

Cardiac Monitor

Model : HR2000 series User manual

BioSenseTek Corp.

Cardiac monitor system

Caution! Please follow the instruction to use the product.
This product should be used by doctors or trained staff under the
guidance of doctor for clinical usage.
This product is not the only means to provide basis for diagnosis.

About HR2000

Cardiac monitor system is the medical instrument suitable for patient electrophysiological signal transducing, this instrument contains the ECG amplifier (Transducing terminal) and a patient lead which can obtain electrophysiological signal from patients. Electrophysiological signal is transferred wirelessly to the receiver, and then to the computer by TCP/IP.

Cardiac monitor system will take a small, easy to carry device, so that patients can get continuous physiological signal monitoring; it can monitor several patients at once, protect patient safety, reduce the burden of health care workers, increasing productivity, improving the quality of health care.

The system, using a set of wireless receiver, can simultaneously monitor multiple groups of wireless ECG machine, its signal transducing area can be modified in accordance with the current situation needs by the set-ups of antenna through major space.

Feature

1. Suitable for continuous transmission of electrophysiological signal.
2. Detection of one of subsections I, II or III lead ECG signal.
3. Transferring signal to the computer via RF and TCP/IP.
4. A set of wireless receiver can simultaneously monitor up to six wireless ECG machine. °
5. Signal connection indicate, signal interrupt and low battery warning.
6. Indicate the present and full charge status, charging auto cut off power.
7. Light weight and portable.
8. RF ranges U.S.A.: 902MHz~928MHz. Taiwan: 922MHz~928MHz
(Alternative options available according to local legislation, ex: 315/433/868/915MHz)

Accessories

HR2B8D	Wireless Vital Sign
HR2B9D	Transmitter
HR2B8M	Wireless Vital Sign
HR2B9M	receiver
Lead wire for ECG signal	
Charging cable	

Specification

Vital Sign Transducer - transmitter

Power	Built-in rechargeable 650mAh Li-ion battery , voltage 3.7V
Operating Time	7 days after fully charged (real working time varied based on battery condition and RF environment)
RF range	Taiwan : 922MHz ~ 928MHz, USA : 902MHz~928MHz (Alternative options available according to local legislation, ex: 315/433/868/915MHz)
Output power of RF	10dBm(max) to antenna for rated battery voltage
Dimensions	62 x 55 x 13 mm(thickest part)
Weight	<50g , include a patient lead wire for ECG signal
Suggesting operating temperature	15℃~40℃
Suggesting operating humidity	30~80% , no condensation
Storage and transportation temperature	-10℃~65℃
Humidity for storage and transportation	30~80% , no condensation
Lead	I 、 II or III Lead
Input dynamic range	±1.25mV
DC offset range	±1250mV
CMRR	>90dB
Frequency response	0.5Hz _{max} ~ 40Hz
Input interface	Snap-type lead wire

Patient lead wire

Dimensions	600mm in length
Connector	Custom connector
Snap	ψ4.2mm(male side ψ3.9mm)

Vital Sign Transducer – Receiver

Dimension	72mm x 57mm x 14mm(excluding antenna)
Length of antenna	56.6mm , 190mm
RF range	Taiwan : 922MHz ~ 928MHz, USA : 902MHz~928MHz (Alternative options available according to local legislation, ex: 315/433/868/915MHz)
Power consumption	<200mA
Power supply	DC 5V 500mA
Wired transmission interface	10/100Mbps Ethernet

Charging Cable

Length	1000mm±5%
Connector	USB / Custom connector
Maximum current	500mA

Operate system requirements

Operating system : Windows XP (32bites/64bites) , Windows 7 (32bites/64bites)

- Hardware :
- CPU : Intel Pentium 4 / Celeron 2.0 GHz or above
 - Memory : 2 GB or above
 - Residual HD space : 2 GB or above
 - Interface : Internet / USB / Sound
 - Suggested Screen Resolution : Parallel 1280 pixels
Vertical 960 pixels
 - Suggested Screen Size : 17 inch or above(16:9 wide-screen)
 - CD-ROM : 8x or above CD-ROM or DVD-ROM
 - PC multimedia speakers : Output sound pressure 60dBA above

Maintenance

1. Use soft and dry cloth to clean the surface of physiological signal transmitter.
2. Conductive gel or other stains can be cleaning using slide damp soft cloth.
3. Never use alcohol or other organic solution for cleaning
4. Connected to the Patient lead wire cleaning



Caution

1. The received data can help diagnosing for doctor. However, this is not the only way to provide basis for diagnosis.
2. Never put the product and related accessories under the exposure of sunlight or environment of high temperature.
3. Never deconstruct or try to fix the product without the help of manufacturer. It may cause the accuracy and safety of the product to deteriorate.
4. This product meets the standard of EMC requirement, However, we still suggest to use it away from microwave or other RF devices.
5. If there are other wireless transmission module, antennas, and other related facilities, please make sure the working RF band of our product is not overlapping by other devices.
6. Never pile up our product with other devices. If the piling is necessary, please check our product before using it.
7. Some stimulators may interfere with our wireless signal.
8. Never use sharp-pointed or hard objects to press the button. Please press it with finger.
9. Never clean the instrument and wire by soaking, steaming, and high-pressured cleanness.
10. This product should be kept in dry environment. Avoid any kind of liquid from going into the vital sign transmitter and receiver.
11. To avoid defibrillating casualty, please do not touch the transducer and lead while defibrillating. Place the electrode and defibrillator in proper position to lower the potential damage, or remove the device in the first place.
12. Extensive movement may cause lead to come off, or resulting of poor vital sign quality.
13. Please remove the transducer if there are safety concern or directly or indirectly causing discomfort to the patient.
14. The product has been certified as a low-powered RF transmission device. Any enterprises, shops, and user is not allowed to modify the working frequency, enhancing the amplifier, or altering the original function °
15. Low-powered RF transmission devices are not allowed to interfere with flying safety and legal telecommunication. If the interference is detected, stop using the device and change the working frequency to the band without interference.
16. The mentioned telecommunication refers to wireless telecommunication which follow the related laws. Low-powered RF transmission devices should be able to endure the interference of legal telecommunication, and science and medical radio wave-generated electronic facilities
17. Power failure or not normal shutdown software may cause data loss ° Don't close PC or software while system is operating , if PC or software is accidentally closed please reopen PC and execute the system software.
18. Don't be used in the intensive care unit (ex. ICU, CCU)

FCC Compliance and Advisory Statement

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference and
- (2) This device must accept any interference received, including interference that may cause undesired operation.

