

Medpage ST-2 Epileptic Nocturnal Seizure Alarm

GENERAL OVERVIEW OF SYSTEM

The Medpage ST-2 is a monitor designed primarily to detect and raise an alarm from a sleeping person experiencing muscular convulsions such as an epileptic seizure or convulsions caused by hypoglycaemia in a diabetic person. The monitor can, in some cases detect a persons breathing and raise an alarm should breathing stop. Apnoea monitoring is described in more detail later. The ST-2 monitor uses patented technology that provides dual detection functionality. Seizure monitoring and breathing monitoring. A sensor is placed under the users mattress, bed or cot. During sleep normal movements are ignored by the sensor. Prolonged irregular movements result in an alarm being generated by the monitor. For breathing detection, the sensor detects the minute movements created by breathing. If breaths become very slow or stop altogether, the monitor will generate an alarm. The breathing monitor can be disabled. In breathing monitoring mode, the monitor will also generate an alarm should the user leave their bed. Seizure activity is detected in either operating mode.

INSTRUCTIONS FOR USE

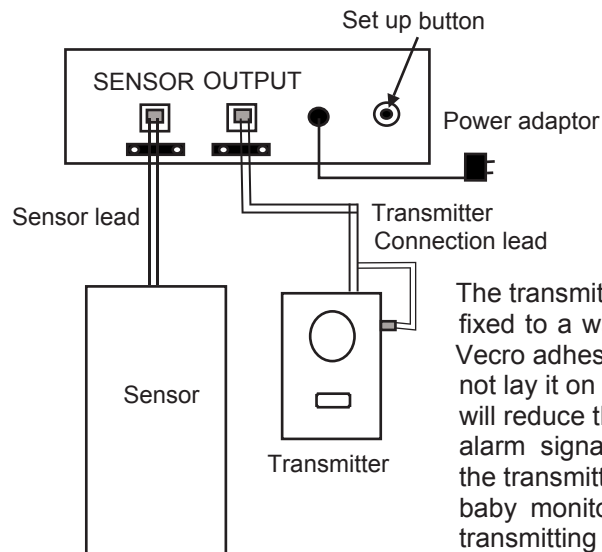
The ST-2 system comprises of: Bed movement sensor monitor. Bed movement sensor. Alarm transmitter. Alarm radio pager. Transmitter connection lead.

SETTING UP THE BED MOVEMENT SENSOR AND MONITOR

Do not plug in the mains power adaptor or switch on the monitor until advised to do so. The ST-2 monitor should be positioned on a bedside cabinet or table next to the users bed. It is not recommended to lay the monitor on the floor as this could reduce the alarm transmission signal range. The monitor has two rear sockets marked "SENSOR" and "OUTPUT". Each socket has a cable clamp. It is important that the cables are firmly clamped. Remove one screw from each clamp. Insert the sensor plug into the socket marked "SENSOR". Feed the cable through the clamp, replace the screw and lightly tighten the screws so that the cable is firmly clamped without crushing it. Repeat this process for the output lead. See diagram.

ALARM TRANSMITTER

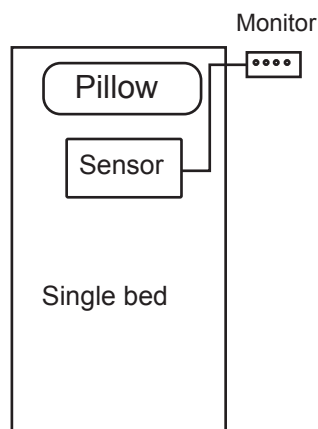
The alarm transmitter is connected to the ST-2 monitor with a connector lead as shown. The cable end with two plugs is for the transmitter. The telephone style plug is inserted into socket on the top, the DC jack plug is inserted into the DC socket on the side. There is a cable strain relief clip adjacent to the telephone style plug. The cable should be fed under the clip to prevent damage to the plug and socket.



