EMFIT®

Non-Contact Vitals Monitor and Nurse-Call System

Networked (IP) Non-Contact Vitals Monitor and Nurse-Call System

Self-monitoring wireless or wired SafeBed IP devices together with DVM Suite software create a new kind secure and scalable networked non contact vitals monitoring and nurse call system for any care environment. It innovatively integrates non contact vitals, presence/absensce in bed, and movement monitoring with nurse-call functions utilising standard structured cabling. Voice communications can be arranged by integration with VoIP (Voice over Internet Protocol). System has self-diagnostics and automatic alarms.

Besides for recording and visualizing in real time a sleeping person heart rate, BCG signal, respiratory rate and respiratory movement signal, the system has many other possible uses such as recording sleep time movements for sleep quality analysis. BCG and respiratory movement strength, HRV (heart rate variability), apnea periods and movement activity are also calculated and stored into SQL database. When needed the system can also give notification of faster continued movements such as muscle spasms associated with tonic-clonic epileptic seizures.

SafeBed IP measures heart rate, respiration rate and movement activity from below the patient's mattress.

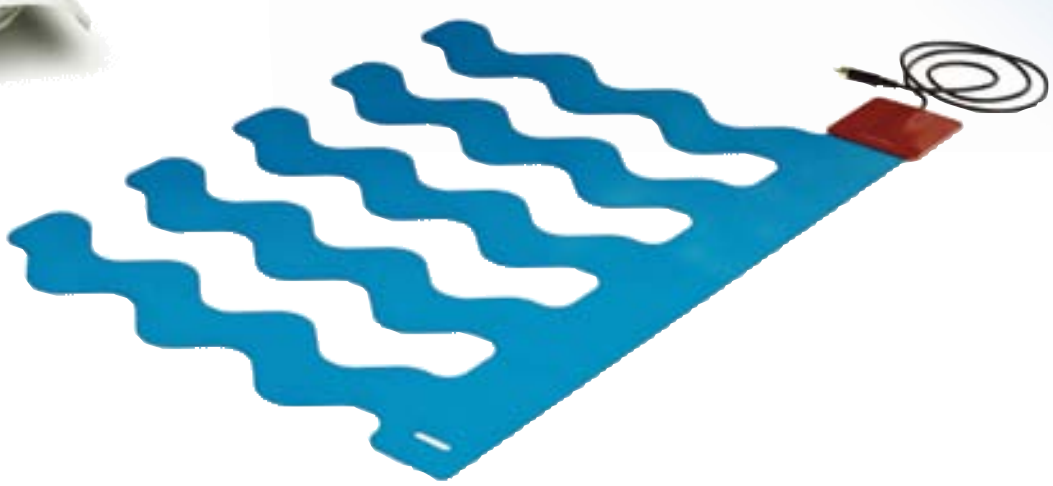
What is it?

SafeBed IP uses Emfit's DVM™ (discreet vitals monitoring) technology for passively measuring basic physiology (e.g. heart rate, respiration rate, movement activity) passively, from below the patient's mattress, without any electrodes, leads, cuffs or cannula. It is a versatile system with integrated basic nurse-call system functions. It can be used for delivering patient nurse-call and giving information of person's presence in bed, notification of absence from bed (also with delay and timing), visualization of respiration movement and BCG, and calculated heart and respiratory rate. All calculated values, among with all events such as nurse present button activation, are stored into SQL database and can be used for example for vitals trend tracking and nurse response time and work load reports.

Why is it needed?

The DVM™ technology was developed to enhance the care environment for both the customers and personnel. There are always patients who need special attention, who should not leave their beds without assistance and are not able to use a nurse-

Emfit Bed-Side Monitor IP-9150



Emfit Under Mattress Bed Sensor L-4060SL

call button. In addition, nursing staff may be required to check a sleeping patient's status and are forced to wake the individual in order to do so. The DVM technology lowers the workload of nurses, alerts of patient falls and wanderings. It also provides better rest for patients by eliminating the need for night-time interruptions of sleep.

How does it work?

The DVM technology consists of Emfit's patented flexible ferroelectret sensor (installed under the mattress or between two mattress layers, a monitor device that utilizes advanced digital signal processing, a standard data network (LAN or WLAN) that serves as the media for all communications, one or more monitoring computers with Emfit's sophisticated DVM Suite software, and optionally for example DECT phone system for delivering alarm messages to nurses. It is also possible to use remote terminals installed in passageways showing all main status information and alarms. A conventional nurse call button, along with nurse-present and nurse-request-for-help buttons are also included.

The sensor responds to small pressure changes caused by patient's ballistocardiographic (BCG) and respiration movements, and generates a respective output voltage signal. Digital data acquisition and a signal processing monitor device use special algorithms developed by Emfit (patents pending) to among others calculate heart and respiration rates and movement activity from the sensor signal. The system transmits all alerts, events, and monitoring data over a standard data network, using standard IP protocol.