FEDERAL COMMUNICATIONS COMMISSION INTERFERENCE STATEMENT

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/ TV technician for help.

CAUTION:

Any changes or modifications not expressly approved by the grantee of this device could void the user's authority to operate the equipment.



Contraindication

1. Physically impaired people may not have safe and accurate testing result.
2. Without the permission of patient.
3. Not allow for Fetal

Troubleshooting

Please check the following list If there is abnormal situation while using the physiological signal transducer, If the problem still exist, please contact us.

1. Check if the transmitter is connected to the patient lead wire properly.
2. Check if the electrode is tightly contact with user's skin.
3. If the noise in the test result is too serious, the subject's skin may be too dry, or cause by improper grounding of computer, or interference on the background. Please check the surrounding for the interference of electronic devices, and make sure the computer is grounding properly, and apply some water or alcohol to clean subject's skin then perform the test again.

* * * Please dispose the transducer properly according to the local laws * * *



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Advantech Europe BV
Ekkersrijt 5708, 5692 ER, Son, The Netherlands



Instruction of signs



2012

Manufacturer
Manufacture date



Serial number



Please follow the instruction



Lot number



Recycling sign for electric
and electronic device



Direct current



CE mark



European Authorized
Representative



Electrode contact part with body-Protection
level BF sign (Electrode patch, which is used
to transfer electric energy and physiological
signal.)



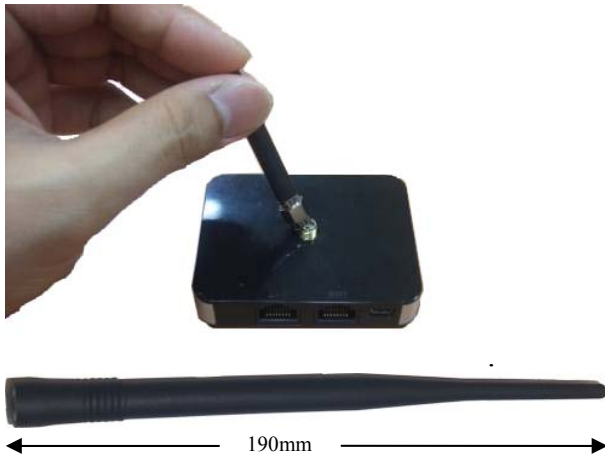
FCC Logo



Prescription only

Operation Instruction

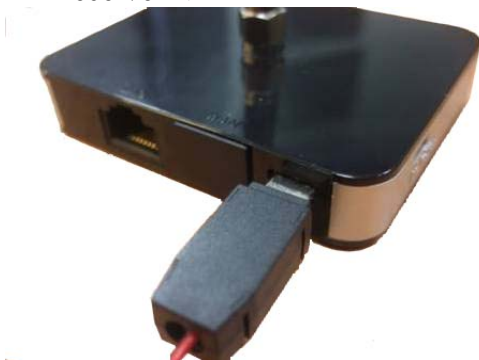
- 1 Screw the antenna on to the wireless transmission receiver ▼



or

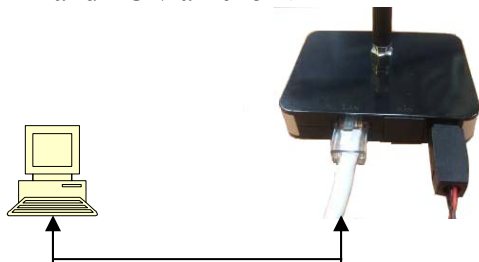


- 2 Connect the USB DC 5V 500mA power supply to the wireless transmission receiver ▼

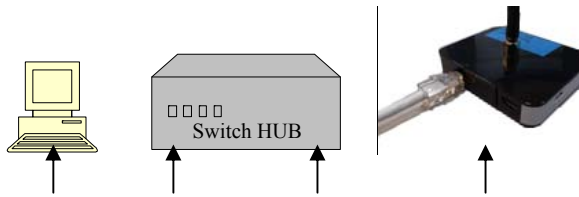


(Power supply is not included in the standard accessory, please use the proper power supply according to the local regulation.)

- 3 Connect wireless transmission receiver and PC via RJ45 ▼

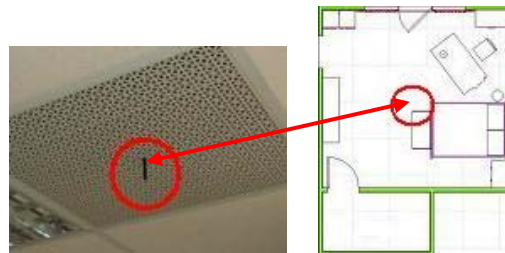


Or connect receiver and PC with 10/100Mbps Ethernet switch Hub ▼



The maximum valid transducing distance is 30M in idea open space, but varies with different actual using scenario.

It is suggested receiver be set at the center of user's activity area and have it up-side down, ex: The receiver of patients' transmitter in hospital should be placed up side down at the center ▼



- 4 Connect the physiological signal transmitter with patient lead wire ▼



- 5 Press the power on bottom of vital sign transmitter ▼



- 6 Clip the ECG electrode with vital sign transmitter and attach it to the lower right torso. Clip another ECG electrode with patient lead wire snap and attach it to the upper right torso.



(Please choose the ECG electrode conform to standard of the medical regulation)

- 7 Switch off: Shut down automatically while charging.

