HRV Acquire

Heart Rate Variability Acquisition

Rev. 5/1/24
Instructions for Use

P/N 5651

For more information, contact:

WR Medical Electronics Co.
1700 Gervais Avenue
Maplewood, MN 55109 USA
Phone: 651-604-8400
Phone: toll-free within the United States and Canada 800-635-1312
Fax: 651-604-8499
Fax: toll-free within the United States and Canada 800-990-9733
E-mail: neuro@wrmed.com
Web Site: www.wrmed.com

EC REP

EU Authorized Representative:
Medical Device Safety Service (MDSS) GmbH
Schiffgraben 41
30175 Hannover
Germany

Comments or Questions?
We appreciate receiving any suggestions, comments, or questions that would help us to improve this manual. Please forward comments to the address above.

Contents

This page left intentionally blank

Overview

The HRV Acquire (HRV) Device along with WR Testworks software can be used as a standalone cardiovagal device to support heart rate variability testing and expiratory pressure evaluation during Valsalva breathing testing. The HRV device supports measurement of heart rate variability, respiratory effort from commercially available circumferential chest bellows, display of a Valsalva breathing metronome breathing cue, and display of non-invasive beat to beat blood pressure from a commercially available external device, which must have FDA clearance, and provide an external beat to beat blood pressure with an analog blood pressure signal output. The HRV Acquire is not designed for monitoring of vital signs or self-monitoring of patients.

Intended Use

The Heart Rate Variability (HRV) Acquire device is intended to record and indicate the following parameters during autonomic testing maneuvers:

- Expiratory pressure recording and display
- Respiratory effort
- Breathing Cue metronome
- Heart rate via electrocardiography (ECG)
- Non-invasive blood pressure from optional external device

The HRV Acquire does not make a diagnosis or indicate by itself that any disease state exists. The HRV Acquire is not designed for self-monitoring of patients.

Indications for Use

The HRV Acquire allows clinicians to perform a broad range of tests in the search for autonomic neuropathies and dysfunction. All tests are non-invasive, standardized, quantitative, and easy to perform. A full autonomic assessment can be performed in as little as one hour per patient. Tests and analyses available include:

HRV Acquire

- Heart Rate Response to Deep Breathing (HRDB), using ECG or R-R interval.
- Heart Rate via electrocardiography (ECG)
- Valsalva Maneuver, using ECG or R-R interval.
- 30:15 Ratio, using ECG or R-R interval.
- E:I Ratio.
- Baroreflex sensitivity including cardiovagal and adrenergic analysis.
- Head-Up tilt analysis (requires optional tilt table).

Intended Patient Population

- Age: Adolescent and adult
- Health: Suspected of, or having, autonomic disorders.
- Patient State: Not relevant.

Intended Users Profile

Intended users of the software are:

- Trained medical technicians
- Nurses
- Physicians

Usage Environment

The equipment is intended for use in an indoor clinic, hospital, or professional healthcare facility. Refer to the Instruction for Use for the Operating Environment temperature and humidity conditions.

Contraindications

The HRV Acquire is contraindicated for use:

- Patients who have electrically sensitive support systems (e.g. pacemakers).
- Not to be used with a Defibrillator.

Warnings and Cautions

Warning: PACEMAKER PATIENTS. Rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon rate meter; *keep pacemaker patients under close surveillance*. See this manual for disclosure of the pacemaker pulse rejection capability of this instrument.

Warning: Not defibrillation proof. Disconnect from patient prior to defibrillation.

Warning: The medical equipment should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the medical equipment should be observed to verify normal operation in the configuration in which it will be used.

Warning: The conductive parts of Electrodes and associated connectors for applied parts, including the Neutral electrode, should not contact other conductive parts including earth.

Warning: Be aware of any safety hazard due to the summation of Leakage currents when several items of equipment are interconnected.

Warning: Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Caution: Do not use this device in the presence of (HF) electrosurgical instruments.

Caution: Line isolation monitor transients may resemble actual cardiac waveforms. Do not allow electrode cables to run parallel with or cross any power cord.

Caution: Federal law restricts this device to sale by or on the order of a physician.

Caution: This device is to be operated only by trained personnel under the direction of a physician.

Caution: The HRV Acquire is not explosion-proof and should not be used in the presence of explosive gases.

Caution: Carefully route patient cables to reduce the possibility of patient entanglement or strangulation.

