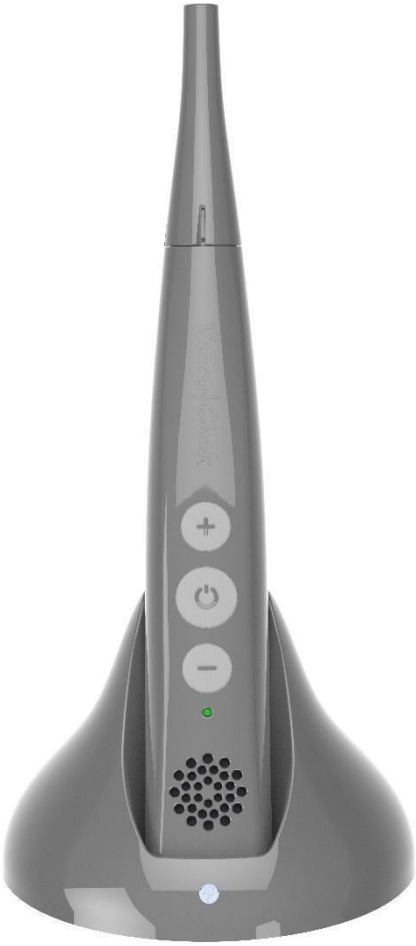
8 MHz Doppler System

For Use with VascuChek® Clinical Probes

Remington® MEDICAL

Instructions for Use



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Description

The VascuChek® 8 MHz Doppler System, manufactured by Remington Medical, Inc., is a diagnostic medical device that provides audible indication of relative flow through blood vessels. A Doppler transducer (probe), which plugs onto the transceiver unit, emits a continuous ultrasonic signal. A varying audible signal is produced when the probe is placed upon the skin adjacent to a vessel within which there is flow. The frequency (i.e., pitch) of the signal is proportional to the blood velocity within the vessel. Distinctive tonal patterns are produced which are indicative of the flow pattern in terms of velocity vs. time. The volume of the tone may be adjusted by means of buttons located on the transceiver. A transmitter in the transceiver drives the ultrasonic transmitting crystal located at the tip of the probe. The ultrasonic waves generated by the crystal travel through the tissue just under the probe tip. They are then reflected back towards the probe whenever they encounter a boundary between tissues of different densities. This circuit amplifies the returning echoes, compares their frequency to that of the transmitted signal and converts the Doppler shifted frequencies to audible tones.

Indications for Use

Clinical Use

The VascuChek® device is intended for the non-invasive transcutaneous evaluation of blood flow in Peripheral Vasculature.

Contraindications

The VascuChek® device is not intended for use in direct cardiac application.

The VascuChek® device is not intended for fetal or pediatric use.

The VascuChek® device is not intended for abdominal, intraoperative, small organ (breast, thyroid, testes, etc.), neonatal cephalic, or adult cephalic use.

Warnings

WARNING: Bodily injury is possible if procedures are not followed exactly.

WARNING: Never sterilize the Transceiver with autoclave, ultraviolet, gamma radiation, gas, steam, or heat sterilization techniques. Severe damage and personal injury could result.

WARNING: Do not submerge VascuChek® or charger during reprocessing.

WARNING: Do not reprocess the charger while connected to a hospital grade outlet.

WARNING: There are no user serviceable components inside this device. Disassembly of the internal components of this unit may result in circuit damage. Do not modify this device.

WARNING: Not for use in oxygen enriched atmospheres.

WARNING: The VascuChek® should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the VascuChek® should be observed to verify normal operation in the configuration in which it will be used.

WARNING: Never reuse single-use Clinical Doppler probes. Reuse may lead to cross contamination and mechanical damage. No proven method exists which can eliminate the possibility of transmitting prion-based brain wasting disease such as variant Creutzfeldt-Jakob Disease (vCJD). Probes which come in contact with brain tissue must be disposed of by incineration.