- 8 Charging :

8.1 Unplug the patient lead wire

8.2 Plug in the charging cable. ▼



- 8.3 Connect the USB side of the charging wire to 5V 500mA power supply to begin charging. (power supply is not included) ▼



(Power supply in the picture is for reference. Please use the proper power supply according to the local regulation)

- 8.4 LED on the switch will turn red while charging.
- 8.5 LED on the switch will turn green when fully charged.
- 8.6 The charging time is roughly 2.5 hours, depending on the condition of the battery.

Indication signals on the receiver : ▼



Light	Instruction
AP	Lights-on after internet connected
LAN	Always on after 10 seconds blinking
VT	Blinking while receiving data
PWR	Power indicator

- 9 Setup multimedia speakers(Speakers in the picture is for reference. Please use the speaker can output sound pressure above 60dBA. Ex: Logitech Stereo Speaker Z120) ◦

- 9.1 In accordance with the multimedia speakers the original instructions book installed and connected to the PC



- 9.2 Set the sound output of the operating system to execute 『Control Panel』

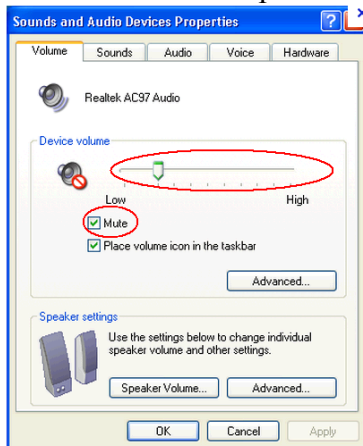


- 9.3 Execute 『Sounds and Audio Device』



- 9.4 Confirm the device volume adjustment to the maximum

- 9.5 Confirm the mute option is canceled



- 9.6 Multimedia speaker volume knob up to maximum (Attention! Had a

small voice will cause not hear to the voice prompts)



Software installation instruction

1. Execute \HR2000\Setup.exe in CD-ROM
(ex: The CD-ROM symbol is D , execute D:\HR2000\Setup.exe)




2. Follow the prompts to complete the software installation

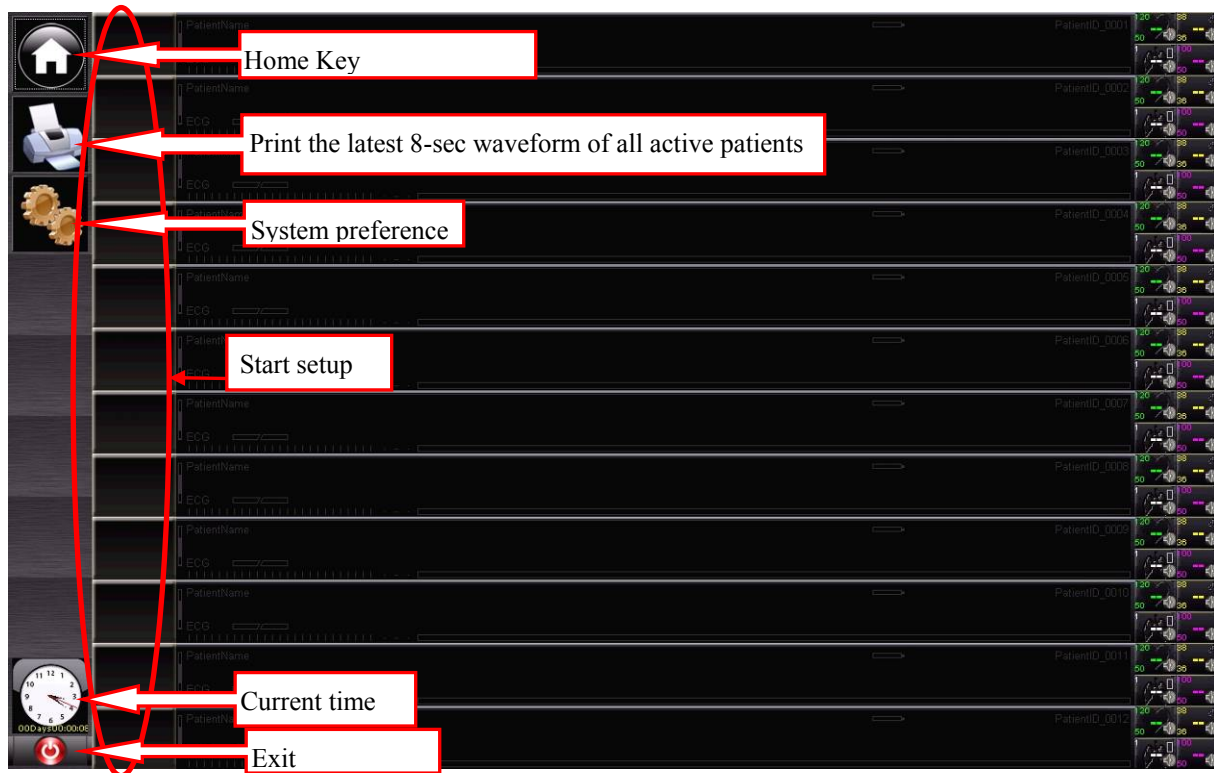


3. After installation the shortcut 『HR2000』 will be auto-generated on windows desktop



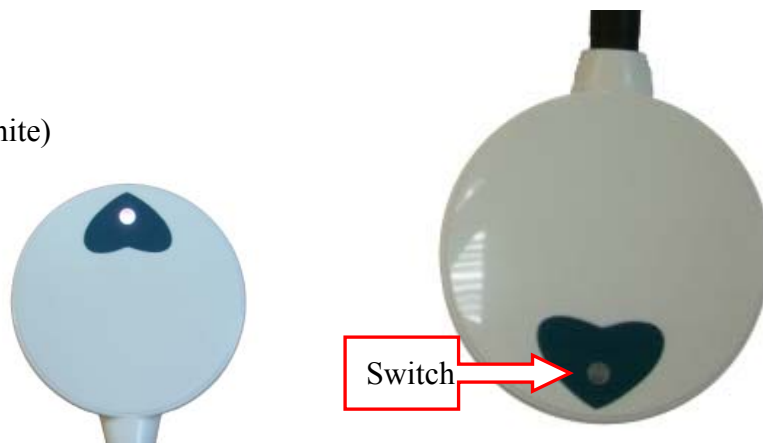
Start

Execute shortcut  on windows desktop , Follow GUI will appear ▼
(After installing when the computer starts automatically execute the program)