Caution: ECG Electrodes and Valsalva bugles are intended for use by a single patient only and are to be disposed of after patient has been tested. Reuse of single use components may represent risk to health of patient.

Caution: The HRV will not remember operator settings and patient data if an interruption of supply mains exceeds 30 seconds.

Caution: This device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this document.

Caution: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the HRV, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Caution: The Power Conditioner, HRV Acquire, computer, and monitor may require reset after an EMI event. This is considered a normal and safe condition of the operation of the HRV Acquire device.

Caution: Physiologic conditions that may result in an inadequate test: a very small signal amplitude, cardiac arrhythmia, or a large negative spike.

System Classification (IEC601-1 / EN 60601-1)

Degree of protection against moisture ingress (IEC529)	IPX0 - Ordinary
Degree of protection in the presence of a flammable anesthetic mixture with air or with oxygen or with nitrous oxide	Not protected (unsuitable)
Mode of operation	Continuous
<u>Valsalva and Chest Expansion</u> Type of protection against electric shock: Type BF	
<u>ECG</u> Type of protection against electric shock: Type CF	

Safety and Information Symbols

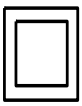
- This device is to be independently tested to comply with UL 60601-1.
- Unit meets the specifications for IEC 60601-2-27 Electrocardiographic Monitoring.
- **Latex Statement:** The accessory chest bellows WR #5582 contains latex. Direct skin contact should be avoided and should be applied over snug fitting clothing for all patients.

Attention, consult accompanying documents

Type CF Applied part – F type patient contact part isolated from other parts of the equipment such that patient leakage currents cannot exceed allowed limits in NORMAL and SINGLE FAULT CONDITION.

Power ON

Power OFF



Class II Equipment for Medical Grade power supply

Type BF Applied part – for Valsalva and Chest Bellows inputs

Direct current power for HRV Acquire

Consult Operating Instructions

Approval marks. ETL listed for North America & CE with notified body number (Intertek SEMKO AB) for Europe.

Modes

All modes are selected by the WR Testworks software when running the selected test. See the WR Testworks manual for additional information on performing tests. All modes combine the ECG signal and external signals (*Optional* – Beat-to-Beat Blood Pressure, device must be FDA approved) to output via USB connection to the host computer.

HRDB - This mode displays a moving cadence of LEDs of 5 seconds up / 5 seconds down. This is a visual reference or cue for patient breathing.

Valsalva - This mode displays a target equal to 40mmhg and moving bar referenced to the patient bugle input. This is for patient feedback to exert a consistent effort during the maneuver.

ECG - This mode displays a 'heart' and is used to record ECG during other maneuvers such as tilt or standing tests.

ECG Specifications

Defibrillator Protection:	None. See **Warnings and Cautions.**
Patient Cable:	6-pin AAMI Standard – WR PN#5047/5048
Patient Lead:	LII (RA, LA, LL)
Frequency Response:	0.2 to 100Hz
Response time:	≤8 seconds
Patient Electrodes:	Silver-Silver chloride (Recommended)

No alarms are provided

NOTE: The HRV Acquire is not intended for use with pacing devices.

R-Wave Detection Specifications

Range:	15 to 300 bpm
Accuracy:	±2%
Resolution:	1 bpm
Sensitivity:	300 µV peak
Response time:	≤ 8 seconds
Tall T Wave Rejection:	Rejects T waves of amplitude less than 55% of the R-wave

Pacemaker Pulse Rejection

Width:	0.1 ms to 2 ms @ +/- 2 mV to +/- 700 mV
Overshoot:	4 ms to 100 ms and not greater than 2 mV
Detector disabling:	None provided

Pressure Sensor Specifications

Valsalva:	0 to 2 psi
Chest expansion:	0.5 to -5.0 psi ± 0.5psi of ambient
Abdominal expansion (Optional):	0.5 to -5.0 psi ± 0.5psi of ambient

Analog Inputs (optional)

DB15 Input Signal for blood pressure: 0 to 5vdc.
DB15 Input Signal for up to four (4) auxiliary inputs: 0 to 5vdc. Signals are sampled at a rate of 25Hz.
DB15 Input Signal for Input External ECG Signal: 0 to 5vdc.
DB15 Input Signal for Input Trigger Sync: 0 to 3.3vdc.
Signals are filtered with a 250Hz ±25Hz first order low-pass filter.

