

VitalSim Directions for Use

Overview and Intended use.

The VitalSim™ Base Unit and Remote Control are intended to be used in conjunction with an approved manikin to simulate vital signs on the manikin.



The system consists of a Base Unit, connecting to a manikin, and a radio controlled Remote Control for device operation. Both the Base Unit and the Remote Control are battery operated. The Base Unit can also be used with an AC wall adapter.

VitalSim System includes:

- Carry Case
- Base Unit including battery case and batteries (6 C-cell)
- Remote Control including batteries (4 AA-cell)
- Remote Control to Base Unit connection cable
- USB cable for connection to PC
- DC power supply
- Direction for Use
- Operating Software on CD-ROM

Important Information

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.

NOTE: 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.
- Consult the dealer or an experienced radio/TV technician for help.
- 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: Changes or modifications not expressly approved by Laerdal could void the user's authority to operate this equipment.



Hereby, Laerdal Medical declares that when carrying the CE-mark, the VitalSim product is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC.

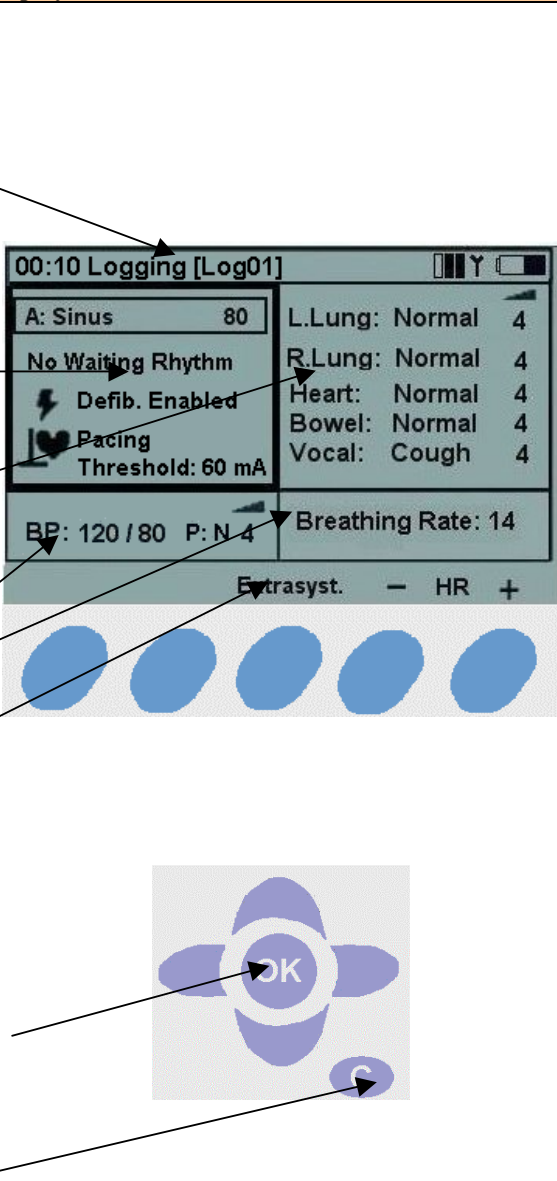
Use with Laerdal Manikins
The VitalSim is designed to work with a variety of manikins manufactured by Laerdal. The manikins range from adult, child and infant advance life support manikins to nursing manikins. The VitalSim will detect which type of manikin is connected and adjust physiological and menu functions accordingly. Selection of manikin can be overridden from the Setup Menu.