POSITIONING THE SENSOR

Single bed When the sensor is used with a single bed, the breathing monitor may be used. **A single sensor should not be used for breathing monitoring in a double bed.**

The sensor should be positioned under the bed mattress of the user at a chest high position (not under the pillow) as shown in the diagram. The sensor lead should travel from the sensor to the bed head under the mattress. **Do not pull on the cable to move or remove the sensor from under the mattress as this will over time cause unnecessary wear to the sensor cable.**



The breathing movement monitoring element of the ST2 monitor is intended to ensure that the sensor is operating effectively and will alarm if breathing movement is not detected as a result of cessation of breathing movement, failure of the sensor or the subject leaving the bed; it is not intended as an apnoea monitor where there is immediate danger from cessation of breathing as it can be manually disabled where it is not appropriate.

SETTING UP THE ALARM PAGER

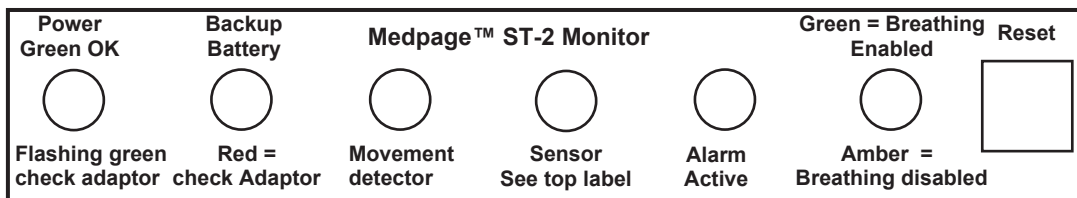
The pager has the following options: Tone alarm, volume adjustment, voice announcement of monitor number for use in multiple bed monitor set-ups with language selection, vibrate only, visual display of bed monitor number, low battery warning LED. The pager will have been set to English announcement of bed monitor alarm number during factory final inspection. The pager will automatically respond to all bed monitor transmitters.

SETTING THE PAGER

Remove the battery cover by sliding it sideways away from the main case. Insert the 2 x AA size batteries observing the polarity markings embossed in the battery compartment. Do not replace the cover just yet. Slide the power up towards the two musical notes 🎵. The display will show 000. In the battery compartment there is a switch labelled "Unlock" "Lock". Slide the switch to unlock (to the left). If you want tone sound only, press the Language button on the front of the pager until a tone only is heard. Slide the switch to lock (to the right), a pen or small screwdriver works well. If you require numeric announcement of monitor number, slide the switch to unlock, press the language button until "Number Zero" is announced in your preferred language. Slide the switch to "Lock", then replace the battery cover. Select the required volume by pressing the volume button. There are three volume levels. The volume setting is not protected by the "Lock" switch, always check that the volume setting is to your preferred level. When battery power becomes low, the green LED on the top of the pager will slowly flash green. This will continue for around two weeks or until batteries are replaced. The pager is on when the display is showing 000 or a monitor call number.

MONITOR INDICATORS

Before testing of the monitor familiarise yourself with the labelled LED indicators and what they indicate.



POWER LED

With the power adaptor plugged into the mains and power switched to on, the power LED will glow constant green. With the mains adaptor unplugged or during a power failure the power LED will flash slowly green. If there is no power failure check that the power adaptor is plugged into the mains supply and that the mains socket is switched on.

BACK UP BATTERY LED

The back up battery LED indicates the status of the back up battery. The back up battery is trickle charged when the mains power adaptor is plugged into a mains power socket regardless of the monitor being switched on or off. It will do no damage to leave the adaptor plugged into the mains supply permanently to ensure the back up battery is fully charged. The back up battery will be fully charged after a period of 12 hours. The back up battery will provide in excess of 24 hours back up in the event of a power failure. Should the monitor operate on battery only for a period of 24 hours or more the back up battery LED will begin to flash red slowly. Mains power should be restored as soon as possible. The monitor is designed to send an alarm signal to the pager should the power switch off altogether.

MOVEMENT DETECTOR LED

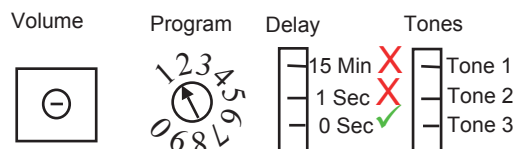
The movement detector LED will flash amber as body/breathing movements are detected. The movement detector LED does not respond immediately to rapid taps on the sensor. It is designed to indicate a breathing pattern lasting two seconds or more. To test the sensor out from the bed, press the sensor gently on its edges **DO NOT BASH IT**.

