SHL
Telemedicine International Ltd.

RIVER-1
User Manual

⚠	**Caution** Federal Law restricts the use of this device by or on the order of a physician.

Version 9.v
May 29th, 2007 (Draft)

The content of this user manual is subject to change. Please inquire with the medical call center for any possible updates.

	Note
	**It is strongly recommend that you read this manual carefully and in its entirety before using the River-1 device for monitoring. A thorough understanding of the operation and use of the River-1 is required for correct and accurate heart monitoring.**

In case of any doubts or questions regarding the use of this device, do not hesitate to call our medical call center for support:

 **800 227 3462**

Write down your physician's telephone number in the space provided below

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Indications for use

The River-1 is indicated for the evaluation of patients who experience transient symptoms such as dizziness, palpitations, syncope, or chest pain that might suggest arrhythmia. The device is intended to record cardiac activity associated with these infrequent and transient symptoms. Once the data is recorded, the patient transmits this ECG data over the telephone or cellular network to a remote central receiving station to be reviewed by a healthcare professional.

- **DO NOT use the River-1 to replace regular physician care.**
- **The River-1 is intended for use by only the registered user and should NOT be shared with others.**
- **Patients unwilling or unable to follow the instructions detailed in this manual should refrain from using the River-1.**

	Caution for use in conjunction with other medical devices
	1. <u>Pacemakers or internal cardiac defibrillators:</u> The River-1 device contains an antenna and cellular modem for transmitting data through the cellular telephone network. To avoid any potential interference, carriers of pacemakers or internal cardiac defibrillators, should maintain a distance of at least 6 inches (15 centimeters) from any implanted medical device. There are no known personal safety hazards due to the use and operation of a cardiac pacemaker, internally implanted defibrillators or other electrical cardiac stimulators with the River-1. 2. <u>External cardiac defibrillators:</u> DO NOT use the River-1 in combination with an external cardiac defibrillator or high frequency surgical equipment. Disconnect the patient leads from the electrodes prior to performing external defibrillation or using electro surgical equipment. 3. <u>Hearing aids:</u> Maintain a minimal distance of 6 inches (15 centimeters) between the River-1 and hearing aids to avoid potential interference