WARNING: Use VascuChek® only with compatible VascuChek® Doppler probes.

WARNING: Electrostatic discharges of +/-15KV around the LED and AC to DC power supply have damaged the AC to DC supply. Consult Remington Medical for help if a severe ESD event occurs that prevents the charger from powering on.

WARNING: 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 VascuChek® device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING: Portable and mobile RF communications equipment such as diathermy, electrocautery, and RFID equipment may affect the transceiver and charger. The charger should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the charger LED should be observed to verify normal operation while charging. The transceiver may temporarily experience a disruption in function while near devices emit strong radiated fields. If undesirable effects are observed, try one of the following:

1. Reorient or relocate the other equipment.
2. Increase the separation between the VascuChek® and the other equipment.
3. Connect the other equipment into an outlet on a circuit different from that to which the VascuChek® charger is connected.
4. Consult Remington Medical for help.

WARNING: Electromagnetic interference has been observed in testing at 80 MHz and 94 MHz causing the charger to temporarily stop charging. If performance of the system is lost or degraded due to electromagnetic interference, unplug the charger and reconnect to reset the charger. If the interference persists, it may be necessary to relocate the charger farther away from the source of the interference.

WARNING: Check the VascuChek® Transceiver is sufficiently charged before use. Refer to “Charging the Transceiver” section below.

WARNING: User should not touch VascuChek® transceiver pins when in contact with the patient.

Cautions

CAUTION: Equipment or software damage is possible if procedures are not followed correctly.

CAUTION: Because the VascuChek® needs to be sensitive to very weak signals from blood flow, by design it may be susceptible to picking up interference from other equipment. Refer to Technical Description Table 2.

CAUTION: Properly dispose of Transceiver according to EPA’s Universal Waste Regulation. VascuChek® Transceiver and Charger may be returned to manufacturer for proper disposal.

CAUTION: The VascuChek® should not be used in the presence of any high frequency equipment, including high frequency surgical generators, MRI, or short-wave therapy equipment.

CAUTION: Do not use the device in close proximity (<1m) to electromagnetic (RM) emitters such as wireless power transfer (WPT) and 5G during use. If interference is observed during use, increase distance from potential sources of EM interference.

CAUTION: The VascuChek® should not be used in emergency medical services and home healthcare environments.

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.

CAUTION: Do not re-use single-use disposable Clinical Doppler probes. Reuse may lead to cross contamination or mechanical damage of the device.

CAUTION: Prior to use, inspect Clinical Doppler probe for damage, such as cracks that could allow for the ingress of fluids into the probe, and sharp edges.

CAUTION: The Clinical Doppler probe is delicate. Do not drop or strike against hard surfaces. Avoid excessive mechanical pressure on the Doppler probe.

CAUTION: Check to ensure connection between Clinical Doppler probe and VascuChek®.

CAUTION: To avoid biological hazards, properly dispose of Clinical Doppler probe according to accepted medical practice and within local, state, and federal laws and regulations.

CAUTION: The Clinical Doppler probes are not to be used on or near the eyes.

Operation

Transmission Frequency	8 MHz
Transmission Characteristic	Continuous wave

Environment

Ambient Operating Temperature Range	+15º to +30ºC
Ambient Operating Humidity Range	35% to +85% RH, non-condensing
Ambient Operating Atmospheric Pressure Range	70kPA to 106kPA
Ambient Shipping Temperature Range	-15º to +55ºC
Ambient Shipping Humidity Range	35% to +85% RH, non-condensing
Ambient Shipping Atmospheric Pressure Range	50kPA to 106kPA
Ambient Storage Temperature Range	-15º to +25ºC
Ambient Storage Humidity Range	35% to +85% RH, non-condensing
Ambient Storage Atmospheric Pressure Range	50kPA to 106kPA
IPX1 (Transceiver/Probe/Charger)	No special protection
Surface Temperature - Doppler probe	Less than 41ºC