Analog Outputs (Optional)

DB15 Output Signal for ECG: 0 to 3.3vdc.
DB15 Output Signal for Trigger: 0 to 3.3vdc

Electromagnetic Compatibility

CAUTION: MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANING DOCUMENTS.

CAUTION: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the HRV, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

CAUTION: The Power Conditioner, HRV Acquire, & computer and monitor, may require reset after an EMI event. This is considered a normal and safe condition of the operation of the HRV Acquire device.

Guidance and manufacturer's declaration – Electromagnetic emissions		
The HRV Acquire is intended for use in the electromagnetic environment specified below. The customer or the user on the HRV Acquire should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The HRV Acquire uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The HRV Acquire 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 61000-2-3	Class B	
Harmonic emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – Electromagnetic immunity			
The HRV Acquire is intended for use in the electromagnetic environment specified below. The customer or the user on the HRV Acquire 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 61000-4-2:2008	± 6 kV contact ± 8 kV air	± 6 kV 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 61000-4-4:2012	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5:2005	± 1kV line(s) to line(s) ± 2 kV line(s) to earth	± 1kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage	<5% Ut (>95% dip in Ut) For 0.5 cycle	<5% Ut (>95% dip in Ut) For 0.5 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the

variations on power supply lines IEC 61000-4-11:2004	40% Ut (>60% dip in Ut) For 5 cycles 70% Ut (>30% dip in Ut) For 25 cycles <5% Ut (>95% dip in Ut) For 5 s	40% Ut (>60% dip in Ut) For 5 cycles 70% Ut (>30% dip in Ut) For 25 cycles <5% Ut (>95% dip in Ut) For 5 s	user of the HRV Acquire requires continued operation during power interruptions, it is recommended that the HRV Acquire be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8:2009	3 A/m	na	Power supply magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: Ut is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – Electromagnetic immunity			
The HRV Acquire is intended for use in the electromagnetic environment specified below. The customer or the user on the HRV Acquire should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6:2013 Radiated RF IEC 61000-4-3:2006/AMD2:2010	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used to closer to any part of the HRV Acquire, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** **d = 1.2 √p** **d = 1.2 √p 80 MHz to 800 MHz** **d = 2.3 √p 800 MHZ to 2.5 GHz** 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). Field strength from fixed RF transmitters, as determined by an

			electromagnetic site survey [a], should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

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 radios, 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 HRV Acquire is used exceeds the applicable RF compliance level above, the HRV Acquire should be observed to verify operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the HRV Acquire.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the HRV Acquire.

The HRV Acquire is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the HRV Acquire can help prevent electromagnetic interference by maintaining a minimum distance between mobile and portable RF communications equipment (transmitters) and the HRV Acquire as recommended below, according to the maximum output power of the communication equipment.

	Separation distance according to frequency of transmitter m		
Rated maximum output power of transmitter W	**150 kHz to 80 MHz** d = 1.2 √p	**80 MHz to 800 MHz** d = 1.2 √p	**800MHz to 2.5 GHz** d = 2.3 √p
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.79	3.79	7.27
100	12.0	12.0	23.0

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 manufacturer.

NOTE 1 – At 80 MHz and 800 MHz, the separation distance for 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.

NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally

required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Testing Results Summary.

IEC 60601-1:2005 Safety. IEC 60601-1-2:2014 EMC. IEC 60601-2-27:2011 Ed 3 Electrocardiographic Monitoring. IEC 60601-2-27:2011 Ed 3 Letter Report.

Responsibility of the Supplier

WR Medical Electronics Co. accepts responsibility for the effects of safety, reliability, and performance of the equipment, only if:

- Assembly operation, extensions, readjustments, modifications, and repairs are conducted by persons authorized by WR Medical Electronics Co.
- The electrical installation of the room complies with local regulations.
- The equipment is used in accordance with the Instructions for Use.

Parts of the Device

The HRV Acquire and its supporting parts are regarded as Class IIa.