SENSOR LED

The Sensor LED indicates the status of the sensor. When the monitor has not been in use for a while and is switched on, the SENSOR LED will glow red until a movement is detected by a person laying on the sensor. When movement is detected the sensor LED will change colour from red to green, Should the sensor light not change to green check that the sensor plug is firmly inserted in the socket. See sensitivity set up and breathing monitor enable/disable.

FUNCTIONS OF THE ALARM TRANSMITTER

The alarm transmitter has many functions that are useful for patient care. In addition to providing alarm signals from the Medpage ST-2, the transmitter has a call button and a socket that allows connection of standard hospital type nurse call switches and some specialist easy operation switches for the physically disabled. The transmitter has a built in tone alarm that can be set to produce a sound alarm when a bed monitor has detected a seizure or cessation of breathing. The switch settings are described below. **DO NOT SET THE DELAY SWITCH TO ANY OTHER SETTING TO THAT INDICATED WITH THE GREEN TICK.**



The tones and volume settings refer to the built in sound alarm. If you do not require an alarm sound at the monitor turn the volume control fully clockwise using a small screwdriver.

WIRELESS TRANSMITTER FUNCTIONS AND INDICATORS

Reset Button The transmitter when activated by the ST-2 monitor, is reset by pressing in the reset button on the ST-2 monitor. If the call button on the transmitter is pressed with the ST-2 monitor power switched on, the transmitter can be reset by pressing the reset button on the ST-2 monitor. If the transmitter call button is pressed with the ST-2 monitor switched off, the transmitter reset button should be pressed.

Transmitter Low Battery The transmitter low battery warning indicates the status of the transmitter back up battery only. If the Low Battery warning begins to flash, the battery should be changed within 48 hours. Note: The ST-2 monitor also provides battery back up to the transmitter in the event of a mains power failure. The transmitter back up battery provides continued monitoring of the connection between the ST-2 monitor and the transmitter in the event of a mains power failure or serious monitor fault causing power cut off to the transmitter. The transmitter back up battery should always be in good condition to allow an alarm to be generated should a fault develop with the monitor. See (Powering Down The Monitor).

Pad Lost LED If the connector lead between the transmitter and ST-2 monitor fails for any reason, a bright flashing blue LED will be visible behind the transmitter call button. At the same time, the transmitter will continuously send alarm signals to the pager and produce a chirp sound until the transmitter is reset. Pressing the reset button on the ST-2 monitor will not cancel the alarm, you need to press the transmitter reset button. If the connection link is not repaired between the monitor and the transmitter, the Pad Lost LED will flash and a chirp sound will be produced by the transmitter until the connection is restored. Pressing the transmitter reset button again will cancel the alarm. Re-check the system before using the monitor.

Call Button The Call Button can be used as a patient help call button to send a signal to the pager independently of the ST-2 monitor. Press the call button, a bright blue light flashes behind the call button, if the alarm volume has not been set to silent, an alarm tone will sound until the transmitter reset button is pressed.

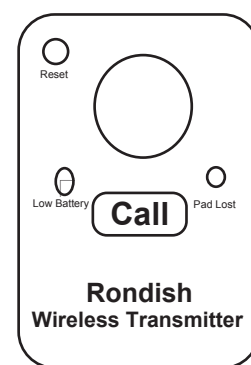
When the ST-2 monitor is in use, a faint blue light will flicker periodically behind the call button. The light confirms a good connection from the ST-2 Monitor to the transmitter.

NOTES AND GUIDANCE REGARDING POTENTIAL RADIO INTERFERENCE PROBLEMS

There may be occasions when radio interference can affect operation or performance of the the ST-2 system. It is quite common for parents or care homes to use baby monitoring systems. These are the devices that broadcast audio from one room to another so that care providers can listen in on the patient. These are the worst source of radio interference and can totally block low level alarm signals travelling through a building. If you experience signal problems with your ST-2 system (your pager does not respond to the alarm transmitter) and you use such a device, try turning it off, then retest your ST-2 system. The baby monitor may not be in the same room as the seizure monitor but it can still block the alarm signal.

