

VeriChip H2™ Reader



VeriChip H2™ Reader

USER INSTRUCTIONS

Description

The VeriChip H2 Reader is hand-held Radio Frequency Identification (RFID) reader which activates an implanted VeriMed™ RFID Microtransponder with a low power, low frequency (LF) electromagnetic field. The Reader receives a unique 16-digit ID number from the VeriMed Microtransponder. The ID number is used to provide, with patient consent, physicians and other health professionals access to a secure database that will provide the implanted person's identity and health information provided by the patient.

Indications

The VeriChip H2 Reader is indicated for use as a portable instrument that non-invasively reads the ID number of an implantable VeriMed Microtransponder that is inserted into the arm of the patient. When activated, the VeriMed Microtransponder transmits a unique identification number that will be displayed by the VeriChip H2 Reader and may be used to access the patient's identity and authorized health information from a secure database.

Contraindications

None.

Contents: VeriChip H2 Reader Assembly Part Number 600-000515-000 (includes all of the following):

Description	Part Number
VeriChip H2 Reader (1) <i>with lanyard and instruction card attached</i>	600-100313-000
Instructions for Use (1)	981-000302-000
Batteries AA (1 set of 4)	303-000014-000
Test Microtransponder (1)	670-000001-000
Bluetooth Receiver (1) with related Driver CD (1)	672-000001-000
Folder Poster (1)	420-000025-000
Instructional CD (1)	672-000002-000
USB Cable (1)	301-000025-000

VeriChip H2™ Reader Activation with Manufacturer Settings

1. Press Button F1 and release to power on the Reader.
2. The Reader will enter a self diagnostic mode displaying the following on the LCD screen:
 - a. "Initializing"
 - b. "VeriChip H2 Reader"
"BT Master Rev x.xx"
 - c. All Pixels active on the two line screen display
 - d. The number "8" will display in all positions
Check for missing segments. If segments are missing, do not use and return Reader immediately for repair or replacement.
 - e. "Battery OK"
 - f. "BT Connecting - Inquiry Done - Please Wait"
3. Screen will display "PRESS F1 TO SCAN"
4. Press the F1 button and "SCANNING" will be displayed.
5. Perform the scanning process as described on page 3.
6. When a VeriMed ID number is found, an audible chirp will be heard and the VeriMed ID number will be displayed on the top line of the LCD and on the second line the instruction "PRESS F1 TO SCAN" is displayed.
To initiate a new scan session press F1 again.
To scan for a different VeriMed Microtransponder press the F1 button to clear the previous ID number and to restart the scanning mode.



Prior to Scanning Patient

Scan test Microtransponder provided with VeriChip H2 Reader to verify unit functionality prior to use (photo).

Scanning Procedure for Locating an Implanted VeriMed Microtransponder

To scan/locate a Microtransponder first activate the Reader as described above. Press and release the F1 button when instructed on the LCD. **DO NOT** hold down F1 button during scan operation. Place the Reader next to the skin, parallel and along side the area to be scanned (see photo). Starting about 2 inches above the elbow, move the scanner slowly up the rear part of the arm. The injection site may vary but it typically will be between the elbow and shoulder of the triceps area of the upper arm. When a VeriMed Microtransponder is located, the VeriChip H2 Reader will emit an audible chirp and display the 16-digit ID number on the LCD screen.

Depending on which communication configuration is established, the VeriMed ID number will be entered via USB or Bluetooth into the designated entry field in the web enabled VeriMed Patient Registry. If no communication is established, the PC keyboard can be used to manually enter the ID number.



Turning the Reader Off

The Reader can be turned off manually at any time by simultaneously pressing and holding down the F2 and F3 buttons.



If the Authorization Code is enabled and an incorrect Authorization Code be entered, the unit will immediately power-off.

The Reader will automatically power down should it remain idle for 5 minutes.

Use of VeriMed Reader with Passive Microtransponders of Different RFID Frequencies

The VeriMed H2 Reader is capable of reading the VeriMed Microtransponder frequency of 134.2 kHz as well as 125 KHz. Place the Reader within the effective range of the passive RFID Microtransponder (no more than 2.5 inches) to obtain the ID number from the Microtransponder.

Installing/Replacing the Batteries

Remove the battery compartment door by pressing the tab and sliding towards the base of the Reader case. Insert 4 AA alkaline batteries into the battery compartment as indicated (see photo). Replace the battery compartment cover and test the Reader using the provided test RFID Microtransponder.



When the Reader battery power level drops to a point insufficient to read a VeriMed Microtransponder the Reader will automatically shut off. The Reader will display "LOW BATTERY" followed by "REPLACE BATTERY". When these messages appear on the LCD, replace batteries immediately.