Table of Contents

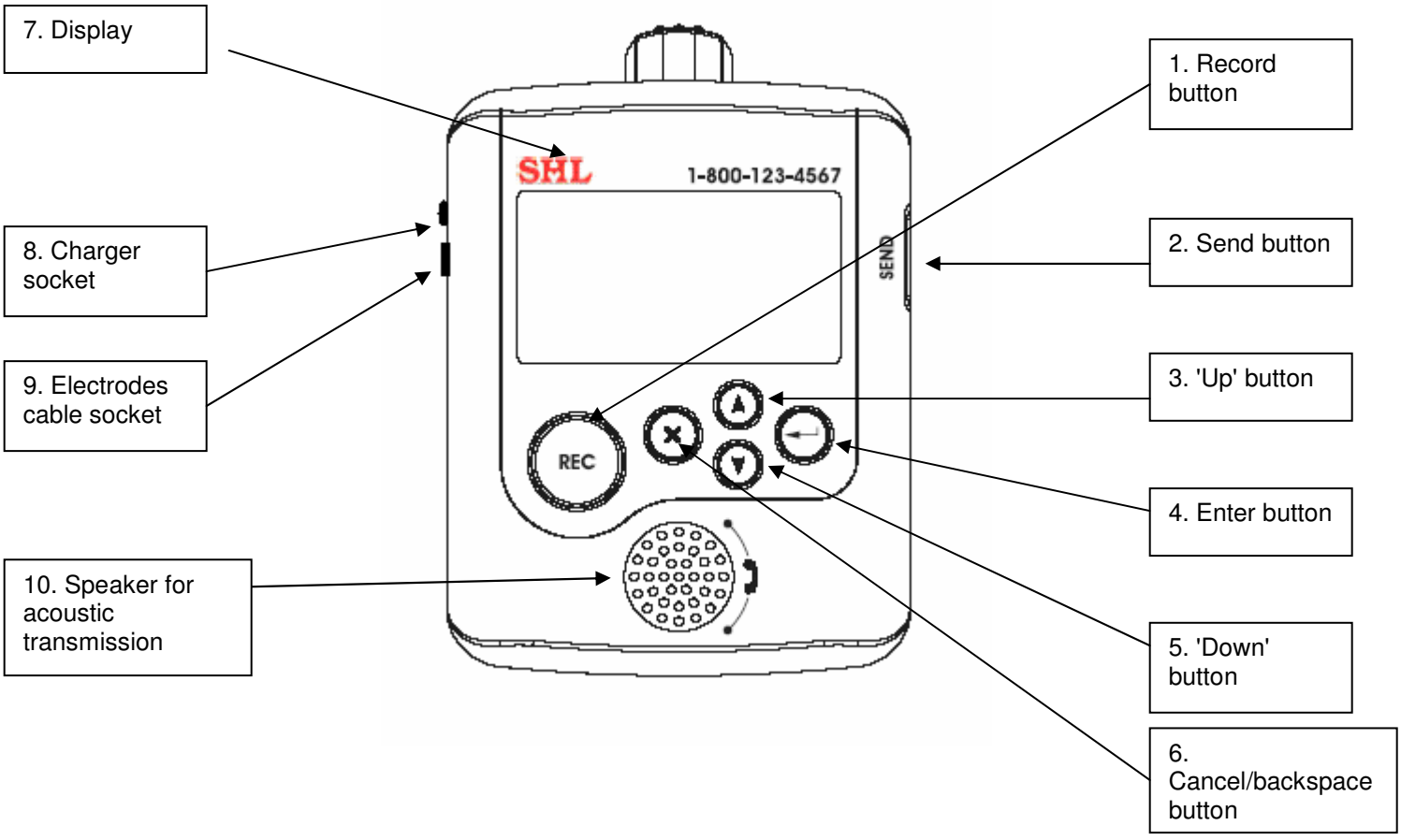
1 The River-1

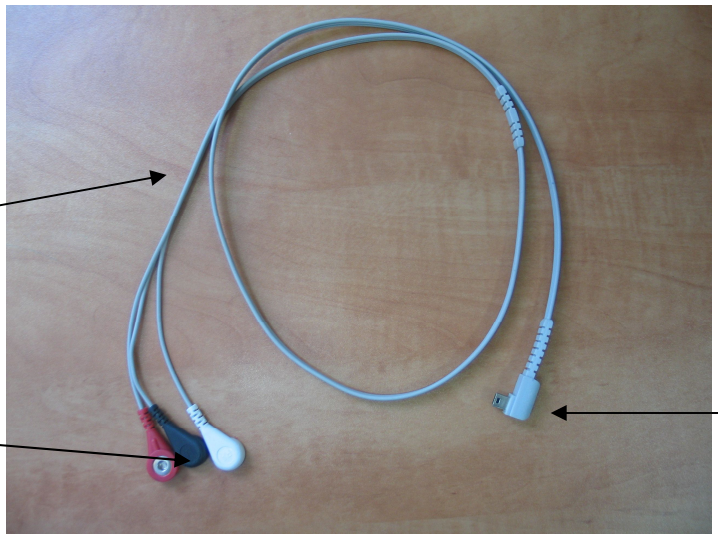
The River-1 is a patient-activated ECG event recorder that helps physicians document heart problems, which may not be found during a routine ECG examination in a healthcare facility. The device stores the ECG data and transmits it either automatically or manually to a receiving center, which can be a physician's office, hospital or medical center. The receiving center is staffed by healthcare professionals and contains advanced software to convert the data and interpret the results, providing rapid diagnosis of the user's condition.

For its source of energy, the River-1 utilizes rechargeable batteries. The device has been specially designed to use a minimal amount of energy, allowing the patient to wear the device for over a day without the need to recharge.

The following diagram identifies the device's components and related accessories. A more detailed specification of the individual components is listed on the following page.

Picture 1: The River-1 with component specification





1. **Record button** initiates ECG recording of a cardiac event
2. **Send button** transmits the data to the medical receiving center by both methods:
    a. Cellular transmission: the send button is pushed once for transmission over the cellular telephone network
    b. Acoustic transmission: the send button is pushed twice in quick succession to emit tones for transmission over regular or mobile telephone
3. **'Up' button** selects upper option in menu
4. **Enter button** confirms option selected in menu and initiates the user menu
5. **'Down' button** selects lower option in menu
6. **Cancel/Backspace button** reverts to the previous or main screen
7. **Display** for displaying user menu
8. **Charger socket** connects with charger for recharging the batteries
9. **Electrodes cable socket** connects with the electrode cable
10. **Speaker for manual transmission** emits series of tones for manual transmission of the recorded ECG data
11. **Electrodes cable** communicates the ECG leads from the user to the River-1.
12. **Connector to the River-1** connects the electrode cable to the River-1 and turns the device on
13. **Body electrodes** are adhered to specific locations on the patient's chest to record his or her ECG
14. **Carrying pouch** stores the River-1 when it is not being used
15. **Battery charger** (re)charges the device's energy source

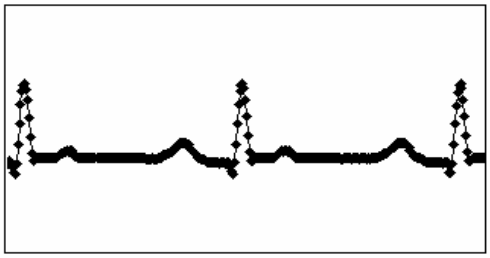
	Warnings
⚠	The River-1 and its related accessories are not waterproof. Remove the system before entering the shower or engaging in any other activity that involves immersing your body in water.