Power

VC-TRX-01 Doppler Transceiver	Permanent two cell lithium iron secondary battery
VC-CH-01 VascuChek® charger	Charger includes external power source, A/C to D/C power supply

Physical

Dimensions	221x 33 x 31 mm
Weight	90 grams

Explanation of Symbols

Clinical Probe Only	
Do Not Re-use	
Transceiver Only	
Type CF Applied Part	
Charger Only	
Direct current	
Class II equipment	

All Units	
Follow Instructions for Use	 www.remmed.com
Date Manufactured	
Catalog Number	
Lot	
Protection from Ingress of Water	IPX1
Limit of temperatures (All, see input from environment table)	
Limit of Relative Humidity (All, see input from environment table)	
Limit of Atmospheric Pressure (All, see input from environment table)	
Manufacturer	
By Prescription Only	
MR Unsafe	

Transceiver Description

Figure 1 – VascuChek® Transceiver

1) Power Switch: A push-button that when depressed turns the unit ON resulting in an audible confirmation tone. Illumination of a green LED indicates Power ON and battery voltage is above low battery threshold. A yellow LED shows the internal battery is nearly depleted and flashing red indicates device is shutting down due to low battery. An additional single press Powers OFF the unit resulting in a distinct audible confirmation tone.
2) Volume Increase Switch: A push-button that when depressed will increase the volume of the audible Doppler signal. A double tone will sound at each volume increase with the second tone at a higher pitch. When maximum volume is reached a double tone at the same pitch will be sounded.
3) Volume Decrease Switch: A push-button that when depressed will decrease the volume of the audible Doppler signal. A double tone will sound at each volume decrease with the second tone at a lower pitch. When minimum volume is reached a double tone at the same pitch will be sounded.

Power/ Low Battery Indicator: A yellow LED which, when illuminated, indicates that the batteries are below their low battery threshold. The LED will flash red, and the system will automatically shut OFF when the battery voltage is too low to maintain proper operation of the unit.

No Probe Detected: If no probe is detected by the Transceiver, a series of rapid tones will sound, and the system will automatically shut OFF.

Setup

CAUTION: Prior to use, inspect Doppler probe for damage, such as cracks that could allow for the ingress of fluids into the Doppler probe, and sharp edges.

Carefully unpack your VascuChek® Transceiver. Inspect the transceiver for damage. If the transceiver is missing or any damage is found, contact Remington Medical for further instructions.

Transceiver & Charger Placement

The VascuChek® Transceiver needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information located in Technical Description section of this Instructions for Use.

Portable and mobile RF communications equipment can affect the VascuChek® Transceiver.

Place VascuChek® Charger on a suitable stand, cart, or table outside the sterile field. The VascuChek® Transceiver should not be used in the presence of any high frequency equipment, including high frequency surgical generators. The transceiver has a rating of IPX1. Keep the transceiver away from all open liquids.

Charging the Transceiver

CAUTION: Use only with VascuChek® Charger.

Connect power supply to a hospital grade outlet that is easily accessible. The charger LED becomes illuminated white.

Place Transceiver into the charger with the buttons facing outward. When the transceiver is properly connected, the charger LED switches from white (power connected) to charge status.

- Green Flash – Charging
- Green – Charge Complete
- Slow Yellow Flash - Fault (See Trouble Shooting Guide, below)

Patient isolation from the mains is accomplished in the following ways: When in use, the transceiver is powered by an internal battery and not connected to power main. When placed in the charger, the system provides isolation for two Means of Patient Protection (MOPP) through an AC/DC medical grade class II power supply. During manufacturing, each charger goes through dielectric withstand testing at 4000V. To isolate Charger from AC mains, unplug from AC outlet. To minimize power consumption un-plug Charger from outlet when not charging Transceiver.

Doppler Probe Connection

Doppler Probe Selection

CAUTION: Prior to use, inspect Clinical Doppler probe for damage, such as cracks that could allow for the ingress of fluids into the probe, and sharp edges.