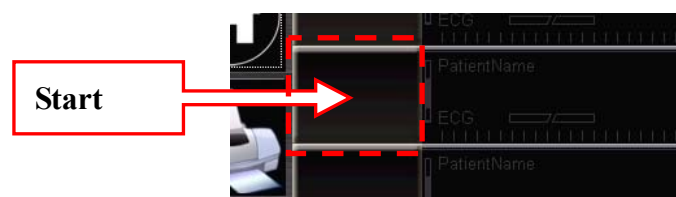


Admit a patient :

1. Press the switch ▼
(All LED on => white)



2. Begin setting form any unused display section ▼



3. Select room number and bed number ▼
4. Enter patient's name and ID (ID required) ▼
5. Set normal HR range ▼

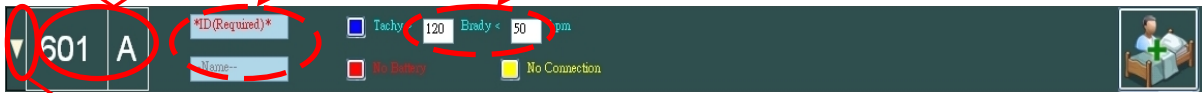


(The default does not apply to all cases ,
Please modify the settings according to the
actual situation ,
Software re-open the settings will be retained)

3. Cyclic selection of
room # & bed #

4. Patient ID &
name

5. Upper and lower HR range



Pop-up room # selection



6. Select Admission icon ▼



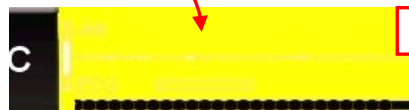
7. Pop-up message to confirm new Transciever is powered on. Press Yes. ▼



8. Ten seconds waveform recorded on work station AP if Transciever work properly
(Random fluctuation noise appeared if no simulator is used) ▼
9. Transciever auto hibernates 10seconds later. ▼



1 Ten second calibration waveform

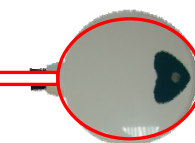
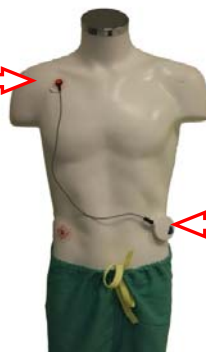


Transducer auto sleep after 10 sec

10. Snap two pre-gel electrodes to RA and LL position and remove the adhesive back layer
to position the sensor and electrode properly on to the patient's chest surface ▼

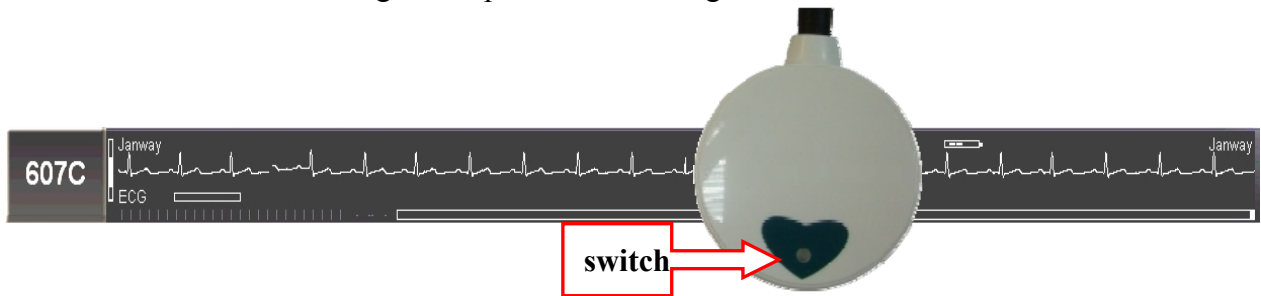


Upper right torso for RA



Lower left torso for transducer

11. Press the ON switch again for patient monitoring ▼



User scenario :

1. Black background indicates under normal operation ▼

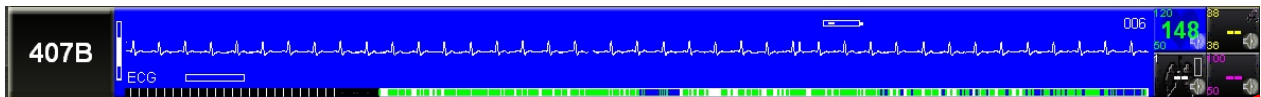


2. Red background indicating battery depletion, it turns off automatically after fully charged transmitter be installed ▼



3. Cyan-Blue background indicating the detected HR is out of limit, it turns off automatically when HR returned to limit, double click left mouse button on speaker icon to turn off the sound, until next double click will turn on. ▼

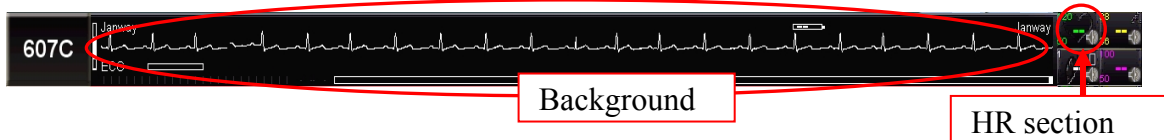
(The maximum delay time of RF communication under normal circumstance is the reciprocal of HR times 6, ex : HR 50 bpm , $((1/50) \times 6) = 0.12$ min , about 7.2 sec delay)



4. Yellow background shows up indicating transmitter RF link failed for more than 5 sec, it turns off automatically after RF link return normal. (Maximum delay time about 5 sec) ▼



5. Screen message annotation ▼



Background priority : Yellow > Red > Cyan-Blue , High priority will be to cover the lower , Until the status lifted

HR section : Display Heart Rate , range 10~300 bpm, Exceeds a set upper and lower limit flicker

Status notes after software restart :

- ~Red background, if the battery depletion continues, will shows up after receiving data from transmitter.
- ~Yellow background, if RF link failure continues the background will be black without any waveform after software restart and patient data will be saved.