2 Using the River-1

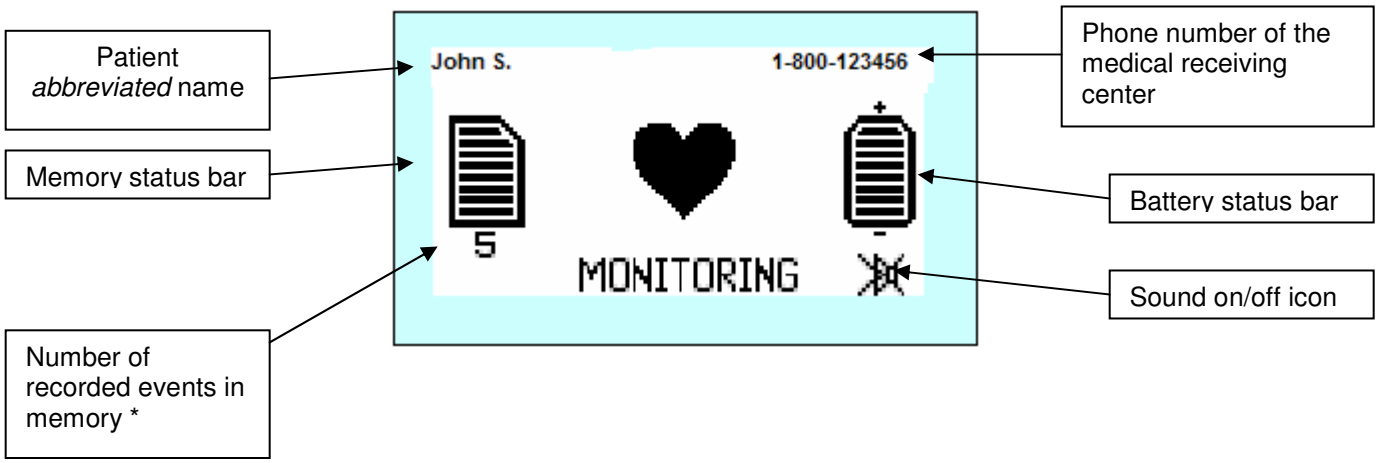
2.1 Starting River-1

Following the application of the electrodes, the attachment of the monitoring cable and the adjustment of any recording parameters, the device is ready for use. Proceed to carry out the following steps:

Connect the electrode cable into the designated socket of the River-1 device. Plugging the electrode turns the River-1 ON. Automatically, a welcome message will appear followed by a preview of your current ECG.



After a few seconds, the ECG preview is replaced by the main menu on the display. Your ECG is now being recorded.



* River-1 can store up to 30 events. However, your physician may program River to transmit more frequently when fewer records are obtained. After each transmission to a medical center, it is preferred to delete the older records. This can occur automatically or manually. For more information, see Record Deletion in section 2.5 of this manual.

	Note • During monitoring, clip River-1 to the belt. In the event of cold weather, River-1 should not be exposed to temperatures less than freezing during monitoring. River-1 can be worn under a sweater or coat during monitoring.

	Caution • Unplug the device's electrode cable before entering an aircraft or in areas where regulations instruct you to turn off your cellular phone.

2.2 Recording an ECG

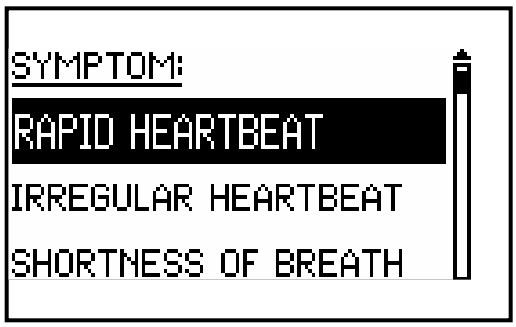
In order to record an ECG, press the **record button** for at least 2 seconds. The following image will appear on the display.