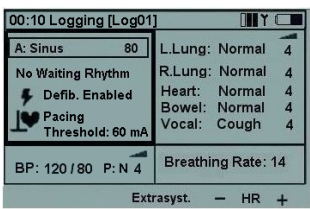
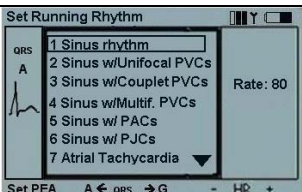
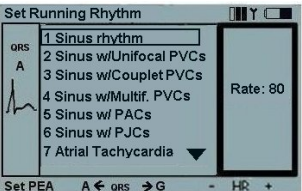
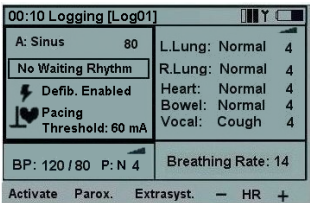
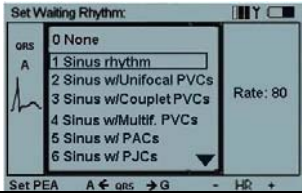
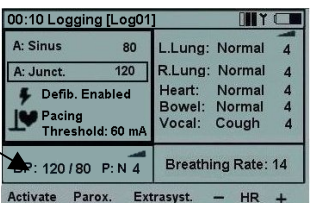
Features
ECG/Defib/Pacing Extensive ECG library. Running rhythm and a Waiting Rhythm that can be activated on command or after a defibrillation External pacing detection with settable pacing threshold 20 – 200 mA External defibrillation (10-360 J), may affect preprogrammed scenario or lead to direct ECG rhythm change
Heart, Lung, Bowel and Spoken Sounds Heart Sounds synchronized with ECG. Lung sounds synchronized with adjustable breathing rate, 0 – 60 BPM. Individual lung or bilateral sound selection. Normal and abnormal bowel sounds. Computer generated sounds, mixed with voice input via microphone.
Blood Pressure Auscultated and palpated blood pressure simulator. Korotkoff sounds synchronized with ECG. Systolic and diastolic pressure individually settable in steps of 2 mmHg up to 300 mmHg. Auscultative Gap, On / Off feature. Calibration function.
Palpated Pulses Controls Brachial, Radial, and Carotid pulses. Pulses synchronized with ECG and pulse strengths dependent on BP. Systolic BP can be palpated on radial pulse. Only 2 pulses active at a time, to save power. Brachial pulse turned off when BP cuff inflated (to avoid sound interference).
Scenario Function Possible to program, upload, and run scenarios on the VitalSim Base Unit. Using a PC Scenario editor. Up to 10 programmable scenarios at one time.
Logging Generate 25 logs for after action review. Log(s) can be retrieved by a PC through the USB connection

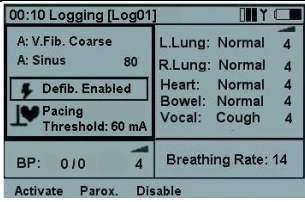
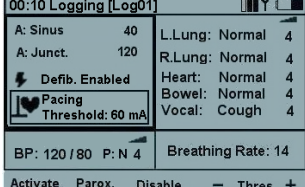
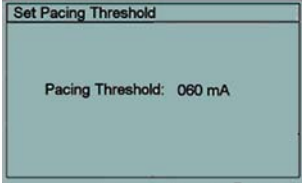
Overview VitalSim Base Unit	
A. On/Off button and Indicator. The button turns the unit on and initiates pre-set vital signs. Press once to turn the unit on. Press again to turn the unit off. The indicator is steady green if it has contact with the Remote Control. If there is no contact with the Remote Control the indicator will be blinking green. If battery needs to be replaced, the indicator will blink, alternating between green and orange.	
B. DC power supply: Use this feature for stationary training and to limit battery consumption. The DC power supply is supplied with VitalSim	
C. Manikin Connector: Connects the Base Unit to the manikin or peripheral accessories. Supplied with manikins.	
D. Microphone: External microphone attachment, sold separately.	
E. USB port: Used for downloading scenarios and uploading of log's.	
F. Remote connector: Used for direct communication with the Remote Control.	
G. Blood Pressure connector: Connects the blood pressure hose from BP-cuff.	
H. Battery: Holds (6) replaceable C-cell batteries.	