CAUTION: Clinical Doppler probe not intended for surgical application.

VascuChek® Transceiver is designed to function only with Doppler probes that are compatible. Keep connectors away from all liquids. Acoustical output tables and information required by IEC 60601-2-37 can be found in the Technical Description section below.

Preparation for Use

Prior to use, charge the VascuChek® transceiver as per the “Charging the Transceiver” section above.

Turn the transceiver on by depressing the Power Switch. The initial volume level will be maintained from the previous use.

Adjust the volume by depressing the Volume Increase or Decrease push-button multiple times until desired volume is achieved. A tone confirms each press with a double tone for maximum and minimum volume.

Some "white" noise (white noise sounds like a radio that is tuned between stations) may be heard from the transceiver speaker.

To verify that the system is operational, gently apply sterile ultrasound gel to the Doppler probe, using aseptic technique, and move along any convenient sterile surface. This will produce a loud rasping noise, confirming that the system is operational.

Flow Determination

Place the tip of the Doppler probe (with ultrasound gel) directly on the skin over the vessel or other site to be evaluated, orienting the Doppler probe as shown in figure 2.

Adjust the angle between the Doppler probe and the vessel until the maximum audible signal is obtained. Typically, this is between 45° and 60° relative to the vessel.

Adjust the volume control on the transceiver to the desired level. If any flow is detected, the pitch of the resultant audible signal will correspond to its velocity, with higher pitches indicating higher velocities. The Doppler probe may be moved to various sites as required. (Note: Only the bottom 2.5 cm of the probe may be immersed in water or other liquids. Applied Part is the 2.5 cm of the probe proximal to the patient)

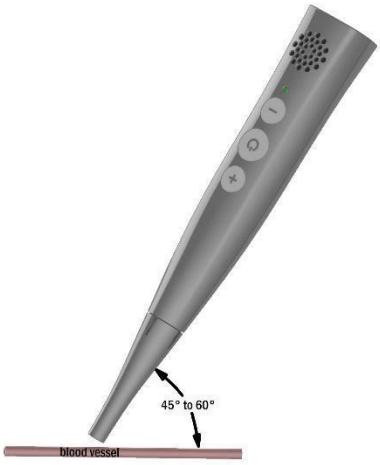

Figure 2 – VascuChek® is typically held between 45° and 60° relative to the vessel being tested.

Probe Removal

Clinical Doppler Probe

When the entire procedure is finished, turn the transceiver power OFF by depressing the Power switch.

Pull the probe from the transceiver. Then dispose of the probe properly, according to accepted medical practice and within local, state, and federal laws and regulations. Reprocess the transceiver as described in the “Reprocessing” section.

Performance Criteria

Failures include any time the unit does not produce an audible signal when detectable flow is present. In addition to component malfunction, failures also include units that produce a false audible that is indistinguishable from a signal produced by flow. Non-intentional audible signal tones are allowed to be produced by the unit, so long as they cannot be easily mistaken for flow.

Essential Performance

The VascuChek® is not intended to be used as the primary indicator of blood flow detection and therefore does not have nor rely on essential performance. Other clinical means should be utilized to check for failure or degradation of the VascuChek® Transceiver and confirm blood flow in critical applications.

The equipment or system may exhibit degradation of performance (e.g., deviation from specifications) that does not affect basic safety. In this instance, the device may produce reduced audio quality or audible clicks.

