special care might be necessary for the safe and effective use of the product.
  Failure to observe a warning may result in minor or moderate personal injury and possibly a remote risk of more serious injury.

• System refers to the entire Patient Assessment Monitor (PAM™3000) system.

• Display refers to the physical PC monitor. Terms **Display Screen** and **Screen** refer to everything you see on PC monitor's display, such as measurements, alarms, patient data and so forth.

2 Introduction

The PAM™3000 Patient Assessment Monitor measures heart rate, respiration rate, duration of presence or absence of patient in bed, and duration of movement or lack of movement of patient in bed. No electrodes need to be attached to the patient's body to monitor these functions. The data from the Bed Sensor are sent wirelessly to the Display Monitor located at the nursing station. System alerts from Display Monitor may be transmitted to pocket pagers and/or wireless handsets.

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2.1 System Description

The PAM™3000 system consists of Bed Sensor Panel (BSP P/N 200.003.10.00) placed under the mattress of the patient's bed, one or more Repeater Base Stations (RBSP/N 200.001.10.02) that transmits the digitized patient heart beat data, respiration data and alert condition information to the Central Base Station (CBS P/N 200.002.10.01). The CBS unit is plugged into a Central Computer Station (CCS P/N 200.008.10.00) typically located at the nursing station. The heart rate and respiration rate data, bed occupancy data and the alerts generated by system are displayed on the monitor of the CCS. Alerts are also relayed to nurses' pagers.

⚠️ The Bed Sensor is for use ONLY with Wireless2000 Power Supply p/n 375.001.10.00.

⚠️ Use CCS for monitoring purposes only. Do not install any additional programs or applications.

3   Intended Use

The PAM™3000 system is intended to measure heart rate and respiration rate in adult patients, in a general care hospital environment including nursing homes. The system will also monitor presence or absence of a patient in bed (bed exit).

⚠️ PAM™3000 is **NOT** for Critical Use.

⚠️ PAM™3000 should be operated only in environmental conditions specified in PAM™3000 Technical Specification (100.100.22.03). The operating temperature should not exceed +10℃ to +40℃

4   Intended Users

The intended users of the PAM™3000 system are clinical professionals within general care hospitals including nursing homes.

⚠️ FCC Regulatory Note per FCC Part 15.517

This equipment may only be operated indoors. Operation outdoors is in violation of 47 U.S.C. 301 and could subject the operator to serious legal penalties.

5   Safety Information

COMPLIES WITH:
- UL 60601-1 Medical Electrical Equipment, Part 1: General Requirements for Safety
- IEC 601-1:1988 + A1:1991 + A2:1995
- CSA C22.2 No 601.1-M90
- CSA C22.2 No 601.1-S1-94
- CSA C22.2 No 601.1-B-98
- IEC/EN 60601-1-2 Medical Electrical Equipment
- FCC Part 15/B
- FCC Part 15/C 15.247
- FCC Part 15/F 15.517

The Label must bear a symbol of Type BF APPLIED PART (Reference IEC 60417-5333):

🧍 IEC 60601-1 Patient Applied Part for devices that have conductive contact with the patient, or have applied parts that are fixed in medium or long term contact with the patient.

6 Managing Patients

6.1 Admission Procedure

The monitor starts collecting physiological data and trends as soon as a patient lies in the bed. However, since all monitoring is done remotely with no display of data at the patient's bed, it is important to admit patients properly so that you can identify your patient on the Display Screen at the nursing station, on recordings, reports, and communication devices such as pagers, wireless handsets etc.

During admission you enter data such as the safety limits that apply for some measurements and the alarm limit ranges, the monitor needs to safely and accurately monitor patients.

To admit a patient,

1. Select **Login** Icon
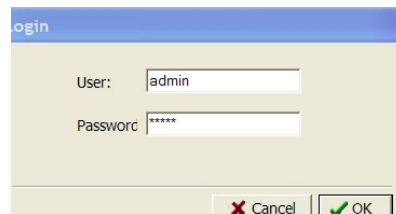
2. Log in using your name and password (Fig.1_a).

Fig.1_a

3. Select **Admit** icon
4. In the **Unit #** window (See Fig.1_b) fill in the serial number of the Bed Sensor.
5. Fill in Patient Name, Room #, allowed absence limit, limits for highest and lowest allowed Heart and Respiration Rate, time limit for continuous movement and time limit for continuous absence of movement.
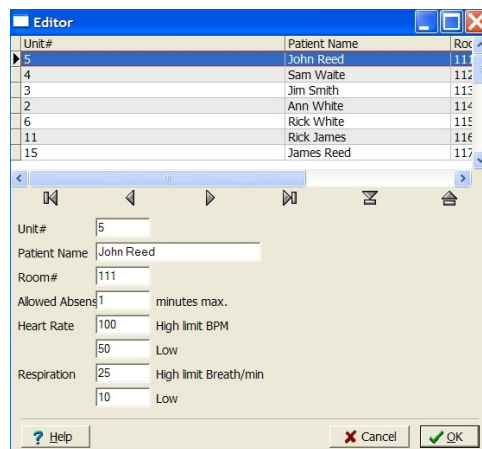6. Repeat for every patient to be admitted. Confirm by pressing "OK".

Fig.1_b

6.2 Alerts (red)

A flashing word **Alert** will appear inside the Status Sector (#4, Fig.3) and the sector's color will change to red when one of pre-set limits for heart rate, respiration rate, absence of patient from the bed, allowed motion or absence of motion is exceeded.