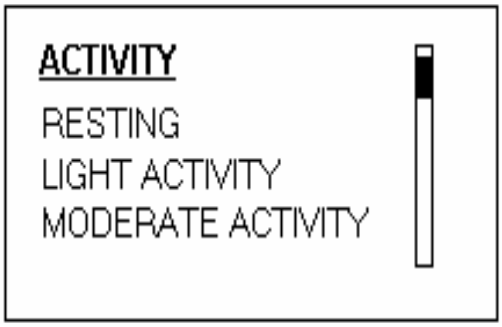
	Note The device indicates it is recording by emitting a tone intermittently. Do not move while the recording is taking place.

2.3 Entering symptoms and activity

Once the recording is completed, the tones will cease. On the display, a preset list of symptoms and activity levels will appear automatically. Choose the appropriate symptom you are experiencing using the **'up' and 'down' navigation buttons** and confirm your selection by pressing the **enter button**. The following screen gives you the option to select additional

symptoms. Next, choose the level of activity you were physically engaged in at the time of the event from the options appearing on the display. Again, confirm your selection by pressing the **enter button**. On the screen, you will see your symptom and activity selection. Confirm your complete selection by pressing the **enter button** or use **the cancel/backspace button** to reenter your selection.





2.4 Transmitting the ECG

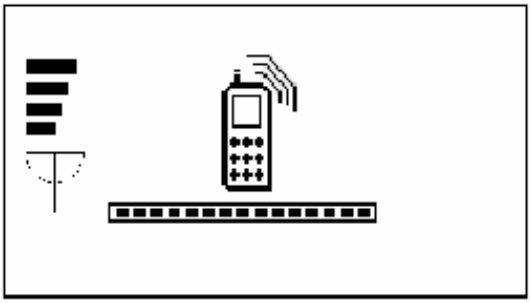
Transmission Modes:

The River-1 can transmit recorded ECGs to a medical center via River-1 internal wireless digital modem over a cellular network. Also, when required, River-1 can transmit ECG records by an acoustical path by coupling River's speaker to the mouthpiece of any telephone. Although the River-1 complies with many of the provisions of European and American standards for ambulatory devices, the best transmission quality (digital) is obtained when using a cellular network.

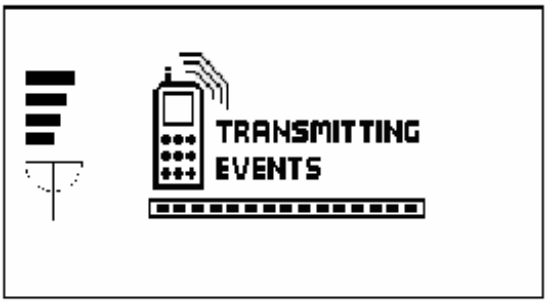
In some rural areas and other metropolitan cellular "dead spots", cellular transmission may not be possible. If cellular transmission is not possible, River-1's acoustical transmission mode can be utilized. Since this transmission mode is via an acoustical path, it is best to choose a quiet place where background noise is at a minimum.

Cellular Network Transmission:

After confirming your level of activity by pushing the **enter button**, the system will now begin connecting to the cellular network in order to transmit the recorded data automatically. Once the connection with the medical receiving center has been established, the ECG is transmitted. After every successful transmission is verified by the medical center, River's memory will automatically cleared.



ESTABLISHING CELLULAR COMMUNICATIONS



TRANSMITTING EVENTS

	Note
	Prior to cellular transmission, the River-1 will check if there is sufficient battery power available. If there is not enough power, the following will be displayed:  Proceed to recharge the battery or transmit the data manually

Weak Reception: In the event that the River-1 is unable to pick up reception of the cellular telephone network, the data is not transmitted (see screen indications below).

Find an area in the vicinity with (increased) cellular coverage according to the reception bars on the display and attempt to transmit again.
Press the send button **once** to transmit the recorded ECGs via the cellular telephone network.
If the network reception level remains insufficient, the recorded ECG is stored for a later attempt at either cellular or acoustic transmission. The number of stored ECGs is indicated in the main menu.

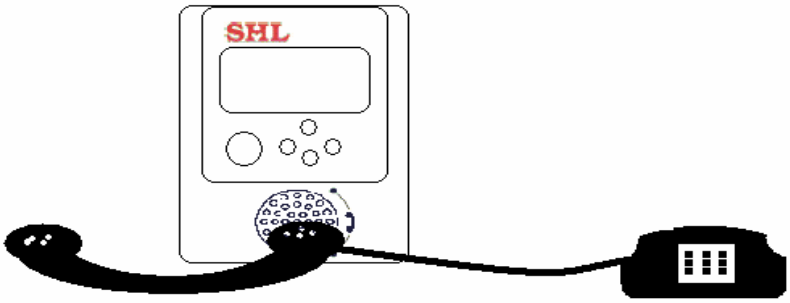
Later, the stored ECG data can be transmitted manually, either digitally or acoustically. For digital transmission, ensure there is cellular coverage and press the **send button <u>once</u>** to transmit the recorded ECGs via the cellular telephone network.