Part #.	Description	Intended Use
5047	ECG, Three Lead patient cable. Cable length, 2.8 meters.	Patient cable connects lead wires to the HRV Acquire.
5048	ECG cable lead wires. Cable length, 0.46 meters.	Connection from the electrodes to the ECG patient cable.
5051	Medical Desktop power supply. Cable length, 2.5 meters.	Powers the HRV Acquire with +5VDC voltage.
5812	Valsalva Hub and tubing. Cable length, 3 meters.	Expiratory pressure connection to the HRV Acquire.
5813	Valsalva Bugle.	Plugs into the Valsalva Hub. Provides comfortable way for the patient to provide expiratory pressure.
5815	Valsalva Hub and Tubing. Cable length,3 meters. (Pairs with Filtered Mouthpiece)	Expiratory pressure connection to the HRV Acquire, that pairs with item 5816.
5816	Valsalva Filtered Bugle.	Plugs into the Valsalva Hub (5815). Eases concerns of cross contamination between patients.
5582	Chest Expansion bellows. Cable length, 3 meters.	Provides Respiratory effort.
5651	Instruction for Use.	Safety and operating information.
5552	USB cable. Cable length, 1.8 meters.	Data connection, HRV Acquire connection to computer.

5448 / 0327	Power Conditioner.	Low-Impedance Isolation transformer, 120V or 240V.
3214*	Electrodes, Silver-Silver chloride.	Electrical conductor which is applied to the surface of the body to transmit the electrical signal at the body surface to the HRV, via lead wires and cables.

Note: The HRV Acquire outputs the heart rate to WR Testworks via the USB interface.

* These electrodes are manufactured by ConMed Corporation, REF 1750-030. These electrodes are silver/silver chloride type and are CE marked. Use by information is printed on the package.

WARNING: Use of parts other than those specified above may result in increased emissions or decreased immunity of the equipment.

Site Preparation, Placement of Electrodes, and Leads.

Instructions:

Ensure that ECG electrodes are in the correct locations, that they are fully adhered, and that the ECG cable clips are fully in contact with the electrodes.

White – Right arm (RA). Place under right clavicle, mid-clavicular line within the rib cage frame.

Black – Left arm (LA) Place under left clavicle, mid-clavicular line within the rib cage frame.

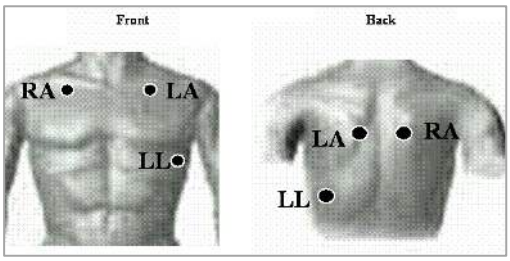
Red – Left leg (LL) Place on the lower left abdomen or back within the rib cage frame. This is the reference. NOTE: Reference electrode site is not critical.

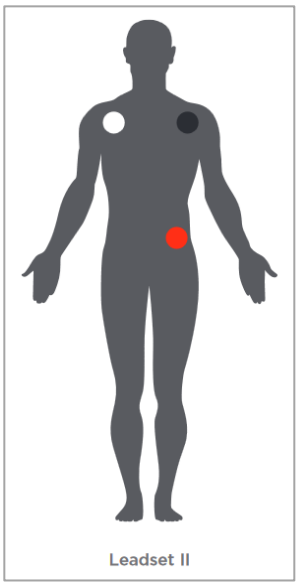
Electrode type recommended is silver/silver-chloride.

Ensure that proper site preparation was done underneath the electrodes with alcohol and Nu Prep, or another standard ECG preparation.

If you are getting a lot of artifact, remove the pads, prepare the skin, and then start again with fresh pads.

Cables may be removed in any order by disconnecting the ECG cable clips and gently peeling the electrodes from the skin.





Sample Protocol HRDB (Heart Rate Deep Breathing)

Several items affect Heart-Rate Deep Breathing (HRDB). These must be considered by the technician and controlled. This is to maintain standardization and consistency between test subjects and for repeated tests on the same patient.

Instructions:

- Have the patient come in, relaxed and comfortable, with an empty bladder. Patient should be supine for a minimum of 5 minutes prior to starting the test.

- Attach the chest expansion bellows to the patient. To start, expand the bellows by 4-5 inches, stretching it over the patient's chest, with the rubber bellow material on the front of the patient and the ball chain on the back (Figure 1). Place on the rib cage, at the location where the greatest expansion is expected. Do not place bellows over the reference ECG electrode as it may cause ECG artifact. Plug the luer fitting in to the specified location on the HRV Acquire main unit AFTER attaching the bellows firmly to the patient (Figure 2).