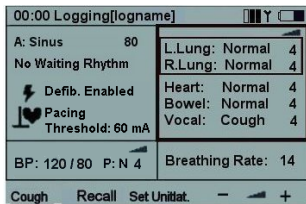
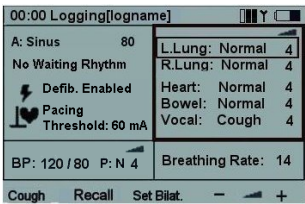
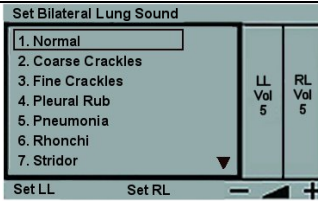
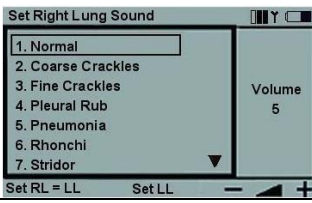
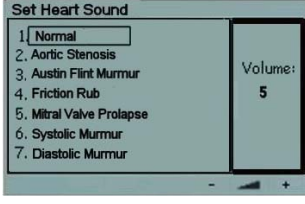
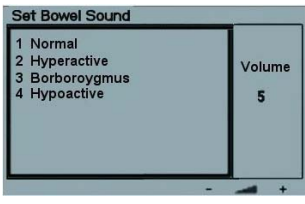
Overview VitalSim Remote Control	
The Remote Control communicates with the VitalSim Base Unit via a short-range radio link. Range from Remote control is approximately 10m / 30 ft. 5 Different channels can be selected to improve immunity to interference and allowing for use of several units within the same area.	
I. LCD display: Displays vital information and activated features such as ECG, Sounds, Blood pressure, Scenarios, Logging, etc.	
J. Function keys: Use these keys to implement quick functions, i.e. set Rate, Volume, PEA, activate waiting rhythm, etc.	
K. Navigation keys: Use these keys to navigate your way through programming phases of operation and to select various functions.	
L. OK / Select key: Use this key to activate specific desired functions and to execute programming.	
M. Cancel/Back key: Go back from sub menus without any changes.	
N. Numerical keys: Use these keys to program user name for logging, or to select numerical entries. Example: To set volume level to (9), simply touch the number key (9) to initiate.	
O. Menu/Setup: Use this key to set up your VitalSim to specific manikins, i.e. adult, child and infant. Also sets up user features such as backlight and disables functions.	
P. Scenario key: Use this button to start scenarios.	
Q. Shift key	
R. On/Off key: Turns the unit. Press once to turn the unit on. Press again to turn the unit off. Remote Control can be turned off and back on without affecting the	

Start	
Once your manikin has been connected to the VitalSim, turn the Base Unit and Remote Control on. The VitalSim will automatically detect the connected manikin and set the initial parameters accordingly.	

Main Display	
The main presents the current status, and allows for modifying some parameters directly using the function keys.	
The main display is divided into five functional areas and a function key area.	
The upper area is the Logging and Scenario status area. The log status and clock is presented here together with the Remote Control battery status and a Radio reception indicator.	
The ECG section is indicating Running Rhythm on the first line, Waiting Rhythm on the second line. “Defib. Enabled” allows change to Waiting rhythm when a defibrillatory shock is given.	
Pacing capture can be enabled / disabled and if enabled the threshold for capture can be set.	
The sounds section control the selected Lung, Heart, Bowel and _Vocal (spoken) sounds. Volume of each sound can be controlled individually.	
The BP Section shows the set BP, pulse strength and the Korotkoff sound volume.	
The breathing rate sections shows the set breathing rate.	
At the bottom of the display are the function keys menus. The functions will change dependent on which function area is selected.	
Using left to right navigation keys, highlight the desired functional area of the display. Once the desired function area is highlighted, use the up and down navigation keys to scroll through to the desired selection. Once the desired selection is highlighted, push the OK key to edit the settings.	
When the selection is complete, press the “OK” button to implement the new selection and return to the main display.	
To cancel the selection, press “C” and return to the main display with the previous setting unchanged.	