System Block Diagram

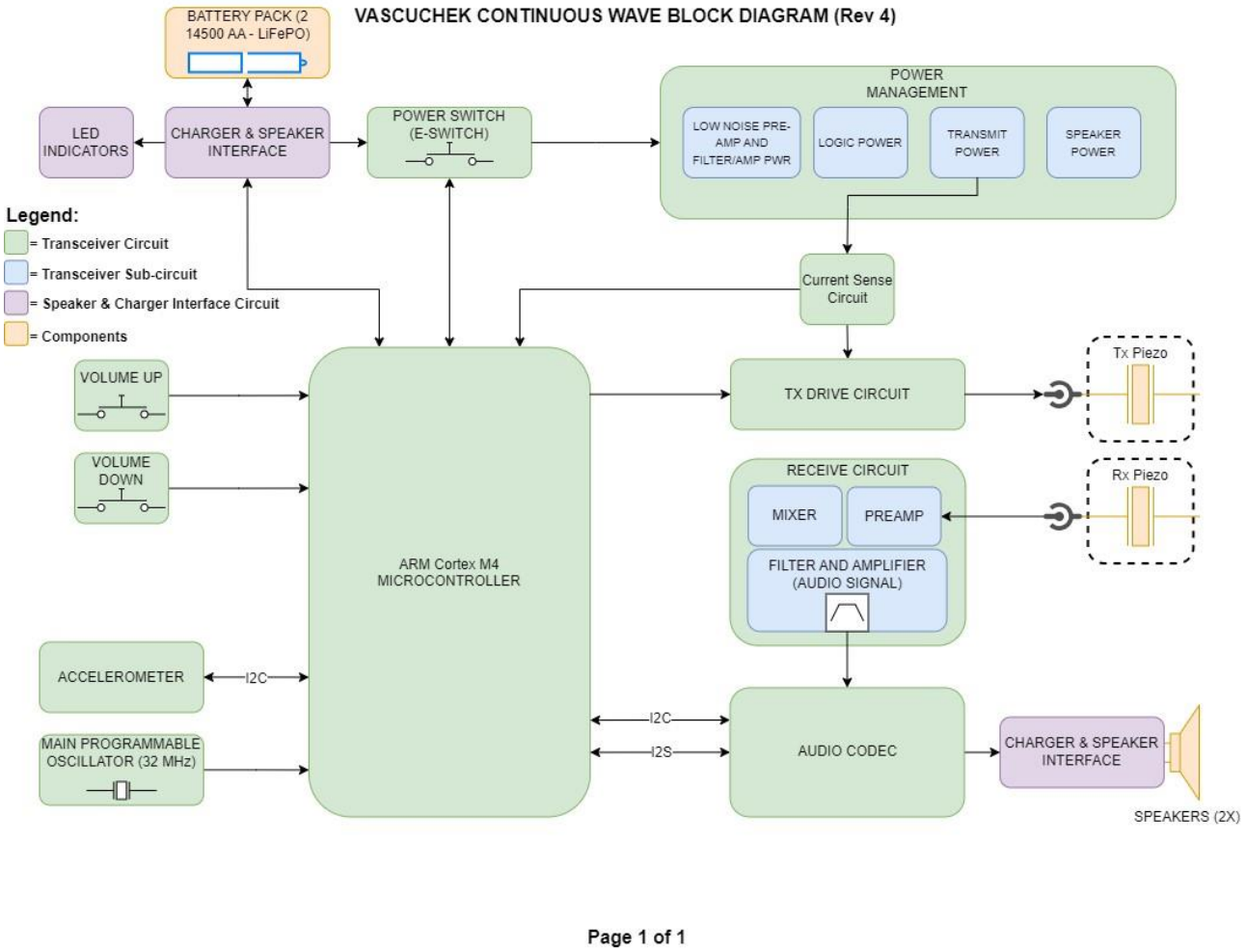

Figure 3 - Block Diagram of the Electronics of the VascuChek® Transceiver.

Technical Description

The VascuChek® is intended for use in the electromagnetic environment specified below. The user of the VascuChek® should assure it is used in such an environment.