Figure 1: Attach the chest expansion bellows over the rib cage at the location of greatest expansion.

NOTE: If chest expansion trace is not visible during the recording, disconnect the bellows from the HRV Acquire, ask the patient to breath out completely, and reattach the bellows to the HRV.

- Attach the ECG electrodes (white on right, black on left, and red is reference).

- Turn on the HRV device and the WR Testworks software.

- Select (or create) the patient in the Test Explorer and select the HRDB test icon.

- Enter visit information and begin recording.

Figure 2: Plug the luer fitting into the HRV Acquire main unit.

- Explain the procedure to the subject:

"We are going to be testing your autonomic nerves. This test is quite simple. We will ask you to breathe deeply at the same rate as the oscillating bar (or to breathe in and out according to my hand movements) for a total of 8 breaths. After a 5-minute rest, we will ask you to repeat the test with another 8 breaths. It is important to breathe as deeply as possible. You can breathe in through your nose and out through your mouth if that is comfortable for you. Do not hold your breath at any time but use a full 5 seconds for breathing in and a full 5 seconds for breathing out. We will have you try it for 2 breaths so you can see how it feels."

- Give the patient a practice test. The practice should be only two breaths. Start/Stop the metronome as needed with the Metronome button on the toolbar.
- Let the subject rest 2 minutes after the practice.
- Press the Metronome button to start the metronome operation when the patient has fully exhaled (metronome begins with inspiration phase). Press again to stop metronome after set is completed. If automatic event markers are enabled (default), event marks will be inserted into the recording at the start and stop points.

NOTE: If the HRV Acquire configuration includes a value for the respiration cycles, the metronome will stop automatically after the specified respiration cycles have been performed.

- Rest for 5 minutes. DO NOT STOP THE TEST IN WR TESTWORKS, CONTINUE RECORDING.
- Start the second set. (Additional sets can be done, repeat after rest period)
- When complete, stop the recording.
- Click Finish Test to finalize recording.

NOTE: Keep recording within WR Testworks throughout the entire test, even while the patient is resting between sets.

Sample Protocol for Valsalva Maneuver

The heart is monitored by ECG, pressure recording, or other methods while the patient performs the Valsalva maneuver; cardiac volume decreases in unaffected patients but may dilate in a patient with impaired myocardial reserve; there is a characteristic complex sequence of cardiocirculatory events, departure from which may indicate disease or malfunction.

Several items affect the Valsalva Recording. These must be considered by the technician and controlled to maintain standardization and consistency between test subjects, for repeated tests on the same patient.

Instructions:

- Have the patient come in, relaxed and comfortable, with an empty bladder.

NOTE: Patient should be supine for a minimum of 5 minutes prior to starting the test.

- Attach the ECG electrodes.
- Connect blood pressure device, where applicable.
- Turn on the ECG device and the WR Testworks software.
- Select the patient in the Test Explorer (if you need to add new patient, refer to Patient List Control on p. 24 of the TestWorks Manual), then select the Valsalva test icon.
- Enter visit information, then click 'Save'.
- Begin recording.
- Explain the procedure to the subject:

"We are going to be testing your autonomic nerves. This test is quite simple. We will ask you to exhale into the mouthpiece and cause the light bar to move upwards to the 40-mmHg line and continue blowing for 15 seconds. After a 5-minute rest, we will ask you to repeat the test. It is important to try and reach 40 mmHg of pressure and hold it as steady as possible. Do not hold your breath at any time. We will have you try a practice test so you can see how it feels."

- Give the patient a practice test.
- Let the patient rest 2 minutes after the practice.
- Start the first set. A mark will automatically be placed when the patient's expiratory pressure reaches the target level (40 mmHg by default), and another marker will automatically be placed after the set Valsalva maneuver time (15 seconds by default).
- Let the patient rest for 5 minutes.
- Start the second set.
- Continue recording 30-45 seconds after the second set finishes, then stop the recording.
- Click Finish Test to finalize recording.

NOTE: Keep recording on WR Testworks throughout the entire test, even while the patient is resting between sets.

Sample Protocol for Performing Tilt

Several factors affect the Tilt Recording. These must be considered by the technician and controlled in order to maintain standardization and consistency between test subjects or for repeated tests on the same patient. It's important to perform the tilt after the patient has been lying down for a standard amount of time, typically 20 minutes.