Authorization Code Option

To provide a means of securing the VeriMed H2 Reader against unauthorized use, an optional start-up Authorization Code function is provided. This modality consists of 8 entries of the two auxiliary buttons, F2 (left) and F3 (right) in a predefined sequence. The factory default setting is 'disabled', i.e. the unit will not prompt the user to enter an Authorization Code, but rather will immediately proceed to scan mode and establishing a link with the host computer. This feature can be enabled or disabled through the Configuration Mode (see configuration mode section below).

If enabled, the Authorization Code is entered after the Reader is turned on and self-tests are complete. The user must press the two auxiliary buttons a total of 8 times in predefined sequence. This sequence can be customized and stored in the EEPROM. The default sequence (programmed at the time of manufacture) is:

F2,F2,F3,F3,F2,F3,F2,F3

Enabling Authorization Code

To enable authorization process, the user must send the '?' character from the HyperTerminal to the unit via a serial link in Configuration Mode.

To disable authorization process, the user must send the '!' character from the HyperTerminal to the unit via a serial link in Configuration Mode.

Changing the Authorization Code

Maintain a record of the Authorization Code for future reference. Loss of Authorization Code access will require a call to customer service.

To change this sequence, the user must power up the unit and go into Configuration Mode. To enter the new

sequence, the user must send the '#' character to the VH2R over the serial link. Immediately after that the unit will accept exactly 8 characters 'l' for F2 and 'r' for F1 ("l" for left and "r" for right button locations in lowercase only) in the user defined sequence and the new key is stored in the Reader EEPROM.

If the Code becomes lost, call customer service for assistance.

If the key sequence is entered incorrectly, the unit displays 'ACCESS DENIED' on the LCD and shuts down after 1 second.

If the sequence is entered correctly, the unit immediately tries connecting to the host according to the set communication mode.

Configuration Mode

To operate in this mode the user should perform the following actions:

- Connect the USB cable from the host computer to the VH2R Reader.
- Turn on the VH2R Reader by pressing the F1 (large center) and F2 button. The VH2R Reader will go through its self-test procedure. Enter the Authorization sequence as described later in this document if you are prompted to "Enter Code" by the message on the unit's LCD.
- Start the appropriate communication program on the host computer system. For example, the user may launch the HyperTerminal program and connect to the serial port created by the USB driver. The VH2R reader will stay in this idle mode for up to 5 minutes. The user has two choices – to initiate a scan (normal operation) or enter the configuration mode. If no choice is made until the timeout, the unit will power down. The communication program (HyperTerminal) should be set to 9600 Baud, 8 data bits, one stop bit, no parity (8-N-1).

To enter the configuration mode, the user should send a predetermined command from the host to VH2R (letter 'c' in lower case). The power down timer will be extended upon receiving any character from the host system. When the timer expires, the unit will power down. All configuration settings are stored in non-volatile memory immediately after they are entered. To exit the configuration mode, the user can either use a special command from PC – letter 'q' in lower case (the VH2R will go into Idle mode), or press the F1 button (the VH2R will enter scan mode).

An example of configuration menu screen:

```
VeriChip H2 Reader CONFIG MODE
m - BT Master
s - BT Slave
u - USB
r - Ricoh G3
@ - BT MAC
# - Unlock Code
? - Unlock Required
! - Unlock Not Required
q - Quit
```

VeriMed H2 Reader Communication

The unit has two communication devices – USB and Bluetooth. Only one communication mode can be used at any time.

Both communication channels are bi-directional. When a passive VeriMed Microtransponder is acquired by the VH2R Reader, the ID number is sent to the host computer. The host computer can also send certain information back to the VH2R Reader. This feature is used to change current configurations of the VH2R Reader, including possible a switch between its communication modes (from USB to BT and back) and utilizing the Authorization Code option.

VeriChip H2™ Reader Operation in USB Mode

To operate in this mode the user should perform the following actions:

- Connect the USB cable from the host computer to the VH2R Reader. The USB port is located in the rear of the case. Lift the protective cover and insert the cable.
- To perform the scan, the user should press the F1 button once again. The VH2R will turn on the LF (low frequency) interrogation field and try to acquire a Microtransponder. The field will stay on for 12 seconds or until a valid Microtransponder is acquired. If a Microtransponder has not been acquired, the VH2R will go into the idle mode. If a Microtransponder has been acquired, its ID number will be displayed on VH2R LCD and sent to the host computer via the USB interface. After this the VH2R will enter its idle mode and be ready for another scan session or power down after 5 minutes. The unit can be powered down from this state by pressing the two smaller buttons (F2 and F3) simultaneously.