Programming ECG	
Set Running Rhythm On the main display; using the left / right navigation keys highlight the ECG functional area and press the OK key to edit the rhythm. Note: you are also able to change some functions using the function keys instead of entering the functional area: • “HR+” and “HR-“ Changes the heart rate up and down. • “Extrasyst.” generates an extrasystole of the selected kind (on Sinus rhythms only), immediately after the button is pushed. If no extrasystole is selected, a Unifocal PVC will be generated.	
The ECG rhythm can be selected using the Up / Down keys or the numerical keys. The arrow on the bottom right of the selection field indicates that there are more selections than presented on the screen. Rate and QRS type can be modified using the function keys, OR By highlighting the QRS or Rate area using the Left / Right keys and then use the numeric pad or up/ down keys. QRS types can be set to A through G:  Available rates are dependent on the selected rhythm. Setting PEA sets the BP to 0.	 
Set Waiting Rhythm On the main display; using the left to right navigation keys highlight the ECG functional area and scroll down to Waiting rhythm; push the OK key to edit the selection.	
Select a Waiting rhythm in the same manner that the Running rhythm is selected. Not that Waiting rhythm has “None” as an option.	
When a Waiting rhythm is selected, 2 additional function keys appear on the ECG menu: • “Activate” Activates the Waiting rhythm, substituting the Running with the waiting. • “Parox.” Activates the Waiting rhythm, and exchanges the Waiting rhythm with the running.	

Enable / Disable the Effect of Defibrillation When “Defib. Enabled” is selected; the Waiting rhythm will be automatically activated and replace the Running rhythm when a shock is delivered to the manikin. When the “Defib Enable” field is selected, Enable /Disable is selected by toggling the “OK” button or the function key labeled “Disable” / “Enable”	 00:10 Logging [Log01] A: V.Fib. Coarse A: Sinus 80 Defib. Enabled Pacing Threshold: 60 mA BP: 0 / 0 4 Breathing Rate: 14 Activate Parox. Disable
Pacing If pacing is enabled, pacing pulses on the manikin with a current higher or equal to the set threshold will activate heartbeats. Pacing threshold can be adjusted directly from the main display using the “Thres. +/-” function keys when the “Pacing” field is selected.	 00:10 Logging [Log01] A: Sinus 40 A: Junct. 120 Defib. Enabled Pacing Threshold: 60 mA BP: 120 / 80 P: N 4 Breathing Rate: 14 Activate Parox. Disable - Thres. +
Pressing the “OK” button, the Pacing threshold can also be adjusted in a sub menu. Threshold can be adjusted using the Up/ Down keys, the “Thres.+/-” keys (steps of 10) or entered directly using the numerical keys.	 Set Pacing Threshold Pacing Threshold: 060 mA Min. Max. - Thres. +

Sounds	
On the main display; using the left / right navigation keys highlight the sounds functional area. The sound volume for the selected / highlighted sound can be set directly from the main display using the “-“ and “+“ function keys. The selected Vocal sound can be activated using the function key. (When Cough is the selected vocal sound, the function key would be labeled “Cough”). The “Recall” function key reactivates the previously selected sound for the highlighted sound category.	
Set Lung Sounds Normally Right and Left lung sounds are highlighted together indicating that the sound for the right and left lung is set the same (bilateral). To set Right and Left sounds individually, press the “Set Unilat.” function key. When the sounds are reset to bilateral, the sound in the Right lung will be used for both lungs. To alter a lung sound, highlight the sound and press the “OK” button. This will activate the sound selection sub-menu.	
The sounds can be selected using the Up/Down keys or using the numeric keypad. The arrow on the bottom right of the selection field indicates that there are more selections than presented on the screen. Volumes can be set using the “+” / “-“ function keys, or by highlighting the volume field and use the up/down keys or the numeric keypad. “Set LL” and “Set RL” function keys are alternative ways to select individual (unilateral) lung sounds. Press “OK” to implement the new selection And return to the main screen. Press “C” to return without any changes.	 
Set Heart Sounds Heart sounds are set in the same manner as Lung sounds. On the main display; using the left to right navigation keys highlight the sounds functional area. Scroll down to the Heart sound. Use the “+”/”-“ keys to alter volume directly, or “Recall” to recall the previously selected Heart sound. Press the OK key to get to the Heart sounds selection menu.	
Set Bowel Sounds Bowel sounds are set in the same manner as Lung and Heart sounds. On the main display; using the left to right navigation keys highlight the sounds functional area. Scroll down to the Bowel sound. Use the “+”/”-“ keys to alter volume directly, or “Recall” to recall the previously selected Bowel sound. Press the OK key to get to the Bowel sounds selection menu.	