- ~Cyan-Blue background, if the detected HR keep staying out of preset range, will shows up after delay time(the reciprocal of detected HR times 6) under normal RF communication (ex : HR 50 bpm , delay about 7.2 sec)

6. Patient information modification during monitoring (ID can NOT be changed)

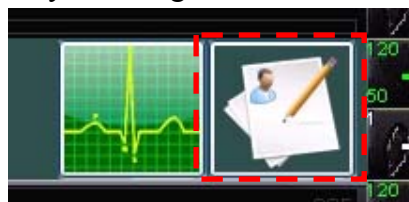
- ~Select patient to be modified ▼



- ~Modify patient's name ▼



- ~Confirm modification by selecting the modification key ▼



7. HR limit modification during monitoring

~Select patient to be modified ▼



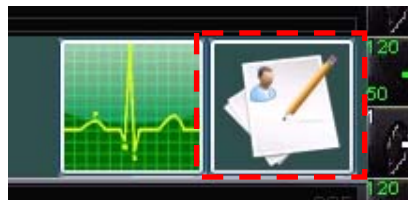
~Change to new threshold limit ▼



(The default does not apply to all cases , Please modify the settings according to the actual situation , Software re-open the settings will be retained)

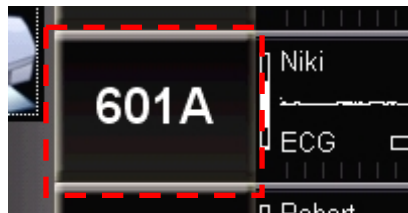


~Press confirm modification key ▼

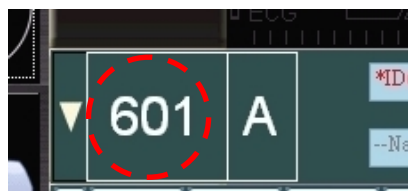


Change room (bed)procedure :

1. Click the number of current bed which is to be changed. ▼



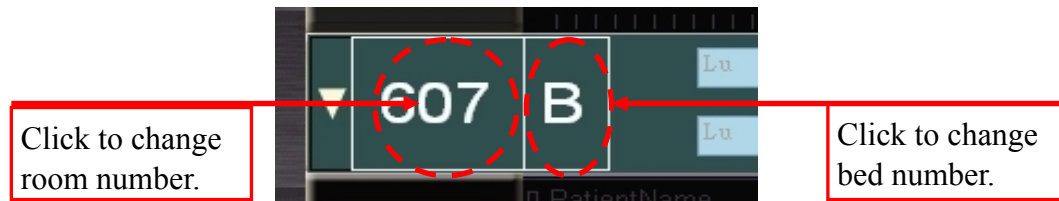
2. Click the 'Room changing' button. ▼



3. Pop-up message "Shift to New Room" shows up; confirm the action of bed (room) changing. ▼



4. Choose the new bed (room) number. ▼



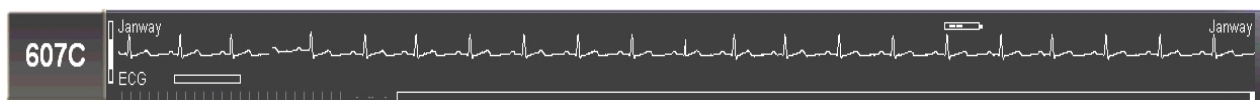
5. Confirm new bed (room) number then click the room-changing button. ▼



6. Pop-up message showing " Old bed number to new bed number " shows up. ▼



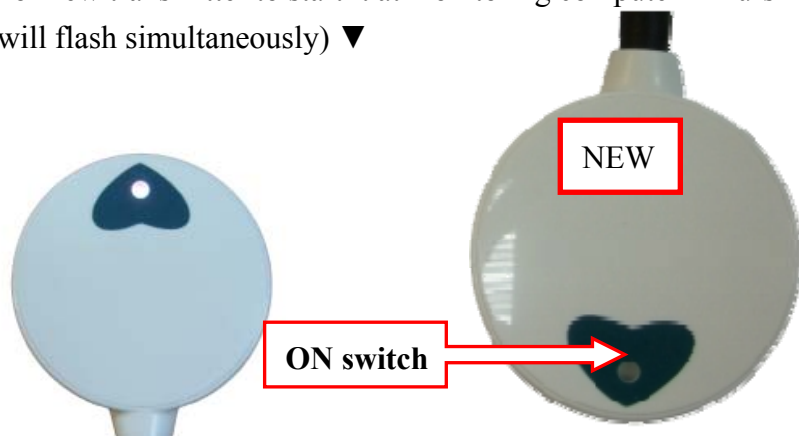
7. Finished. ▼



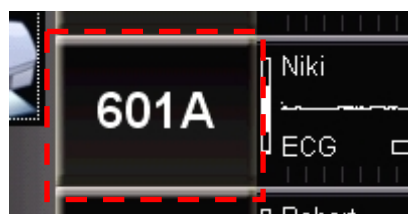
Transmitter changing process :

(Transmitter changing while low battery, blackout or other condition)

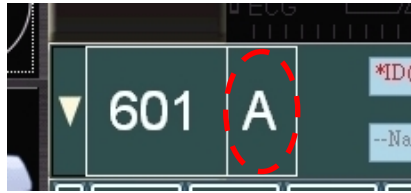
1. Press the ON switch of new transmitter to start it at monitoring computer in nursing station. (All LED's will flash simultaneously) ▼