The System utilizes standard structured network cabling, which can carry not only IP based nurse-call system, but data, telecommunications, security, video and even entertainment. Therefore installation costs are low due to the multiple use of cabling and system is easy to expand. The bed-side devices need only access point to the standard network cabling and installing new devices or making replacement is easy and fast unlike traditional nurse call systems. This keeps costs down through its scalability, flexibility and reliability.

The ability to manage and monitor all of the systems on the network remotely offers significant advantages and cost-savings for the maintenance. Any concerns can be easily resolved by organization IT specialists or by remote service.

Who is it for?

The needs vary and the Emfit SafeBed IP system is easily customized to meet the desired requirements. The system can cover one ward, building, or inter-connect several even over the internet. It is possible to connect home care situations to one larger system as well.

Emfit SafeBed IP system increases the quality and efficiency of patient care, brings new safety and reduces staff work load.

Emfit SafeBed IP system increases the quality and efficiency of patient care, brings new safety and reduces staff work load. The technology can be used for adults and children in various care environments. Establishments like hospitals and elderly, mentally/physically disabled and psychiatric care facilities can benefit from it. It can also be used in home care. The systems main software can be in another location and information can be delivered over the internet. It is possible also possible to build large systems with thousands of homes connected to the main software and database over the internet. This can be useful in many kinds of research and home monitoring. System is scalable and easy to expand.

About System CE-marking

Emfit SafeBed IP system including bed-side device, bed sensor or floor sensor and DVM Suite software, complies with the essential requirements of EMC directive 2004/108/EC and CE mark directive 93/68/EEC and carries the CE marking accordingly.

The whole system (hardware, embedded firmware and software) is designed to meet IEC 60601-1 3rd ed. medical device standard. System has already passed relevant EMC tests.

Currently system is sold as a non-medical hardware and software system for use with healthy persons only and is specifically not intended for diagnostic use, or for monitoring of vitals signs where the nature of variations could result in immediate danger to the person monitored.

It is planned that after clinical validation by second half of 2010, system will be offered as Medical Device Class 2b, conforming with Medical Device Directive 93/42/EC. At that point new types of alerts e.g. of a prolonged high/low heart rate and high low respiratory rate will be included.

Benefits

- Utilize the customer`s existing network infrastructure
- Ensures cost-effective installation and maintenance
- Easy to design and expand
- Increase efficiency
- SQL data base for data storage allows customized reports, for example workload per bed and staff response time control
- Utilising a TCP/IP network and with included SDK (software-development-kit) and open API (application programming interface) allows easy integration with other systems
- SOA (service-oriented-architecture) system architecture maximizes security
- As networked system remote management and maintenance possible
- Comfortable for the patient, being virtually undetectable
- Passive, assisting vitals monitoring data is available from every bed
- Works with adults and children

Features

- DVM Suite software for managing nurse calls and nursing activities
- Possible to connect, monitor and store data from thousands beds (homes) over internet
- Integrates non contact vitals, presence/absensce in bed, and movement monitoring with nurse-call functions
- Based on standard IP-technology
- Utilise standard structured cabling, no dedicated cabling is required
- Each bed can have either dynamic or static IP address
- Possible to integrate with VoIP (Voice over Internet Protocol) voice communications
- Self-diagnostics and automatic alarms
- Supports common Microsoft® server technologies
- Devices are powered over Ethernet (PoE)
- Installation possible both on the wall or inside cable trunking

The Emfit bed sensor is located in bed under the mattress. All measured data is taken from the signal of the same one-and-only sensor; nothing is connected directly to the patient.

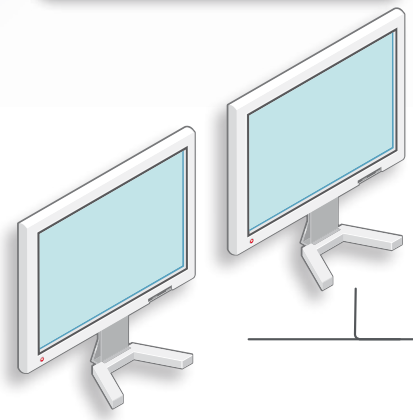
Alarms can be transfered to cordless phone and paging systems

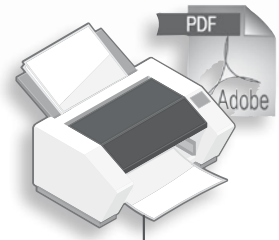
System Overview

Signal Monitor Client
software displays respiratory movement and BCG, HR/min, Resp/min and presence/absence from up to 18 beds on one screen

DECT Client
software transfers all alarms to cordless phones using ESPA protocol. Other similar modules will be available upon request.

Customised reports
are easy available from SQL database



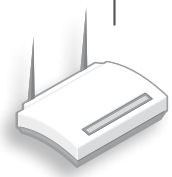


DataBase Client
software stores all data to SQL database. SQL database server can be situated outside the main system connected via LAN/WLAN.