Set Vocal Sounds

On the main display, using the left to right navigation keys highlight the Sounds functional area.

Notice that whenever the Sounds area is selected, the selected Vocal sound can be activated using the Function key. Most sounds are activated once. The continuous sounds are toggled on off.

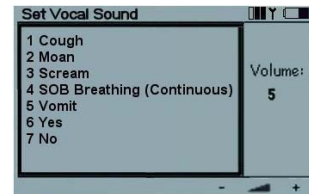
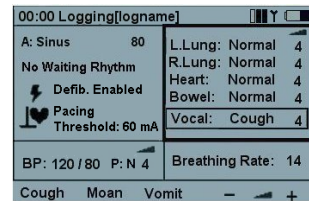
To alter the Vocal sound, scroll down and highlight "Vocal".

Note that when "Vocal" is selected, the three last used sounds are available as function keys.

Use function keys to activate a new sound directly or press the OK key to get to the Vocal sounds selection menu.

Some vocal sounds are continuous. A continuous sound will be repeated until the sound is selected again or another sound is activated.

Use the "+" / "-" keys to alter volume directly.



Blood Pressure and Pulse

Blood pressure and pulse are related as described in specifications.

The "Normal" pulse can in addition be adjusted to 3 levels, Weak, Normal or Strong. If the pulse is set to be normally weak, a weak pulse because of low BP will be almost impossible to detect.

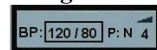
If an ECG rhythm with no BP is set (i.e. VF, or Asystole) as the Running rhythm, BP will automatically be set to 0/0. The BP is not automatically set back to normal if a perfusing rhythm is chosen.

Set Blood Pressure

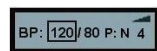
On the main display, using the left to right navigation keys highlight the **Blood Pressure** functional area.

Press the OK key to activate the BP menu or adjust BP directly using the BP +/- function keys:

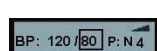
Using the BP +/- keys:



When both Systolic and Diastolic are highlighted, both pressures will change and maintain difference.



When systolic is highlighted, only systolic will change, but diastolic will be kept 10 mmHg below systolic.



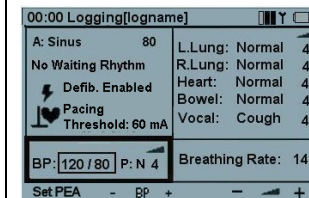
When diastolic is highlighted, only diastolic will change, but systolic will be kept 10 mmHg above diastolic.

The Up/ Down keys are used to change selection.

"Set PEA" function key will set BP to 0/0. "Reset PEA" will set the BP back to what it was before "Set PEA" was selected.

Use the "+" / "-" keys to alter volume of Korotkoff sounds directly.

Pulse strength is indicated as "P:N" (Normal), "P:W" (Weak) or "P:S" (Strong)



Set BP menu:

Use Left / Right keys to select function.

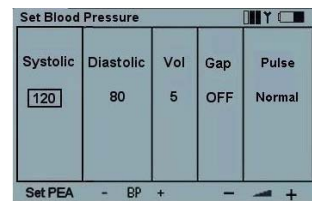
Systolic and Diastolic BP can be adjusted using the Up/ Down keys, the “BP +/-” keys or entered directly using the numerical keys.

If running rhythm is VF or Asystole, BP cannot be set.

Volume can be adjusted using the “+/-” or the Up/ Down keys or directly through the numeric keypad.

Auscultatory Gap (Korotkoff sound disappears in part of Phase II) can be toggled On / Off using the Up/ Down keys.

Pulse strength can be adjusted using the Up/ Down keys.



Breathing Rate

Breathing rate is automatically set to 0 if BP is 0. The breathing rate is not automatically set back to normal if a BP set.

Breathing rate can be adjusted between 0 and 60 breaths per minute.