Table 1 Guidance and manufacturer's declaration - Electromagnetic emissions

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF Emissions, CISPR 11	Group 1	The VascuChek® uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. However, in the event that interference occurs, it may be necessary to take mitigation measures, such as re-orienting or relocating the VascuChek® Transceiver or Charger or shielding the location.
RF Emissions CISPR 11	Class A	The VascuChek® meets the conducted and radiated performance requirements for non-life supporting equipment and meet the harmonic emissions, voltage dips and variations and voltage fluctuation (flicker) requirements for non-life supporting equipment pursuant to IEC 60601-1-2:2014 and CISPR 11, Al & A2, and IEC 61000-3-3. The VascuChek® is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: The VascuChek® is intended for use by healthcare professionals only. The VascuChek® may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the VascuChek® Transceiver or Charger or shielding the location.
Power Harmonic emissions	IEC 60601-1-2 IEC 61000-3-2	
Voltage fluctuations/flicker emissions	IEC 61000-3-3:	

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

Table 2 Guidance and manufacturer's declaration - Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) **IEC 61000-4-2**	+/- 8 kV contact +/- 15 kV air	+/- 8 kV Contact Discharge. +/- 2, +/- 4, +/- 8 and +/-15 kV Air Discharge.	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. WARNING: Electrostatic discharges of +/- 15KV around the LED and AC to DC power supply have damaged the AC to DC supply. Consult Remington Medical for help if a severe ESD event occurs that prevents the charger from powering on.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Radiated RF EM Fields **IEC 61000-4-3**		3 V/m 80 to 2700 MHz 80% AM (1 kHz)	Professional healthcare Environment WARNING: Portable and mobile RF communications equipment such as diathermy, electrocautery, and RFID equipment may affect the transceiver and charger. The charger should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the charger LED should be observed to verify normal operation while charging. The charger may temporarily experience a disruption in function while near devices emit strong radiated fields. If undesirable effects are observed, try one of the following: 1. Reorient or relocate the other equipment. 2. Increase the separation between the VascuChek® and the other equipment. 3. Connect the other equipment into an outlet on a circuit different from that to which the VascuChek® charger is connected. 4. Consult Remington Medical for help. WARNING: Electromagnetic interference has been observed in testing at 80 MHz and 94 MHz causing the charger to temporarily stop charging. If performance of the system is lost or degraded due to electromagnetic interference, unplug the charger and reconnect to reset the charger. If the interference persists, it may be necessary to relocate the charger farther away from the source of the interference.
Electrical fast transient/burst **IEC 61000-4-4**	+/- 2 kV AC mains +/- 1 kV I/O Ports	+/- 2 kV AC Mains +/- 1 kV I/O Ports	Mains power quality should be that of a typical commercial or hospital environment.
Surge **IEC 61000-4-5**	+/- 1 kV line(s) to line(s)	+/- 0.5 kV, 1 kV line to line (DM)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines. **IEC 61000-4-11**	100% dip in U_T for 0.5 cycle. 100% dip in U_T for 1 cycle 30% dip in U_T for 25 ms/30 cycles 100% dip in U_T for 250ms/300 cycles	100 V / 60 HZ: 100% dip 0.5 cycle 240 V / 50 HZ: 100% dip 0.5 cycle 100 V / 60 HZ: 100% dip 1 cycle 240 V / 50 HZ: 100% dip 1 cycle 100 V / 60 HZ: 100% dip 30 cycles 240 V / 50 HZ: 100% dip 25 cycles 100 V / 60 HZ: 100% dip 300 cycles 240 V / 50 HZ: 100% dip 250 cycles	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field **IEC 61000-4-8**	30 A/m	Transceiver: 30 A/m 50 Hz & 60 Hz three orthogonal orientations Charger: 30 A/m 50 Hz three orthogonal orientations	Power frequency magnetic fields should be at levels characteristic of a typical location of a typical commercial or hospital environment.

NOTE: U_T is the a.c. mains voltage prior to application of the test level.

Table 3 List of Symbols Used in Acoustic Output Reporting Table

Ispta.a the attenuated (or derated) spatial-peak temporal-average intensity (milliwatts per square centimeter). It may also be reported Ispta.3 and Ispta.α.