Note: Operating in the USB mode, the unit does not monitor the status of communication link. That is, if the USB cable becomes disconnected, the user will not be notified. If the cable was not connected to the host system, the latter may not be able to open the serial port. Disconnecting the cable during the communication session may produce an error on the host system.

VeriChip H2 Reader Operation in Bluetooth Master Mode

In the Master mode the VH2R performs the discovery and then dials the host computer system acting as a Bluetooth (BT) master. As a consequence, no action is required on the

host computer side. For example, a communication program (HyperTerminal or “keyboard wedge”) may be open and left running regardless of the VH2R being powered on or off. The VH2R stores the host’s BT MAC address in its non-volatile memory, and will dial only this address no matter how many devices it discovers performing the inquiry. The MAC address should be entered into the device by using other communication modes (such as USB or BT Slave) that does not require *a priori* knowledge of this address. When Bluetooth encryption is desired, it must be enabled on both sides of the link (an identical passkey word supplied). In this case the passkey should be entered on the PC side only once, during the ‘pairing’ process. All subsequent connections between the members of the same pair will be encrypted automatically, and establishing subsequent links will not require entering the passkey unless the devices become ‘unpaired’.

The operation is performed as follows:

To operate in this mode the user should perform the following actions:

- Bring the VH2R and host system within Bluetooth range (about 10m under most conditions).
- Start the communication program on the host side (HyperTerminal or keyboard wedge). The exact number of the serial port to be used for this connection should be provided by the Bluetooth service. It has been noticed that although Windows XP has some built-in Bluetooth support that can be used to establish the connection, it is significantly slower than a proprietary stack that comes with particular BT hardware (e.g. BlueSoleil).
- Power up the VH2R by pressing the F1 button and enter the authorization code if prompted. The device will try to discover and dial the host. If this is the first time connection, the user must enter the passkey on the PC side to allow the VH2R connection to the PC. If this process has been successful, the user will be prompted to press the F1 button once again to initiate scanning for a Microtransponder. If the user presses the F1 button without waiting for connection, the VH2R will abort the attempt and go into standalone mode. If the unit

cannot discover the host within 20 seconds, it will automatically abandon the attempt and proceed in standalone mode.

- The VH2R will turn on the low frequency (LF) interrogation field and try to acquire a Microtransponder. The field will stay on for 12 seconds or until a valid Microtransponder is acquired. If a Microtransponder has not been acquired, the VH2R will go into idle mode producing a corresponding message on the LCD. If a Microtransponder has been acquired, its ID number will be displayed on VH2R LCD and sent to the host via the BT interface (if the connection had been established). After this the VH2R will enter its idle mode and be ready for another scan or power down after 5 minutes. To shut the unit down earlier, the user can press the F2 and F3 buttons simultaneously.

VeriChip H2 Reader Configuration Options

USB Override.

As described above, the normal way of changing the connection mode is through the established USB (serial) connection. However, to recover from a situation when the Bluetooth-enabled host becomes unavailable for some reason (for example: The unit had been configured to work as Bluetooth master and programmed with a particular slave MAC address, but that host device is not available), an emergency override procedure exists.

To activate the override, the user should power up the VH2R while holding down the Left auxiliary button (F2) until the unit enters the self-test mode. The unit will switch into the USB connection mode regardless of what had been stored in the EEPROM, and thus enable the user to connect the Reader to the host by means of USB cable and perform necessary changes. This override is not memorized in the EEPROM and so is valid for this session only, until the unit is powered down. This procedure can also be used for temporary work in USB mode if the normal Bluetooth-enabled host is unavailable (a different work location, etc.) without the need to re-configure the device.

Cleaning

Wipe the Reader with alcohol wipes. Do not submerge or spray liquid directly on the Reader.

Table 201: Guidance and manufacturer's declaration – electromagnetic emissions

The VeriChip H2 Reader is intended for use in the electromagnetic environment specified below. The customer or the user of the VeriChip H2 Reader should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	Group 1	The VeriChip H2 Reader uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in the nearby electronic equipment.
RF emissions CISPR 11	Class B	The VeriChip H2 Reader is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage Fluctuations/ flicker emission	Not applicable	