2. Click the number of current bed whose Transmitter is to be changed. ▼



3. Click the transmitter-changing button. ▼



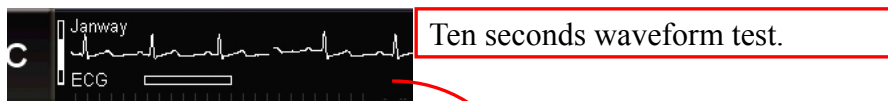
4. Pop-up message to confirm that new transmitter is powered on. ▼



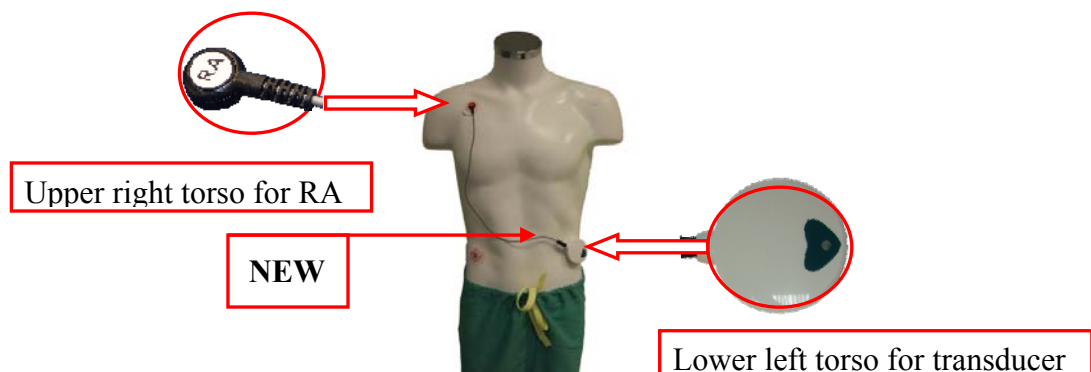
5. Click the transmitter changing confirmation button to confirm the action. ▼



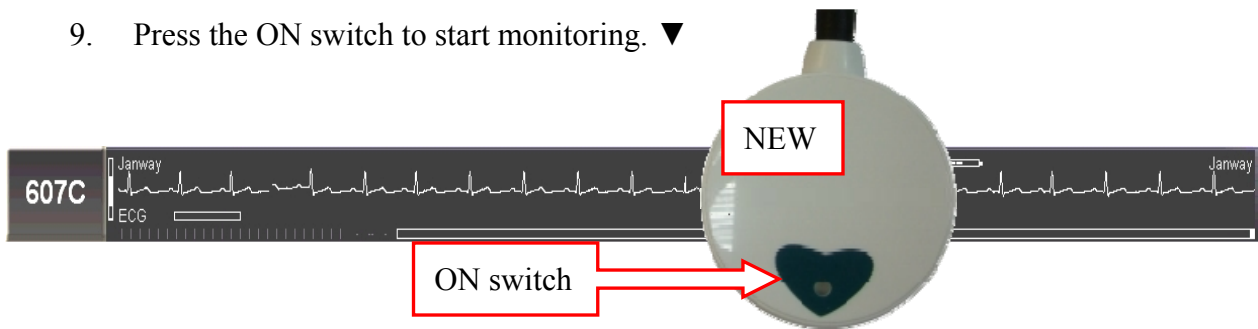
6. Old transmitter should be closed at wards and new transmitter be set up at nursing station and shows the ten seconds waveform. ▼
(ECG waveform only shows up when the VT sensor connected to patient or simulator, if not, there will be random fluctuation noise.)
7. New transmitter auto sleep , reopen it when reach the patient side. ▼



8. Remove the old transmitter and electrodes then put on the new ones. ▼



9. Press the ON switch to start monitoring. ▼



10. Place the old transmitter in the charging base for future use. ▼



Discharge procedure :

1. Select room and bed # to be discharged ▼



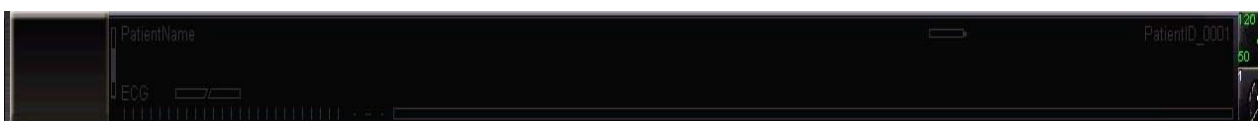
2. Press discharge key ▼



3. Message to confirm discharge patient and shut down transmitter ▼



4. Transmitter power-off and no waveform can be seen. ▼



- Place the transmitter in the charging base for future use. ▼



Retrieve(Data retrieval) :