Acoustical Transmission:

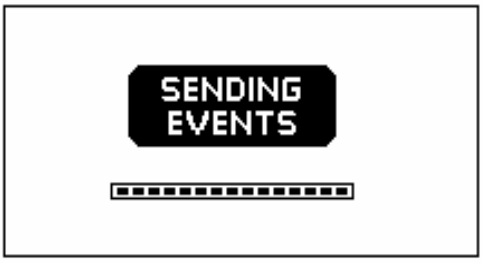
In case you want to transmit the data acoustically, call the medical receiving center using either a mobile or regular telephone.

800 227 3462

When instructed to do so, place the River-1 on a flat surface with the speaker facing upwards. Lay the telephone's handset or mouthpiece on the River-1's speaker.



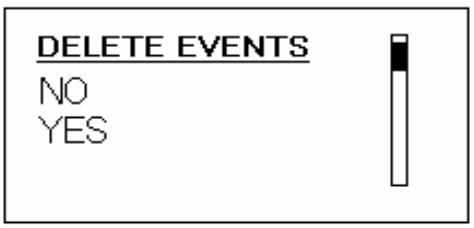
Press the **send button <u>twice</u>** in quick succession (i.e. rapidly after each other). You will hear a series of tones while the data is being transmitted.



The sending of the data has been completed once the tones cease. Resume your conversation with the medical professional to receive further instructions.

2.5 Record Deletion

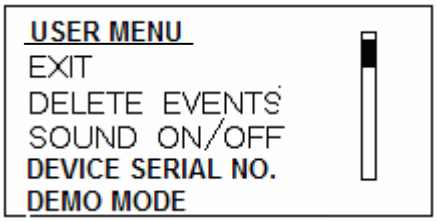
Automatic record deletion will occur after each successful cellular network transmission. However, after recorded events have been sent **acoustically,** you have the option of resending the recorded data or deleting them from the River-1's memory.
After transmitting acoustically the delete menu will appear as shown below. Delete by confirming **yes** on the 'Delete events' menu. In case that you do not delete the event, the event will be kept in the device memory.



2.6 User menu parameters

The River-1 is specifically designed to be as simple and comfortable to use as possible. Therefore, patients are able to modify certain parameters of the device to suit their needs.

Press the **enter button** on the main screen in order to access the user menu. The user menu allows you to delete recorded events after they have been transmitted. In addition, the option is given to disable the sound of the device (such as audio prompts).

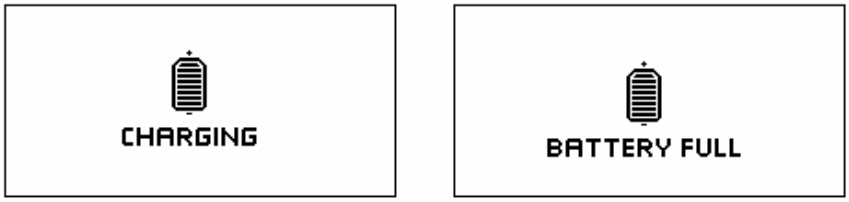


2.7 Customize your device

To access the user programming menu, press the **enter** and **cancel/backspace buttons** **simultaneously** for three seconds. The following menu will appear on the display:
The first option enables you to increase or decrease the volume of the alert sound (silent, low, moderate or high).
Entering the backlight menu enables you to select the amount of time the display's backlight is active (no backlight, 5 seconds, 10 seconds or 15 seconds).

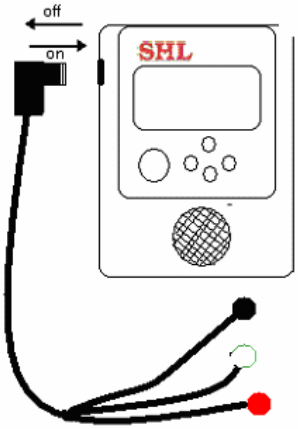
2.8 Charging the River-1's power supply

To ensure optimal performance, you must charge your River-1 once a day for approximately twenty to forty minutes. Further, charge the device when a 'low battery' warning is displayed during automatic transmission (see section2.4). To charge, insert the cable of the charger into the designated charger socket in the River-1 and plug into an electrical socket. The display will indicate when the battery is being charged and when it is full.



2.9 Shutting down the River-1

Shut down the device by simply unplugging the electrode cable from the socket in the River-1.