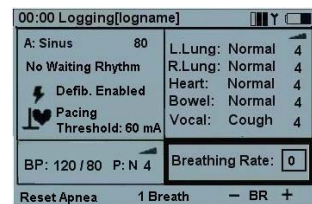
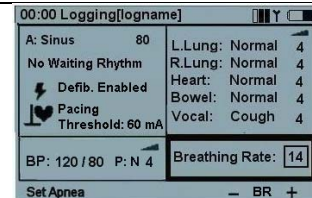
Set Breathing Rate

On the main display; using the left to right navigation keys highlight the **Breathing rate** functional area.

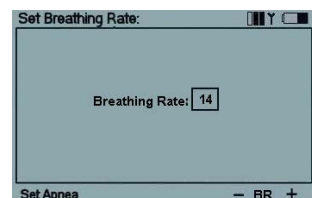
Press the OK key to activate the Breathing rate menu or adjust BR directly using the **BR +/-** function keys.

“**Set Apnea**” function key will set breathing rate to 0. “Reset Apnea” will restore the previously set breathing rate.

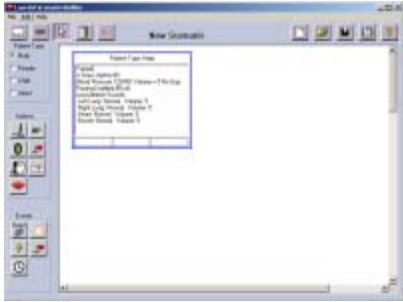
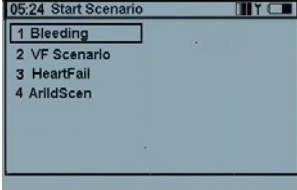
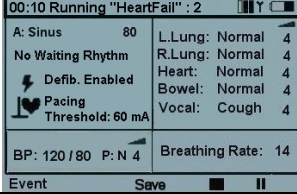
When Breathing rate is 0, the function key “**1 Breath**” becomes available. This function will activate one breath cycle, allowing for generating breath sounds on the manikin in synchronism with forced ventilations.



Breathing rate can be adjusted using the Up/ Down keys the “BR +/-” keys (steps of 5) or entered directly using the numerical keys.



Log	
05:24 Logging [logname] The top section of the main display controls log and scenario. The VitalSim automatically generates a log of events from it is turned on. Elapsed time and name for the current log is displayed in the upper left corner of the display. Unless saved, the log will be erased when the Base unit is turned off. The Log / Scenario section have controls for Pause and Resume, Restart and Save logs. In addition it is possible to log “Manual” events from the Remote Control.	
Saved logs can be retrieved later using the VitalSim PC utility program. Logs can be transferred to the PC for permanent storage, addition of comments and printing.	
Log Controls On the main display; using the left to right navigation keys highlight the logging functional area. Press the OK key to activate the Log Control menu or select functions directly from function keys. Pause. Stops the clock. Any events or changes in settings will not be logged. Resume logging and clock. Restart. Restart the log. Erase current log.	
Save Log. Saves the current log. Log is given a default name by VitalSim, “Logxx”, where xx is a sequential number. This name can be modified, using the backspace function key and the alphanumeric keyboard. Up to 25 logs can be saved. Logs are erased when transferred to PC, or they can be erased using the “Clear All Logs” function.	
Log Events The Event function allows for entering an event into the log. The events are chosen from a list of up to 14 events stored in the Remote Control. To log an event, select the event using the arrow keys, and press the OK button. The first seven events are preprogrammed. They can be deleted using the “Delete” function key then be reprogrammed by the user. The “Default” function key restores the factory setting of preprogrammed events. The last seven events are left open (“---”) for the user to program. To program an empty event, highlight the event and press the “Add” function key. Enter the event name using the alphanumeric keys and the backspace function key. The shift key is functional. Up to 13 characters can be used for the event name.	