Table 202: Guidance and manufacturer's declaration- electromagnetic immunity

The VeriChip H2 Reader is intended for use in the electromagnetic environment specified below. The customer or the user of the VeriChip H2 Reader should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6KV contact ±8 KV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	Not applicable
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60 % dip in U_T) for 5 cycles 70% U_T (3 % dip in U_T) for 25 cycles <5% U_T (>95 % dip in U_T) for 5 sec	Not applicable	Not applicable
Power Frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 204: Guidance and manufacturer's declaration – electromagnetic immunity			
The VeriChip H2 Reader is intended for use in the electromagnetic environment specified below. The customer or the user of the VeriChip H2 Reader should assure that it is used in such an environment.			
Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the VeriChip H2 Reader, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Immunity Test	IEC 60601 test level	Compliance level	Recommended separation distance
Conducted RF IEC 61000-4-6	Not applicable	Not applicable	Not applicable since the VeriChip H2 Reader is not connected by cabling and does not use a power cord.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	<p>80 MHz to 800 MHz</p> $d = 1.2 \sqrt{P}$ <p>800 MHz to 2.5 GHz</p> $d = 2.3 \sqrt{P}$ <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p>
Table 204: Guidance and manufacturer's declaration – electromagnetic immunity (continued on next page)			


Table 204: Guidance and manufacturer's declaration – electromagnetic immunity (continuation)			
Immunity Test	IEC 60601 test level	Compliance level	Recommended separation distance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	<p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the VeriChip H2 Reader is used exceeds the applicable RF compliance level above, the VeriChip H2 Reader should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the VeriChip H2 Reader.			

Table 206: Recommended separation distances between portable and mobile RF communications equipment and the VeriMed reader.

<p>The VeriChip H2 Reader is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the VeriChip H2 Reader can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the VeriChip H2 Reader as recommended below, according to the maximum output power of the communications equipment.</p>			
Rated maximum output power of transmitter	Separation distance according to frequency of transmitter		
	150 KHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
W	Not applicable, per IEC 61000-4-6 "Conducted RF" since no power cords or cables are used with the Reader.	$d = 1.2 \sqrt{P}$	$d = 2.3 \sqrt{P}$
0.01		0.12	0.23
0.1		0.38	0.73
1		1.2	2.3
10		3.8	7.3
100		12	23
<p>For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.</p> <p>NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

Physical and Electronic Characteristics

Operating Frequency	134.2 KHz
Frequency Modulation Type	Amplitude Shift Keying (ASK) Modulation
Bandwidth	± 4KHz
Effective Radiated Power	0.185mW
Radiated Output at 10 meters	28.1 dBuA/m
Case Size	178mm L x 82mm W x 32mm H
Weight	300g +/- 10g (w/o batteries)
Material	PC/ABS blend Plastic
Operating Temperature & Humidity	32°F to 122°F (0°C to 50°C) and a maximum relative humidity of 90%, noncondensing
Storage Temperature & Humidity	-4°F to 140°F (-20°C to 60°C) and a maximum relative humidity of 90%, non-condensing
Batteries	Quantity 4-AA Alkaline Batteries
Display	LCD 32-character, 2 line, backlit
Range	2.5" when optimum conditions are met. No external interference, no metal near transponder or reader and new batteries

Sterility: Non-sterile. Do not sterilize.

Usage: Multiuse, battery dependent.

Caution: U.S. Federal Law restricts this device to sale by or on the order of a physician or licensed practitioner.

Caution: To ensure proper interpretation of VeriChip H2 Reader output, perform display check on unit prior to use.

Caution: Do not expose VeriChip H2 Reader to excess moisture or electrostatic discharge.

Caution: If VeriChip H2 Reader is dropped, perform display check through a power-up cycle (see Reader Activation) and read functionality check using the test Microtransponder.

Caution: **Not MRI Compatible.** Do not attempt to use the VeriChip H2 Reader to read a Microtransponder while patient is exposed to active MRI equipment.



The VeriChip H2 Reader is a Radio Frequency (RF) device and needs special precautions regarding electromagnetic compatibility (EMC), read these instructions for EMC information before putting the device into service.

Warning: VeriChip H2 Reader should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the VeriChip H2 Reader should be observed to verify normal operation in the configuration in which it will be used.

Warning: The VeriChip H2 Reader generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at personal expense.

NOTES:

[illegible]

FCC Regulations: 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
- (2) This device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for 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 and cause 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 the receiver
- Consult the dealer or an experienced radio/TV technician for help

Modifications: Any changes or modifications not expressly approved by VeriChip Corporation for compliance could void the user's authority to operate the equipment.

Manufactured by: VeriChip Corporation
Delray Beach, FL 33445

Distributed by: VeriChip Corporation
Delray Beach, FL 33445

Patient Support Line: 1-866-402-CHIP (*US only*)

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Warranty: The VeriChip H2 Reader is warranted against defects in materials and workmanship, under normal use and service for one (1) year from the date of shipment. This warranty will not apply if adjustment, repair or parts replacement is required because of accident, neglect, damage during transportation or causes other than ordinary use. VeriChip Corporation's sole responsibility under this warranty shall be, at its option, to either repair or replace any product which fails during the warranty period. In no event shall VeriChip Corporation be liable for any indirect or consequential damages or loss of profit.