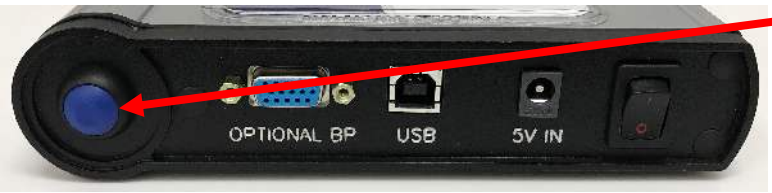
Instructions:

- Have the patient come in, relaxed and comfortable, with an empty bladder. **IMPORTANT:** The patient should be supine for a minimum of 20 minutes prior to starting the test.
- Attach the ECG electrodes.
- Connect blood pressure device, where applicable.
- Turn on the ECG device and the WR Testworks software.
- Select the patient in the Test Explorer (if you need to add new patient, refer to Patient List Control on p. 24), then select the Tilt test icon.
- Enter visit information, then click 'Save'.
- Begin recording.

- Explain the procedure to the subject: "We are going to be tilting you up to a near vertical position and will be monitoring your heart rate and blood pressure while doing so."
- If the tilt test is configured for manual blood pressure entry, enter the baseline blood pressure.
- After at least a minute of baseline recording, tilt the patient up (to 70 degrees).
- Press the Mark key in WR Testworks to signify the beginning of the tilt.
- Press the Mark key again when the patient is tilted back down. Continue recording at least one minute following the tilt down.
- When complete, stop the recording.
- If providing manual blood pressure, check the entries for accuracy prior to saving the test. Once saved, these values cannot be changed (as they are part of the 'recorded' test).
- Click Finish Test to finalize recording.

Peak Detect Sensitivity Selection

During normal operation, the HRV Acquire uses an algorithm that ensures proper peak detection for Heart Rate and R-R Interval values. If the “Check ECG” error is displayed and electrodes have been properly applied, the ECG signal may not be meeting the peak detect rules. If necessary, the peak detect sensitivity can be adjusted using the pictured button on the top of the HRV Acquire:



The Peak Detect Sensitivity Selector allows for a relaxing of the requirements to detect a beat in noisy or non-ideal circumstances.

There are 4 LEDs to indicate relaxation of these requirements.

No LEDs lit – Standard Operation

1st LED lit – This disables the width and amplitude of the ‘R’ wave checks.

2nd LED lit – As 1st, and disables the requirement for multiple crossing back and forth of a set baseline.

3rd LED lit – As 2nd, and disables the requirement for a blanking period with each pulse.

4th LED lit – As 3rd, and disables the required 4 threshold crossings of the internally calculated threshold.

Note: The endcap with optional abdominal expansion may look slightly different than what’s pictured above.

Maintenance

The HRV Acquire does not require regular maintenance. Visually examine the equipment and look for damages or changes. Hose assemblies should be examined for nicks, cuts, or other sources of leaks.

Cleaning Instructions

Before cleaning, ALWAYS ensure that the unit is powered off and that the power cord is disconnected. NEVER immerse the unit or any components. NEVER apply cleaning solutions or moisture the unit directly, instead apply to the cloth and use it to then clean the requisite components. ALWAYS ensure that the unit is clean and completely dry before reconnecting power to resume testing.

- The main unit may be cleaned with a dry, lint-free clean cloth.
- If the main unit becomes visibly soiled, it may be cleaned using a damp, lint-free cloth, enzymatic cleaner, quaternary ammonium compound, or bleach wipes.
- Isopropyl alcohol (70%) may be used as an alternative but may over time strip ink from printed labels and printed materials on the surface of the unit.
- Inspect the device and cables before using to detect any damage.
- Do not immerse unit or any cables. Cables should be carefully coiled when not in use to prevent tangling or breaking.

Sterilization

Not Required.

Troubleshooting

Problem	Possible Cause	Correction
"Check ECG" Error	Poor patient connection.	Perform skin prep and/or adjust electrode placement.
Flat-line ECG signal	Temporary corruption of USB connection to computer.	End any test that may be running. Power the HRV Acquire off for 15 seconds, then turn power back on.
Device does not record data.	Device is not connected. Device is not powered on. Cables are improperly connected.	Ensure device is powered on, connected to the host computer, and all cables are properly connected.
Unable to save recorded data.	Cables disconnected before testing completed. Device powered off before testing is completed.	Ensure cables remain connected and device remains powered on during testing. Retest patient as current data may be invalid.