6.3 Flashing numeric

The numeric of the measurement (#8 and #10, Fig.3) at alarm condition will change color to red and will start flashing.

6.4 Warnings (yellow)

- A word **Wait…** will appear inside the Status Sector (#4, Fig.3) when unit is undergoing self-calibration routine. The brief display of this warning requires no action from the medical personnel. If this warning stays on for longer than 30 seconds, the maintenance personnel must be notified.

- A phrase **No Data** will appear inside the Status Sector (#4, Fig.3) when stream of data from bed sensor was suddenly interrupted. This can be caused by either a) unplugging the bed sensor that resulted in the power loss to the sensor or b) failure of one or more of the system components such as bed sensor, power supply, RBS or CBS. This warning requires checking the system by the maintenance personnel.

6.5 Nurse call systems

If configured to do so, alarms and warnings will be indicated on any device connected to the Nurse Call relay.

6.6 Viewing Individual Alarm Limits

You can see the **Alarm Limits** set for each measurement under the measurement numeric on the main screen in both small and large patient displays.
You can also see **Alarm Limits** in the **Unit #** window of the setup menu.

6.7 Screen Display Layout

The Screen Display (See Fig.2) designed to display vital signs information of up to 12 patients simultaneously. Their information is displayed in small windows. It is also possible to watch one selected patient's data in the larger window. Double-click on small window in order to display this patient's data in the large window.

Fig.2

6.8 Understanding the Screen Display
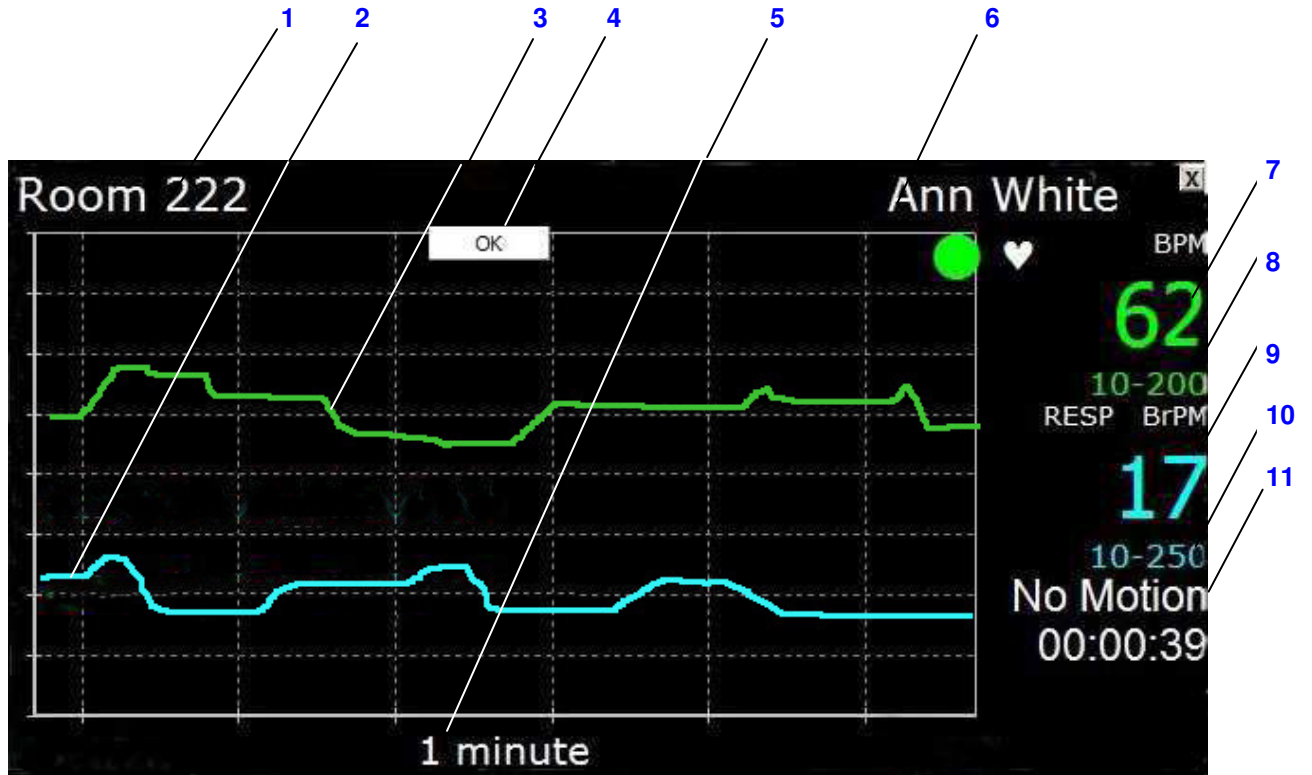
Fig.3

1	Room Number	7	Heart Rate Reading (beats/min)
2	Respiration trend line	8	Heart Rate preset limits for specific patient
3	Heart Rate tend line	9	Respiration Rate reading
4	Status Indicator Sector	10	Respiration Rate preset limits for specific patient
5	Trend line scale (1, 4, 8 or 30 min, 1 hr, 4 hrs)	11	Elapsed Time (motion or no motion)
6	Patient Name	12	

⚠️ Caution: Federal law restricts this device to sale by or on the order of a physician