	Note
	• It is recommended to shut down the device any time the electrodes are removed from their positions on the body. This will save the system's energy source. • Records will remain in memory for a minimum of 30 days after unplugging.

3 Maintenance information

The device's exterior and monitor may be cleaned with a damp cloth moistened slightly with water, mild detergent or alcohol. Be aware that the device is not waterproof and that no ingression of any liquids occurs.

4 Instructions for healthcare professionals

4.1 Configurable parameters

Before the River-1 is given to a patient for first-time use, the device's parameters can be configured by a physician, nurse or technician. Primarily, this is done by adjusting the parameters on user menu of the device. These must correspond with the specific needs of the patient for proper use of the system.

List of programmable Parameters:

Abbreviated Patient Name: For reference purposes, an abbreviated patient name can be entered. This name will appear on the River-1's display.
For privacy, the person's first name and last name can be entered. If no name is entered, the default for this parameter is "Raytel". (Raytel – service provider name)
Note: This parameter can only be programmed using the serial cable or remotely via the cellular network by the call center upon physician instruction (see section 4.2)

Number of events: This is the number of recorded events the device will be able to record, from one to thirty events); the default is set to three events.

Lead loss detection: This option is to activate or deactivate automatic alert when disconnection of electrode is detected; default is set to "activated"

Preview time: This is the number of seconds the menu will appear on the screen. Options are: no preview, ten, twenty or thirty seconds); default is set to twenty seconds.

Pre-event time: This is the number of seconds of data that is retained prior to pressing the recording button, from five to 120 seconds; default is set to thirty seconds.

Post-event time: This is the number of seconds of data that is retained after pressing the recording button, from five to 120 seconds; default is set to sixty seconds.

Transmission speed: This is the speed at which manual transmission occurs (1x or 3x); default is set to 1x.

Pacemaker detection: This option is to activate or deactivate device's ability for pacemaker detection; default is set to "deactivated".

Specific symptom: in addition to the ten programmed symptoms in the device's memory, there is the option to remove or add one more symptom that the user will be able to select. The symptoms that can be added or removed are:

Tightness In Chest, Chest discomfort, Chest pressure, Heaviness in chest, Lightheaded, Feeling faint, Blurred Vision, Not feeling well, Weakness, Tired, Shakiness, Anxiety, Fibrillating, Heart Quivering, Headache, Slow heartbeat, PVCs, Extra Beat, Sweating, Nausea, Numbness, Weird Heartbeat, arrhythmia , erratic heartbeat, hard heart beat, passed out, seizures, syncopal episode

4.2 Configuring the parameters

Using River-1's buttons - for configuring the parameters

In order to access River-1 ~~the~~ configuration menu, press the **'up', 'down', 'cancel/backspace'** and **'enter button'** in **quick succession** in this specific order. The configuration menu will appear and the parameters requiring configuration can be selected.

Search for a specific parameter using the **'up' and 'down' buttons** and select by pressing the **enter button**. Once you have selected the correct option within a specific parameter, confirm by pressing the **enter button**. The main programming menu will reappear to allow for further configuration

Using a PC and serial cable for configuring the parameters

The Rivre-1 can be updated using the designated serial cable by the medical call center upon doctor request.

Install the River-1 configuration software on any PC that has a USB port and is installed with Windows (XP) operating system and MS SQL 2000 data base server.