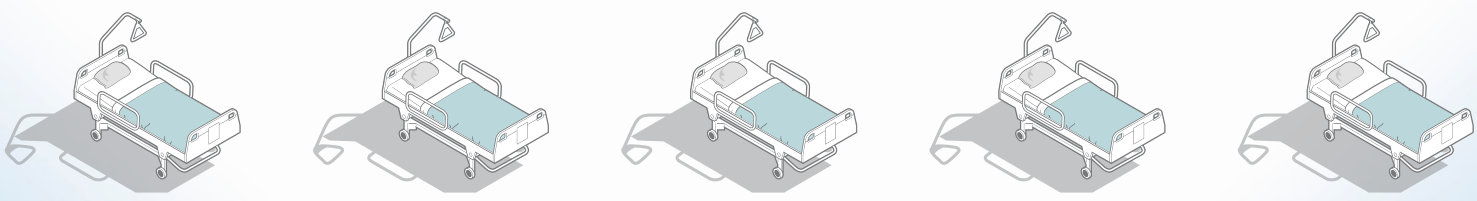
Alarm Monitor Client
displays all alarms

SDK/API available for easy integration
to other software (ie. ERP)

DVM Core
software receives, processes and forwards data from devices to different software clients (SOA = service oriented architecture)



The networked (IP) system is fully functional with standard structured cabling (LAN/WLAN). Devices are powered with standard PoE (power over ethernet)



System makes possible to connect hundreds of beds to ethernet network for monitoring vital signs and providing nurse-call functions.

Emfit SafeBed IP / DVM2009 SW System Main Technical Details

CONTROL UNIT

Model	IP-9150
Classification	Current non-medical. Class 2b after clinical validation expected to accomplished by summer 2010.
CE-mark	Complies with the essential requirements of EMC directive 2004/108/EC and CE mark directive 93/68/EEC and carries the CE marking accordingly.
Safety standard	Designed and developed to meet IEC-60601-1. CE marking according to Directive 93/42/EEC pending.
Description / intended use*	Networked multi-bed nurse call system with integrated non-body-contact vitals and movements monitoring
Main nurse call system features	
	Input for wired patient peer-button (nurse call -button)
	Nurse present -button
	Nurse requests for help -button
	CodeBlue button
	Automatic presence/absence detection + alarm
	Device and network error alarms
	Alarm delivery to DECT phones
Main patient monitoring features	
	Heart rate
	Respiration rate
	Movement activity
	Raw curves for BCG and respiratory movement
	Absence (fall) detection and alarm
	Fast movements (tonic-clonic seizure) detection and alarm
	Data storage to an SQL database
Communications	All communications IP-based over standard data network
Dimensions (W x L x D)	95 mm x 125 mm x 30 mm
Weight, colour	130 g, white
Power source	AC-adapter; 5 V 3.0 A DC Medical Grade, PoE (Power-Over-Ethernet 48 V)
Operating voltage	5 V DC
Connections	Bed (or floor) sensor
	Nurse call peer-button
	Incontinence sensor
	Auxiliary input for 1 external device with dry-contact
	Output Ethernet RJ-45
	Power input 5 V DC
Inbuilt buttons and light indicators	Buttons: Nurse present, Help requested, CodeBlue LEDs: Power on, Presence indicator, Device/sensor fault
Network/software Compatibility	Standard Ethernet or 802.11x WLAN Microsoft Windows XP, Microsoft Windows Vista, Microsoft Windows 2003 Server ®

SENSOR

Type	Dynamic response thin-film ferroelectret sensor
Model	L-4060SL
Placing	Under mattress (floor-sensor on the floor or under flooring)
Dimensions, thickness	400 x 580 mm, 0,5 mm
Wire length	3 m
Surface material, colour	Polyester, blue
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PC SOFTWARE	DVM2009 Suite
Compatibility/platform	Microsoft Windows XP, Microsoft Windows Vista, Microsoft Windows 2003 Server ®
Safety standard, CE-mark	Designed and developed to meet IEC-60601-1 3rd ed. CE marking according to MDD Directive 93/42/EEC pending.
Signal Monitor Client	Visualized on the signal monitor client software are heart rate / min, respiration rate / min, BCG and respiratory movements, person presence/absence in/from bed.
Stored to SQL Database	Calculated and stored to SQL database are HR/min, HRV (heart rate variability), RESP/min, presence/absense, all nurse buttons activations, all events and alarms, signal strengths and qualities, movement activity, raw signal curves, fast movement events, apnea events, Additional detailed documentation available on request.
Compatibility/platform	Microsoft Windows XP, Microsoft Windows Vista, Microsoft Windows 2003 Server ®
Used protocols	TCP/IP, UDP, HTTP {All over IP}
Used ports	Software-configurable
Computer network	Any standard LAN or WLAN

* Intended use: Nurse call system with presence/absence monitoring and alarm, and non-diagnostic, non-body-contact assisting monitoring of vital signs. Product is not intended for monitoring of vital physiological parameters, where the nature of variations is such, that it could result in immediate danger to the patient.

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