Scenario	
The VitalSim can run preprogrammed scenarios, generated on a PC-based scenario builder program. These scenarios can be transferred too the Base unit using the VitalSim PC utility program. Execution of a scenario is started using the “Scen” button on the Remote Control. Logs and Scenarios are synchronized in the following manner: • A new log is started when a scenario is started. • Pause and Resume affects both scenario and log.	
To start a scenario, press the “Scen” button. It usually takes a little time to transfer all the scenario information to the Remote Control. Select the desired scenario and press OK. The scenario will start, the clock is set to 0 and a new log is started. The current log will be erased.	
	

Specifications

Remote Control:

Batteries: 4 AA type (LR6) Alkaline batteries.
 Battery life: Approximately 20 hours.
 LCD display: High Resolution B&W LCD display.
 Backlight can be turned On / Off in Setup menu.

Base Unit:

Batteries: 6 C type (LR14) Alkaline batteries
 DC input: 9V DC, 1.5 A max
 Sound input: Line input level.
 Cuff pressure input: 0 – 300 mm Hg.

RF Communication:

Frequency ranges. Europe version 868,0 – 868,6 MHz
 US version 915,5 – 916,4 MHz

Operation range: 10 m (30 ft) max.

ECG rhythms:

Available ECG Rhythms:

Rhythm	Adult Manikin		Child Manikin		Infant Manikin	
	Rates	Default Rate	Rates	Default Rate	Rates	Default Rate
Sinus	20-200	80	20-200	90	20-200	100
Sinus w/ Unifocal PVCs*	20-200	80	20-200	90	20-200	100
Sinus w/ Couplet. PVCs*	20-200	80	20-200	90	20-200	100
Sinus w/ Multifocal PVCs*	20-200	80	20-200	90	20-200	100
Sinus w/ PACs*	20-200	80	20-200	90	20-200	100
Sinus w/ PJC*s*	20-200	80	20-200	90	20-200	100
Atrial Tachycardia	140-260	180	140-320	180	140-320	180
Atrial Flutter	75-150	100	75-150	100	75-150	100
Atrial fibrillation*	60-200	160	60-320	160	60-320	160
Junctional	30-160	50	30-160	50	30-160	50
Idioventricular	10-60	40	10-60	40	10-60	40
Ventricular Tachycardia	120-240	180	120-320	180	120-320	180
Ventricular Fibrillation	V-Coarse, Coarse, Std, Fine, V- Fine	N/A	V-Coarse, Coarse, Std, Fine, V- Fine	N/A	V-Coarse, Coarse, Std, Fine, V- Fine	N/A
Asystole	N/A	N/A	N/A	N/A	N/A	N/A
1° AV-Block	20-200	80	20-200	80	20-200	80
2° AV-Block type 1 **	50 @3:1 60 @3:1 75 @ 2:1	60	50 @3:1 60 @3:1 75 @ 2:1	60	50 @3:1 60 @3:1 75 @ 2:1	60
2° AV-Block type 2 **	60 @3:1 70 @3:1/2:1 90 @1:1	60	60 @3:1 70 @3:1/2:1 90 @1:1	60	60 @3:1 70 @3:1/2:1 90 @1:1	60
3° AV-Block - Wide QRS on rate 30	30, 50, 60	50	30, 50, 60	50	30, 50, 60	50
Pacemaker - Vent. Pacemaker. - No atrial activity.	80	80		80		80

* Rates are nominal ventricular rates. Actual rate may vary with occurrences of extrasystoles.

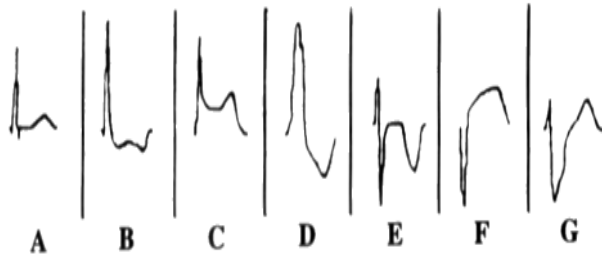
** Rates are nominal atrial rates. Effective ventricular rate will be lower. “@ 2:1” indicates ratio between conducted and not conducted p-waves.