Connect the designated serial Programming Cable provided with the configuration software. Plug the Large USB connector into the PC USB. Plug the other end into River-1's electrode cable jack.
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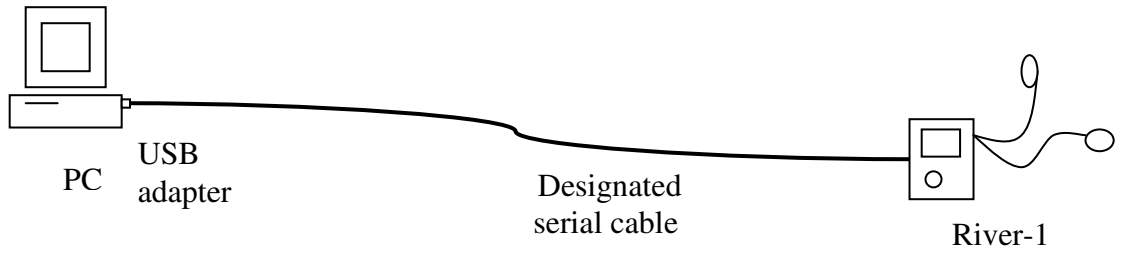
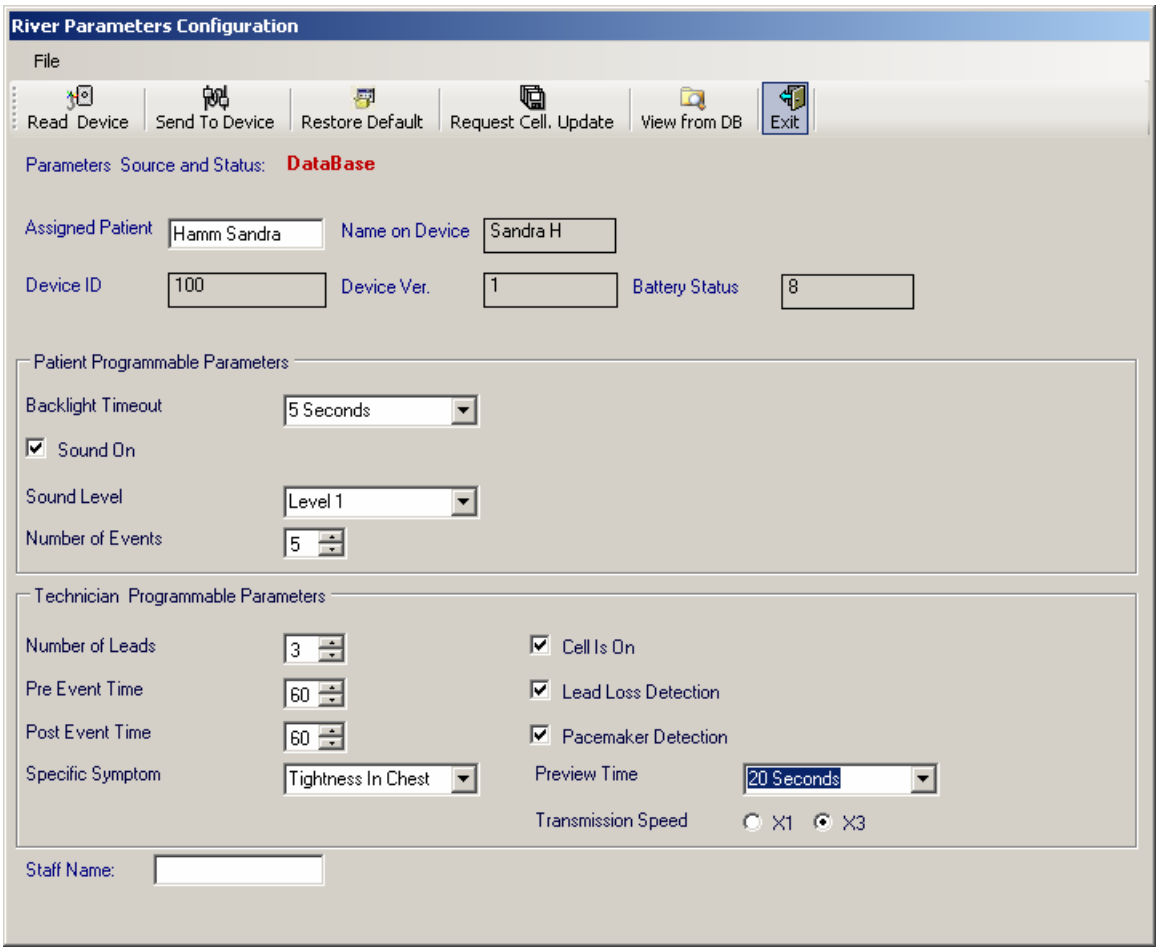
Verify that the River 1 is in the "program mode" by observing the LCD screen.



From your windows Start menu select "programs" and then choose the "River-1 configuration".

The following River-1 configuration software screen will appear:



The following buttons will be operational:

Read device: Will read parameters from the connected device and will show them.

Send to device: Will program device with the parameters that are displayed on the screen and will also save the parameters in the database.

Restore default: Will enter the default values for all configurable parameters.

Request Cell Update: Will update the parameters on the screen to River-1 during a cellular connection.

View from Database: Will let you view parameters from historical records, previously updated on the device.

Using a PC and cellular network to program the device

The Rivre-1 can be updated via cellular communication by the medical call center upon doctor request.