Wo the ultrasonic power (milliwatts). For the operating condition giving rise to Ispta.a, Wo is the total time-average power.

Z the axial distance at which the reported parameter is measured (centimeters).

Symbol	Term	Reference
Aaprt	= -12dB OUTPUT BEAM AREA	IEC 62359, 3.25
d_{eq}	= EQUIVALENT BEAM DIAMETER	IEC 62359, 3.22
f_{awf}	= ACOUSTIC WORKING FREQUENCY	IEC 62359, 3.2
Ipa,α	= ATTENUATED PULSE-AVERAGE INTENSITY	IEC 62359, 3.5
I_{pi}	= PULSE-INTENSITY INTEGRAL	IEC 62359, 3.32
Ipi,α	= ATTENUATED PULSE-INTENSITY INTEGRAL	IEC 62359, 3.6
Ispta	= SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY	IEC 62359, 3.38
$I_{ta,}\,\alpha(z)$	= ATTENUATED TEMPORAL-AVERAGE INTENSITY	IEC 62359, 3.8
MI	= MECHANICAL INDEX	IEC 62359, 3.23
P	= OUTPUT POWER	IEC 62359, 3.27
Pα	= ATTENUATED OUTPUT POWER	IEC 62359, 3.3
$P_{r,}$α	= ATTENUATED PEAK-RAREFACTIONAL ACOUSTIC PRESSURE	IEC 62359, 3.4
P_r	= PEAK-RAREFACTIONAL ACOUSTIC PRESSURE	IEC 62359, 3.28
prr	= PULSE REPETITION RATE	IEC 62359, 3.34
TI	= THERMAL INDEX	IEC 62359, 3.41
TIB	= BONE THERMAL INDEX	IEC 62359, 3.11
TIC	= CRANIAL-BONE THERMAL INDEX	IEC 62359, 3.15
TIS	= SOFT-TISSUE THERMAL INDEX	IEC 62359, 3.37
t_d	= PULSE DURATION	IEC 62359, 3.31
X, Y	= -12dB OUTPUT BEAM DIMENSIONS	IEC 62359, 3.26
z_b	= DEPTH FOR BONE THERMAL INDEX	IEC 62359, 3.17
z_{bp}	= BREAK-POINT DEPTH	IEC 62359, 3.13
z_s	= DEPTH FOR SOFT-TISSUE THERMAL INDEX	IEC 62359, 3.18

Table 4 Acoustic Output Reporting Table. Transducer Model: 8 MHz - Operating Mode: Continuous Doppler (CD)

Index Label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum Index Value		**0.05**	**0.24**		1.41		1.39
Associated Acoustic Parameters	pr.a@zMI (Mpa)						
	Wo (mW)		7.88		7.88		7.88
	W1x1 (mW)		7.88		7.88		
	zs (cm)			0.85			
	zb (cm)					0.85	
	zMI (cm)	0.85					
	zpii.a (cm)	0.85					
	fawf (MHz)	7.99	7.99	7.99	7.99	7.99	7.99
Other Information	prr (Hz)	N/A					
	srr (Hz)	N/A					
	npps	1					
	Ipa.a@zpii.a (W/cm^2)	N/A					
	Ispta.a@zpii.a (mW/cm^2)	462					
	Ispta@zpii (mW/cm^2)	736					
	pr@zpii (Mpa)	0.16					
Operating Control Condition	No operating controls change the acoustic output.						

Trouble Shooting Guide

Symptoms	Possible Problems & Solutions
Weak sound output, even at maximum volume setting.	The flow that is being heard is somewhat deeper than this unit is designed to detect.
	Doppler probe may be defective. Replace the probe. Contact Remington Medical, Inc.
	Transceiver may be defective. Contact Remington Medical, Inc.
"White" noise occurs at maximum volume setting and drawing the Doppler probe tip over a surface results in rasping noise, but Doppler probe does not detect flow.	Doppler probe is correctly evaluating a zero-velocity condition. No problem.
	Doppler probe is not positioned correctly. Review Flow Determination section.
	Doppler probe may be defective. Replace the probe. Contact Remington Medical, Inc.