Specifications

QRS Types:

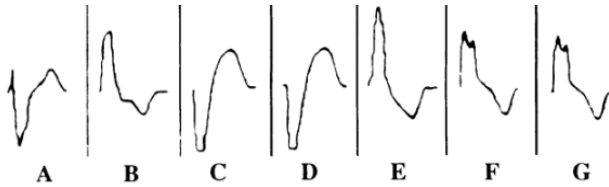
There are seven different QRS waveforms named "A" to "G" which can be selected. Available QRS types vary with each Basic rhythm.

Supraventricular QRS types for: Sinus, A-tach, A-flutt, A-fib, Junctional, 1°AVB, 2°AVB types 1 and 2, 3°AVB (high rates), Atrial Pacemaker, PACs and PJs



- A.** Normal upright QRS-T.
- B.** Upright QRS with ST depression and T inversion.
- C.** Upright QRS with ST elevation.
- D.** BBB. Broad R-wave with T inversion.
- E.** Biphasic QRS with T inversion.
- F.** QS with ST elevation.
- G.** BBB. Broad R-wave with upright T.

Ventricular QRS types for: Idioventricular, V-Tach and PVCs:



- A.** Broad rS wave.
- B.** Broad R wave.
- C.** Broad QS wave
- D.** Broad QS wave. Same as C.
- E.** Broad R wave.
- F.** Broad Rr Wave.
- G.** Broad Rr Wave. Same as F.

Heart sounds:

Heart sounds are synchronized to ECG.

Available Heart sounds.

Heart sounds:	Adult Manikin	Child Manikin	Infant Manikin
Normal	√	√	√
Aortic Stenosis	√	√	√
Austin Flint Murmur	√	√	√
Mitral Valve Prolapse	√		
Systolic Murmur	√	√	√
Diastolic Murmur	√		
Friction Rub	√		
Opening Snap @70 msec	√		
Still's Murmur		√	√
Atrial Septal Defect (ASD)		√	√
Ventricular Septal Defect (VSD)		√	√
Pulmonary Stenosis			√

Specifications

Lung sounds:

Lung sounds are synchronized to breathing rates, adjustable from 0 – 60 breaths / min.

Available Lung sounds.

Lung sounds:	Adult Manikin	Child Manikin	Infant Manikin
Normal Breath Sounds	√	√	√
Fine Crackles	√	√	√
Coarse Crackles	√	√	√
Pneumonia	√	√	√
Wheeze	√	√	√
Stridor	√	√	√
Pleural Rub	√		
Rhonchi	√	√	√

Bowel sounds:

Available bowel sounds.

Bowel sounds:	Adult Manikin		Child Manikin	Infant Manikin
	Male	Female		
Normal	√	√	√	√
Borborygmus	√	√	√	√
Hyperactive	√	√	√	√
Hypoactive	√	√	√	√
Fetal Normal 140 BPM		√		
Fetal Brady 100 BPM		√		
Fetal Tachy 200 BPM		√		

Vocal sounds:

Vocal sounds are adjusted for age and gender of manikin.

Male Manikin	Female Manikin	Child Manikin	Infant Manikin
Vomit	Vomit	Vomit	Cry
Cough	Cough	Cough	Scream
Moan	Moan	Moan	Content
SOB Breathing	SOB Breathing	SOB Breathing	Hickup
Scream	Scream	Scream	
Yes	Yes	Yes	
No	No	No	

Specifications

Blood Pressure:

Pressure range	0 - 300 mmHg
Accuracy	+/- 4 mmHg
Calibration:	Pressure sensor must be calibrated to sphygmomanometer. See Setup menu.

Pulse:

Available pulses:	Carotid, Brachial and Radial Only 2 pulses can be palpated simultaneously. (Power considerations).
Palpated BP:	Radial pulse turns off at systolic BP. Brachial pulse turns off at 20 mmHg, to prevent noise generation in auscultation area.

Pulses are adjusted to BP as follows:

Systolic BP	Carotid Pulse	Radial/Brachial Pulse
>= 88	Normal	Normal
< 88	Normal	Weak
< 80	Normal	Absent
< 70	Weak	Absent
< 60	Absent	Absent