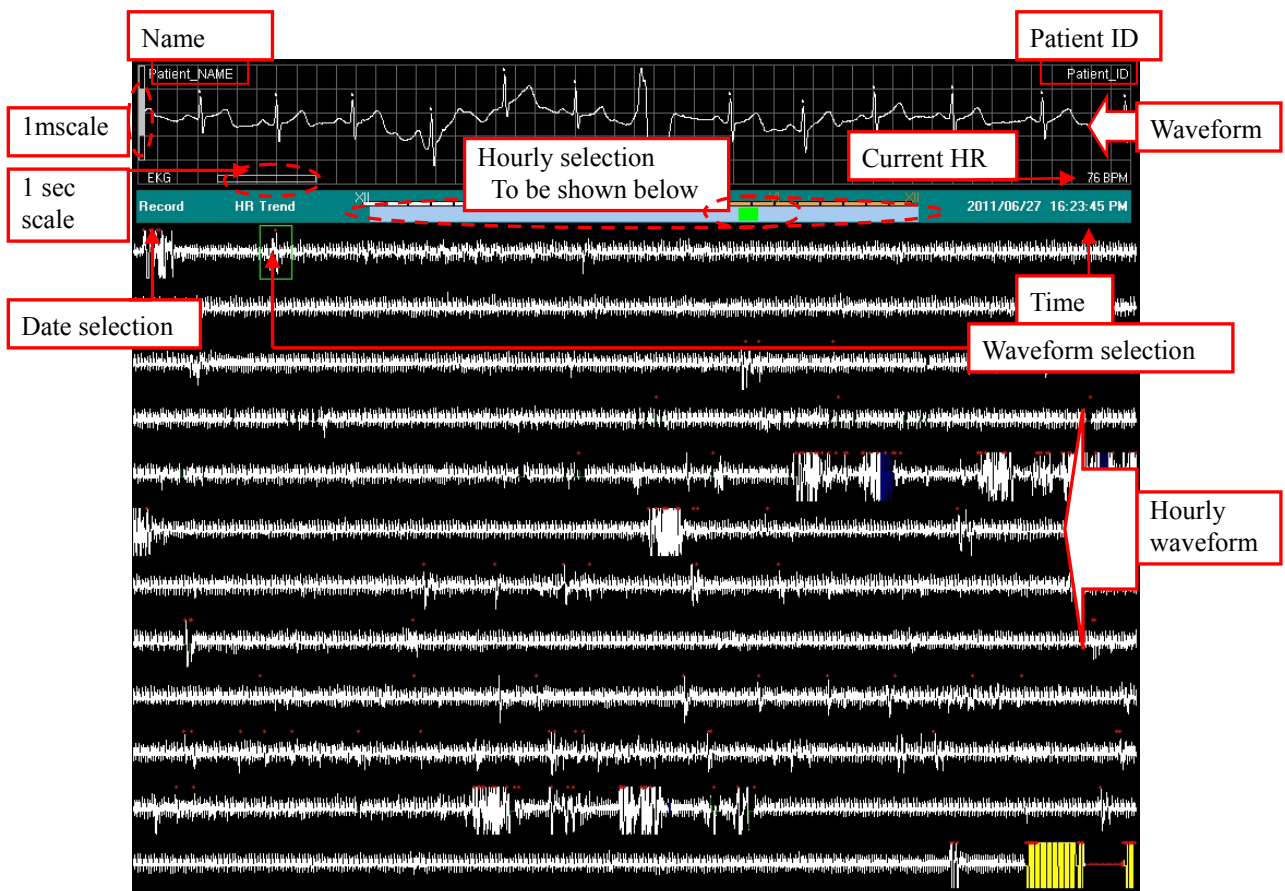
- Select the room & bed # to retrieve the recorded data ▼



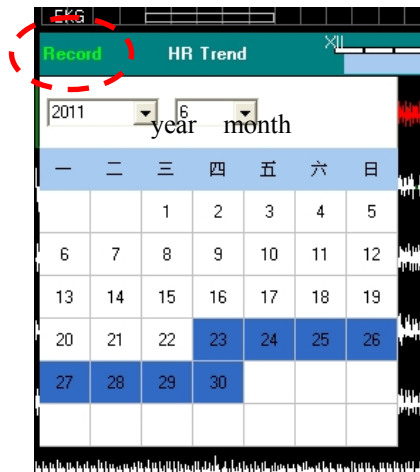
- Select retrieve key ▼



- Initial retrieve display ▼

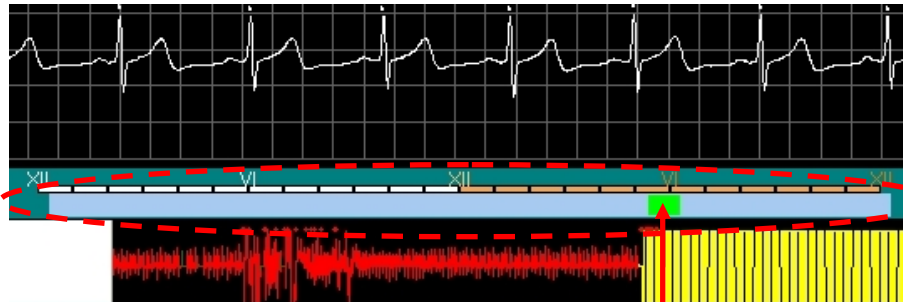


4. Select the date of retrieval ▼



Available date on
blue background

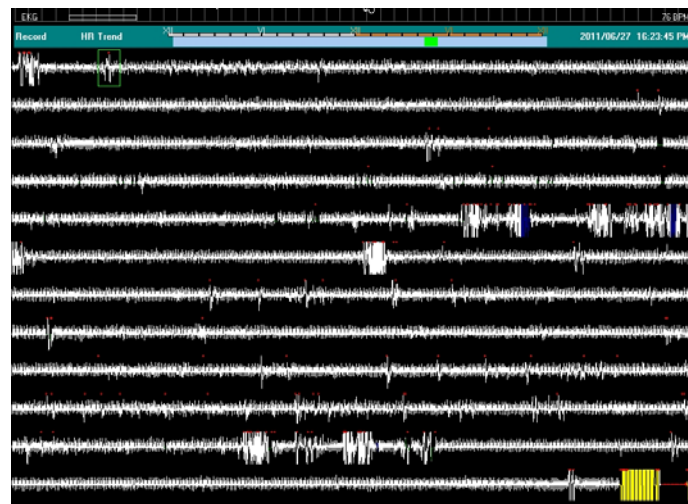
5. Select an hour during the 24 hrs period ▼



24H
data

Selected hour in green background

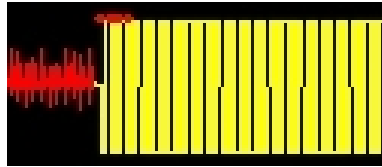
~An hour waveform display with color status indication ▼