To obtain maximum performance from your alarm transmitter it should be fixed to a wall using the supplied velcro stickers as high as the connector lead will allow. If you lay the transmitter on the floor or under the users bed, transmission range will reduce considerably. For domestic use this may not cause a problem. For use in larger care centres where longer transmission range is required signal repeaters are available.

Visit website www.medpage-ltd.com and search for ILB-03 Emergency Call Alarm.




PREPARING THE MONITOR FOR USE

When you are ready to use the monitor, slide out the battery compartment cover of the transmitter then insert the 9 V battery into the battery holder making sure that the battery removal tape is under the battery. This is a back up battery for the transmitter only.

BREATHING MONITOR TESTING

The ST-2 can in some cases detect and monitor breathing. There is no set of parameters to establish suitability of this feature with the patient other than an actual test. Bed types, mattress types, the users weight and size are all contributing factors. For example, a three year old child sleeping in a double bed would be considered beyond sensible risk. Likewise, a child of three years or younger sleeping in a single sized bed with a memory foam mattress would be considered a risk. A child of three years sleeping in a cot (crib) with a normal cot mattress could use the breathing function. The minimum weight for a child for cot use is 14 lb's. Seizure detection would still be possible in all examples. The following test can only be performed with the intended user laying on their own bed.

Providing you have followed the connections, pager set up and sensor placement instructions, a test can now be performed for breathing monitoring suitability. With a single sensor this applies to a single bed only. Breathing monitoring for a double bed can only be attempted with two sensors. Seizure activity can be detected on a double sized bed with a single sensor.

Switch the alarm pager to on . Ensure the ST-2 power adaptor is plugged into the mains and that the mains outlet socket is switched to on. Turn the monitor power switch to on by pressing it down. A green tab will be visible on the switch, the monitor internal beeper will operate briefly, the sensor LED will light red then flash red slowly until movement is detected, the Power LED will light constant green. The Breathing enabled LED will glow constant green if movement is detected.

Ask the user to lay on the bed in their normal sleeping position. The initial movement should result in the sensor LED changing colour from red to green. If breathing movements are detected the movement LED will flash amber approximately in time with breathing movements.

For a physically disabled person with limited or no motor skills, the monitor can be set up as described, then position the person on their bed, then switch the monitor on.

The monitor samples movements over 10 second intervals. If no movement (breathing) is detected during a 10 second period an amber flash will be visible from the Sensor LED. Providing a breathing movement is detected within the next six seconds, the monitor will reset and begin again. If, after the amber LED starts flashing no movement is detected the sensor LED will light constant red and all alarm outputs will become active. The transmitter will send a signal to the alarm pager and the transmitter audible alarm will sound (unless set to silent) until the rest button is pressed on the monitor. The monitor reset button resets the monitor and the transmitter.

If breathing movements have been successfully detected with the user laying on the bed and breathing normally then the breathing function can be used. Proceed to seizure testing.

If no movement is detected and the monitor goes to alarm, a sensitivity adjustment can be attempted. If after adjustment the test fails again then the breathing function must be disabled as detailed in the following sections.

ADJUSTING SENSITIVITY OF THE MOVEMENT SENSOR

ADJUSTMENT OF THE SENSITIVITY CAN ONLY BE PERFORMED WHEN THE MONITOR IS OPERATING FROM MAINS POWER. NOTE: Adjusting the sensitivity increases sensor gain for breathing monitor only. Seizure detection sensitivity is automatic. To adjust the sensitivity the monitor needs to be switched on. Press and hold in the setup (rear) and reset (front) buttons together until a single beep is heard from the monitor. Let go of both buttons. The breathing LED will flash red/amber to confirm set up mode. Press and hold in the reset button (front) the breathing LED will cycle through green, amber and red. Green is most sensitive red is the least sensitive. When the LED lights to the colour (sensitivity) you require let the button go. Press and hold in the Setup and Reset buttons until two beeps are heard from the monitor. Let go of the buttons. You can check the sensitivity setting by pressing in the reset button on the front of the monitor. If the LED stays green when the button is pressed then it is set on maximum sensitivity, amber medium and red minimum.

Repeat the procedure for breathing test as detailed in last section. If successful proceed to seizure test. If not disable the breathing monitor function as detailed in next section.