Symptoms	Possible Problems & Solutions
	Transceiver may be defective. Contact Remington Medical, Inc.
"White" noise occurs at maximum volume setting, but drawing the Doppler probe tip over a surface does not result in a rasping noise.	Doppler probe may be defective. Replace the probe. Contact Remington Medical, Inc.
	Transceiver may be defective. Contact Remington Medical, Inc.
Transceiver beeps briefly and powers off.	Probe is not connected to the transceiver. Press the probe until it clicks into place or replace the probe.
No sound whatsoever, at any volume control setting; low battery indicator not illuminated.	The internal battery may be depleted. Charge the Transceiver.
	Transceiver may be defective. Contact Remington Medical, Inc.
Charger Fault – Slow Yellow Flash	Ensure the charger is plugged in and the contacts on the charger and transceiver are clean.

If the problem cannot be corrected after making the above checks and adjustments, contact Remington Medical, Inc. for additional help or return authorization at 1-800-989-0057 between the hours of 8:00 A.M. and 5:00 P.M. Eastern Time, Monday through Friday.

Maintenance

VascuChek® transceivers should be recharged within 1 month of receipt, and at least once every 6 months thereafter for best battery life.

Service

There are no user serviceable components inside this device. Disassembly of the internal components of this unit may result in circuit damage.

Device Lifecycle

The Transceiver contains a non-user replaceable rechargeable battery. Its capacity will gradually decrease and eventually will require replacement of the transceiver. The useful life will vary depending on usage and environment.

The date of manufacture is indicated by the first 5 characters of the Lot number (YYDDD, where YY is the last 2 digits of the year and DDD is the 3-digit day of the year).

End of Life Management

The Transceiver should be disposed of properly at life end as it contains a rechargeable battery. The Charger should be disposed of properly at life end as it contains a magnet.

Reprocessing

The transceiver or charger requires little maintenance. Keep them clean and free of dust. The exterior may be cleaned and disinfected using the following steps:

1) After every use, check the transceiver or charger for any sign of damage or wear.
2) Wipe the transceiver or charger with a dry soft cloth.
3) Flush each difficult to clean area, such as speakers & seams, of the device with 60 ML of cold water two (2) times using a 60mL syringe.
4) Using a soft bristle brush, brush the device for one (1) minute paying close attention to the speakers, seams, and labels.

5) After cleaning, wipe the transceiver or charger with a dry soft cloth to remove any moisture prior to initiating the disinfection process.
6) Wipe the transceiver or charger with PDI® Super Sani-Cloth® Germicidal wipe (Quaternary/high-alcohol formula (14.85%)) for three (3) minutes. Do not squeeze the cloth directly on the transceiver or charger.
7) Rinse by flushing each difficult to clean area such as speakers & seams, with 60mL of cold water two (2) times using a syringe.
8) Wipe the transceiver or charger with a lint-free cloth dampened with deionized water for one (1) minute two (2) times using a fresh cloth for each wiping session.
9) Allow to air dry before use.
10) Check the transceiver for any residual organic material. If any is present, remove it and disinfect the transceiver again by repeating steps 2-9 above.

The transceiver should not contact mucus membranes, blood, or compromised tissue. The VascuChek® device, when used with the Clinical probe, is not intended to be used inside the sterile field.

Accessories & Parts

Item	Catalog Number
VascuChek® Kit	VC-KIT-01
VascuChek® Transceiver	VC-TRX-01
VascuChek® Clinical Probe	VC-CP-01
VascuChek® Charger	VC-CH-01

For Pricing and Additional Information Please Call
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