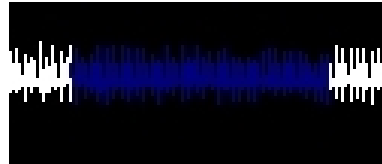
~Red waveform : Battery is depleted ▼



~Yellow waveform: Disconnected RF link ▼

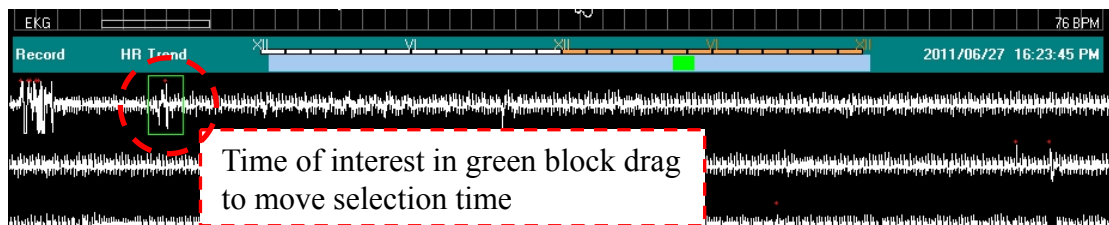


~Cyan-Blue waveform: HR over preset threshold ▼

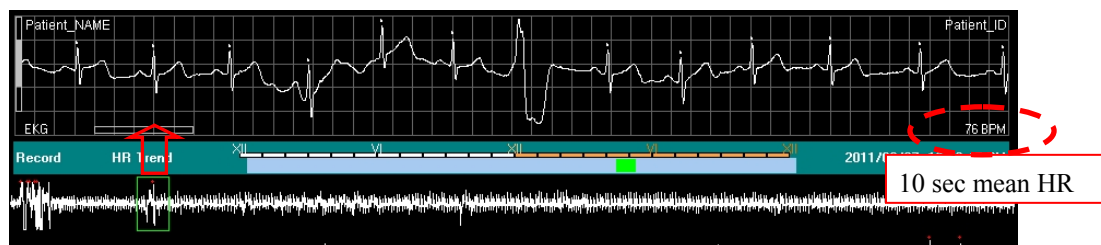


6. Detailed waveform display.

~Choose time point to display in hourly waveform ▼



~Upper window to display selected ECG waveform ▼



7. Data storage :

Data will be temporarily kept before stored as official file after 1 hour, all temporary data less than 1 hour will be lost in case of abnormal software closure (didn't execute discharge for all current used bed#)

Turn off software :

Click turn off button , All bed need to execute the discharge flow can be turned off software .



Visual indication and Alarm

1. User interface

A. Black, normal.



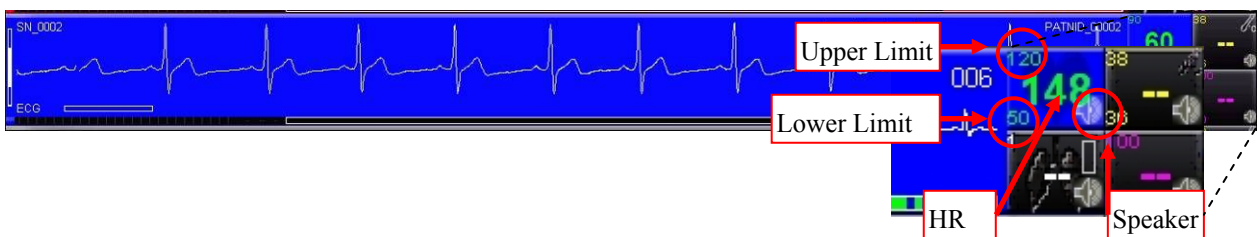
B. Red background : Depleted battery.



C. Yellow background : RF disconnected more than 5 seconds.



D. Cyan-Blue background , HR over threshold limit . (Software continuously beeping. Alert speaker can be switch off by double click the speaker icon)



2. The screen prompts delay time

Red : Every 10 minutes to detect , the maximum delay time is 10 min.

Yellow : indicating transmitter RF link failed for more than 5 sec, Maximum delay time about 5 sec

Cyan-blue : Measured the heart rate exceeds a set upper and lower limits will show up, Delay time and measurement of heart rate are related to, The maximum delay time in the heart rate falls below the lower limit, The minimum delay time in the heart rate higher than the upper limit, Delay time calculated the reciprocal of the heart rate multiplied by 6(Under normal conditions in the wireless communications)
Ex : Lower limit of 51, when measured continuous heart rate 50 bpm, Delay time = $(1/50\text{bpm}) \times 6 = 0.12 \text{ min} = 7.2 \text{ sec}$.
Upper limit of 119bpm, when measured continuous heart rate 120 bpm, Delay time = $(1/120\text{bpm}) \times 6 = 0.05 \text{ min} = 3 \text{ sec}$.

3. Verify

Red : Continuous operate transducer and to observe whether to produce prompt

Yellow : Execute admit patient flow, Not connected to the body directly to the transducer charging observed to generate prompts

Cyan-blue : Can in 10 seconds of test time of admission procedures of step 8 or step10 connect transducer and patient simulator, Adjusting the simulator output observation function correctly

4. Transmitter sound indicator

Indicate	Condition	Frequency
1 beep	~Transmitter start up ~Set-up completed	N.C.
2 beeps	~After 10 sec test, transmitter auto-sleep	N.C.
3 beeps	Transmitter closed	N.C.
Continuous beeps	Abnormal communication for 1~2 min's	About 4 times per second
3 beeps	Continuous communication failure over 2 min's	About once per minute

5. Transmitter LED indicator

Sign	LED status	Device status	Frequency
Blue	Flashing	Communication normal	About 1 time/ 4 sec.
Green	Flashing	Switch to other receiver	About 1 time/ 4 sec.
Red	Flashing	Receiver signal lost	About 1 time/ 4 sec.
		Low battery	About 1 time/ 4 sec.
Red	Continuous	Charging *	N.C.
Green	Continuous	Charging completed	N.C.
Blue+Green	Flashing	Auto-sleep to be restart by patient side	About 1 time/ 1 sec.
Red+Blue+Green	Flashing	Start to be set up	About 1 time/ 1 sec.

* Be sure to remove from body while charging