Disposal

WEEE Directive 2012/19/EU - Do not dispose of WEEE products in general waste. At the end of life of the product, contact WR Medical Electronics Co.'s Customer Service for return instruction. Disposal of devices or consumables must be done in accordance with local, state, and federal laws and regulations.

Service and Technical Support

This device is to be serviced only by WR Medical Electronics Co. If servicing is done by any party other than WR Medical Electronics Co., the product warranty and/or safety or quality certifications could become invalid. Contact WR for advice before returning for repair.

No readjustments or modifications are to be made by anyone other than persons authorized by WR Medical Electronics.

Prior to returning the HRV Acquire unit for repair, please contact the Technical Support/Help Desk for a Return Authorization Number.

Technical Support/Help Desk
WR Medical Electronics Co., 1700 Gervais Avenue, Maplewood, MN 55109 USA
Phone: 651-604-8483 or toll-free: 800-635-1312
Fax: 651-604-8499
E-mail: helpdesk@wrmed.com
Web: www.wrmed.com

The Help Desk staff is available during normal business hours (8:00 am to 4:30 pm, Mon - Fri, CST).

Warranty

WR Medical standard 1-year warranty from date of purchase for main device. Cords and Cables are 90-days. If additional warranty is needed, please contact the sales department for additional information.

Suggested Readings

Phillip A. Low, MD. Autonomic Nervous System Function, J Clin Neurol 10(1):14-27, 1993.

Phillip A. Low, MD. Effect of Age and Gender on Sudomotor and Cardiovagal function and Blood pressure response to Tilt in Normal Subjects. Muscle Nerve 20: 1561-1568, 1997.

Phillip A. Low, MD. Autonomic function tests: some clinical applications. J Clin Neurol 2013;9:1-8.

Phillip A. Low, MD. Postural tachycardia syndrome (POTS). J Cardio Electrophysiol. 2009/3;20(3):352-358.

Phillip A. Low, MD. Autonomic Symptoms and Diabetic Neuropathy. DIABETES CARE. VOLUME 27, NUMBER 12, DECEMBER 2004.

Elizabeth R. Vogel. Effect of Position on Valsalva Maneuver: Supine vs. 20 Degree Position. J Clin Neurophysiol. 2008 Oct; 25(5): 313-316.

SALES SPECIFICATION SHEET - **HRV ACQUIRE®**

WR Medical Electronics Co.
1700 Gervais Avenue
Maplewood, MN 55109
www.wrmed.com | 651-604-8400

PHYSICAL DIMENSIONS

Height:	10.5 in. (26.7 cm.)
Width:	6.5 in. (16.5 cm.)
Depth:	1.25 in. (3.2 cm.)
Weight:	2.3 lbs (1 kg)

POWER ADAPTOR REQUIREMENTS

WR Medical Part # : 5051

RATED AC INPUT	RATED DC OUTPUT
100 - 240 VAC, 50/60 Hz	+5VDC - 20VA

ENVIRONMENT

	OPERATING	TRANSPORT AND STORAGE
Temperature:	20 - 25.6 degrees C	0 - 40 degrees C
Relative Humidity:	30 - 85% (non condensing)	0 - 80% (non condensing)
Atmospheric Pressure:	N/A	300 hPa – 1060 hPa

DEVICE SPECIFICATIONS

Pressure Transducers:	3 inputs - Expiratory Pressure (Valsalva), 2 Chest Expansion (1 optional)
Optional Output:	ECG Signal and ECG Trigger Sync
Custom Input:	External ECG and External ECG Trigger Sync; 4 Analog Inputs via Optional Breakout Box
Mount Type:	Vesa 75
Conforms to:	IEC 60601-2-27 Electrocardiographic Monitoring

SOFTWARE REQUIREMENTS

Application Software: WR TestWorks®

REGULATORY

FDA MDL Number:	D158173
FDA 510K:	K092809
FDA Device Class:	II
Health Canada License Number :	87605
Device Directive 93/42/EEC for Medical Devices	
Certificate No.:	41314493-02
EC Class:	IIa

ETL CLASSIFIED
C ETL US LISTED
Intertek
CE 0413