DISABLING BREATHING MONITOR FUNCTION

Press and hold in the setup (rear) and reset (front) buttons together until a single beep is heard from the monitor. Let go of both buttons. Press and hold in the rear set up button until the breathing monitor LED changes colour from green to red/amber. Release the button. Press and hold in the Setup and Reset buttons until two beeps are heard from the monitor. Let go of the buttons. The breathing LED should now be amber/red. If not repeat the procedure.

SEIZURE DETECTION TEST

With the monitor switched on and set up as described on page 1, ask the user (if physically able) to simulate seizure movement. This need not be violent thrashing, simple rocking from side to side on the bed will be detected. Observe the sensor LED. When irregular movements are detected for a period exceeding 15 seconds the Alarm Active LED will light to indicate seizure detected and all alarm outputs will become active. The transmitter will send a signal to the alarm pager and the transmitter audible alarm will sound (unless set to silent) until the reset button is pressed on the monitor. The monitor reset button resets the monitor and the transmitter.

EVENTS THAT CAUSE AN ALARM TRIGGER TO THE ALARM PAGER

- 1 BREATHING OR LACK OF MOVEMENT 18 SECONDS APPROXIMATELY (IF ENABLED)
- 2 SEIZURE DETECTION - IRREGULAR MOVEMENT FOR 15-20 SECONDS
- 3 MONITOR ALARM SWITCH SET TO OFF - PRESS THE TRANSMITTER RESET BUTTON TO STOP ALARM
- 4 SENSOR REMOVED OR DAMAGE TO SENSOR IN BREATHING MODE
- 5 PATIENT LEAVES THEIR BED - ALARM WILL RESULT AFTER 20 SECONDS (Breathing enabled).

POWER DOWN - SWITCHING OFF THE SYSTEM

If the patient is not going to be in their bed and the breathing monitor is enabled, the monitor should be turned off. Turn the monitor power switch to off. A signal will be transmitted to the pager. Press the transmitter reset button. Note: If the transmitter audible alarm is set to silent, it is possible to accidentally leave the transmitter operating. This will cause the back up battery to run down very quickly. Make sure that you press the transmitter reset button if the monitor is switched off and will not be in use for a while. If the monitor is not likely to be used for several days, remove the back up battery from the transmitter to save battery power. The back up battery is not charged by the monitor and should only be replaced with a good quality 9V Alkaline or Lithium battery.

A system test should be performed prior to each period of use. It is not necessary to simulate a seizure each time. Check the volume level of the pager. Switch the monitor on with the user in their bed. Turn the monitor off. An alarm signal will be set to the pager. Press the transmitter reset button. Turn the monitor back on after 3 seconds. System on and monitoring.

Any problems should be reported to your distributor immediately or by contacting the manufacturer as detailed on the foot of the first page of this manual.

Declaration of Conformity to:

Medical Device Directive 93/42/EEC as amended 2007/47/EC
and the R&TTE Directive 1999/5/EC

For Epilepsy Monitors MP2, MP5, MP6 and ST2

This is to certify that the class IIa equipment specified above conforms to the above Directives as transposed in to national regulations and statutes of the United Kingdom, such compliance having been demonstrated via:

- A Technical File compliant to 93/42/EEC Annex VII
- Compliance to the Essential Requirements as per 93/42/EEC Annex I
- Compliance to 93/42/EEC Annex V Production Quality Assurance
- Quality Assurance procedures in accordance with BS EN ISO13485:2003

The CE marking of product being subject to the achievement and maintenance of certification to 93/42/EEC Annex V by BSi, Notified Body 0086, Certificate number CE 80927.

Based on assessment of compliance to:

BS EN 60601-1 Electrical Safety for Medical Devices
BS EN 60601-1-1 Electrical Safety for Medical Systems
BS EN 60601-1-2 EMC for Medical Devices
BS EN 301489-1 Electromagnetic Radio Spectrum Matters
BS EN 301489-3 Electromagnetic Radio Spectrum Matters
BS EN 300220-1 Electromagnetic Radio Spectrum Matters Short Range Devices
BS EN 300220-3 Electromagnetic Radio Spectrum Matters Short Range Devices

This is to certify that the above statement is true and relates to product manufactured from this date.

Signed  Authorised Management Representative

Name Mr M Dines

Date 11 August 2009

Being a duly authorised officer of the Company

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