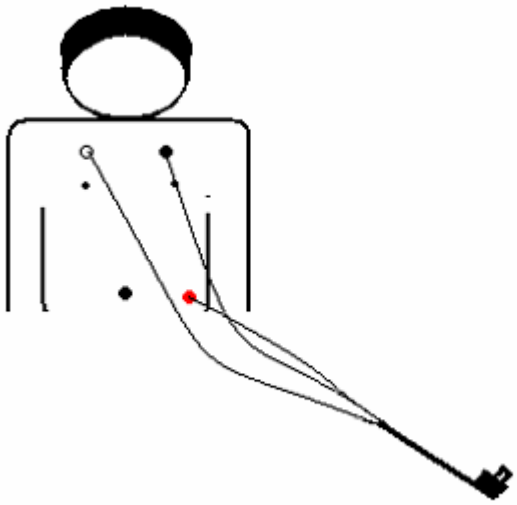
In order to configure the parameters the River-1 PC configuration software will be used.

The doctor or the user will be called and asked to press the button in order to create communication with the center during which the parameters are updated.

4.3 Placing the electrodes

The River-1 has either two or three electrodes (depending on the number of leads that are recorded) that are used to measure the patient's ECG. These electrodes must be attached to specific locations on the body in order to obtain a clear reading. The following illustration indicates where they must be placed.

Picture 3: locations for electrode placement



The electrodes must be kept in place throughout the entire period the user is required to carry the device, as prescribed by his or her physician. The only exception is when showering or engaging in any other activity that involves immersing the body in water.

	Note to physicians
	It is recommended to use self-adhesive electrodes, which have been approved for marketing by the FDA.

5 Equipment classification

CE 0344

Type of Protection Against Electrical Shock	
Internally battery powered and isolated equipment	No mains or earth connections provided or required.
Mode of operation	Intermittent
Degree of protection against ingress of liquids	Not protected (IP30)
Degree of protection against flammable gases	The equipment is not protected against the presence of a flammable anesthetic mixture of air, oxygen or nitrous oxide

Caution

The RIVER-1 should not be used in the presence of electromagnetic interference or power overload caused by electrosurgical diathermy instruments.
The RIVER-1 should not be used in conjunction with an external defibrillator.
The RIVER-1 should not be used in the presence of flammable anesthetics.
The RIVER-1 is not designed against the ingress of liquids. Do not submerse during cleaning.

Note to physicians

Operation of this device near a source of electromagnetic interface (such as radio transmitters) may adversely affect the quality of the recorded ECG signal. This device complies with AAMI EC38-94 applicable specifications regarding electro-magnetic compatibility

6 Operating and storage conditions

Storage	Temperature	-20o C to +65o C (-4o F to +149o F)
	Relative Humidity	Relative humidity: 5 % to 95% , non condensing
	Ambient Air Pressure	700 – 1060 millibars
Operating	Temperature	0 o C (+32 o F) to +45 o C (113 o F)
	Relative Humidity	Relative humidity: 10% to 95%, non condensing
	Ambient Air Pressure	700 – 1060 millibars

7 Technical specifications

Current Drain	Transmission: Cellular 360 mA avg., Acoustic: 150 mA avg., 2A max. Standby: <2μA. Monitoring: 15mA
Amplifier	CMRR: >80dB min Frequency Response: 0.05-40 Hz min System Noise: < 40μV r.t.i.
Strip Storage Capacity	30 strips max, (one, two or 3 leads)
ECG Record Duration	4 minutes maximum/lead/record (120 sec. pre-event max., 120 sec. post-event max.)
Acoustic Transmission	The uses center frequencies: 1275Hz and 1875 Hz
Cellular Transmission	GPRS network connection
Total Transmission Time	Depend on number of events and event duration
Modem	GC 864-QUAD manufactured by Telit Wireless Solutions
Battery	Lithium ion battery 1440 mAh - 3.7V

	Warnings
	1. 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. 2. SAR compliance for this device is restricted to belt-clip and accessories supplied with this product. Use of other accessories may not ensure compliance with FCC RF exposure guidelines.

8 Limited Warranty

This product is warranted against defective material and workmanship (excluding connecting electrode cables) for one year following delivery of this product to the original purchaser. If this product or any part thereof, in the judgment of SHL Telemedicine or its affiliates, is proven to be defective within the mentioned warranty period, such defects will be repaired or replaced (at SHL option) free of charge for parts or labor. This warranty does not apply to any product which has been damaged by accident or which has been misused, abused, altered or repaired by anyone other than SHL or its representatives. SHL shall not be liable to any person for any direct or consequential damages resulting from or caused by any defect, failure or malfunction of this product. This warranty is in lieu of all other warranties expressed or implied, including any implied warranty of merchantability or fitness for a particular purpose, and no person is authorized to assume for SHL any other liability in connection with the sale of this product.

Manufacturer:
SHL TeleMedicine Ltd. 90 Yigal Alon Street Tel Aviv, 67891 Israel Telephone: +972-3-5612212 Fax: +972-3-6242414