8 MHz Doppler System

For Use with VascuChek® Surgical and 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 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.

Audio from the transceiver may be transferred to the speaker dock by Bluetooth® connection to provide additional volume.

Intended Use

Surgical Use

The VascuChek® device is intended for the intraoperative and transcutaneous evaluation of blood flow in the following clinical applications: Intraoperative (Microvascular and Vascular) Intraoperative Neurological, Transrectal and Peripheral Vascular.

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 use.

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

Warnings

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

WARNING: Do not use the Transceiver while in the Speaker Dock.

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 Speaker Dock during reprocessing.

WARNING: Do not reprocess the Speaker Dock while connected to an electrical 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 Surgical or 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: 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 speaker dock 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®, 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 speaker dock. The speaker dock should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the speaker dock 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® speaker dock is connected.
4. Consult Remington Medical for help.

WARNING: Other cables and accessories may negatively affect EMC performance.

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 or Speaker Dock pins when in contact with the patient.

WARNING: Do not position the VascuChek® Speaker Dock in a manner that makes it difficult to disconnect the device (e.g. remove the plug from the wall).

WARNING: The VascuChek® is MR unsafe.

WARNING: (Surgical Only) - Do not use on patients with less than a body mass of 3.73 kg (8.33 lbs).

Cautions

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

CAUTION: This VascuChek® is not intended for trans-esophageal use.

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 Speaker Dock 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 (EM) 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 use Surgical Doppler probe if sterile barrier is opened or damaged.

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

CAUTION: The Surgical or 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 Surgical or Clinical Doppler probe and VascuChek^{0}.

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

CAUTION: The Surgical 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/Speaker Dock)	No special protection
Surface Temperature - Doppler probe	Less than 41ºC

Power

VC-TRX-02 Doppler Transceiver	Permanent two cell lithium iron secondary battery
VC-SD-01 VascuChek® Speaker Dock	Speaker Dock includes a permanent single cell lithium ion secondary battery and an external power source, A/C to D/C power supply.

Physical

Dimensions	202 x 30 x 28 mm
Weight	88 grams

Explanation of Symbols

Surgical Probe Only	
Sterilized by Ethylene Oxide	
Use By	
Do Not Re-use	
Do Not Re-Sterilize	
Do Not Use if Package is Open or Damaged	
Made in the Dominican Republic	
Transceiver and Speaker Dock	
Bluetooth	
Recycle: Electronic Equipment	
SGS Certification	
Transceiver Only	
Audio Symbol	
Power Symbol	
Speaker Dock Only	
Direct current	
Class II equipment	

Other Device or Packaging Symbols	
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	
MRI Unsafe	
Non-Sterile	
Warning	

Transceiver Description

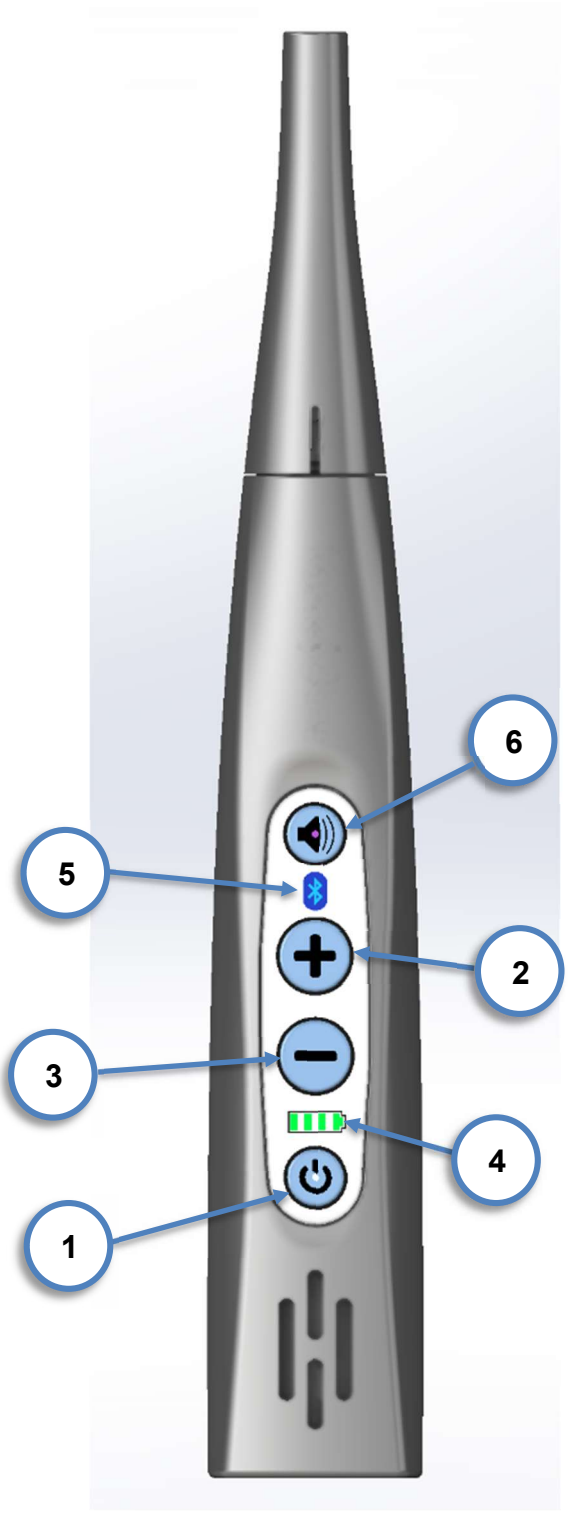


Figure 1 – VascuChek® Transceiver with probe

1) Power Switch: *A push-button that when depressed turns the unit **ON** resulting in an audible confirmation tone. Illumination of a **white** LED indicates Power ON and battery voltage is above low battery threshold. 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.*
4) Battery Indicator: *A battery status display indicates the charging status of the transceiver battery. Four bars indicate a full charge. One bar indicates 24% battery remains. Slow flashing indicates the battery is charging. The system will automatically shut **OFF** when the battery voltage is too low to maintain proper operation of the unit.*
5) Connection Indicator: *A **blue** LED indicates that a wireless connection is established between the transceiver and speaker dock*.
6) Transfer Switch: *A push-button that when depressed toggles between the transceiver's internal speaker and the external speaker dock when connected via Bluetooth. Illumination of a **green** LED indicates audio is being transferred to the speaker dock.*

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

Speaker Dock Controls and Indicators

Figure 2 – VascuChek® Speaker Dock

1) Power Switch: *A push-button that when depressed turns the unit **ON** resulting in an audible confirmation tone. An additional single press powers **OFF** the unit resulting in a distinct audible confirmation tone*.
2) Power/Transfer Indicator: *VascuChek LED illuminates **white** when the speaker dock is powered on. The LED color changes to **green** when the speaker dock is receiving audio from the transceiver.*
3) Wireless connection indicator: *LED flashes **purple/blue** when pairing to a transceiver. LED illuminates **solid blue** when a transceiver is connected and ready to send audio.*
4) Battery Indicator: *A battery status display indicates the status of the speaker dock's internal battery. Four bars indicate a full charge. One bar indicates 24% battery remains. Flashing indicates the battery is charging. The system will automatically shut **OFF** when the battery voltage is too low to maintain proper operation of the unit.*

The connection for the power supply may be found on the back of the speaker dock.

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.

Do not use if damaged or opened. Contact Remington Medical for further information.

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 & Speaker Dock 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® Speaker Dock 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 and speaker dock away from all open liquids.

Charging the Transceiver

CAUTION: Use only with VascuChek® Speaker Dock.

Connect power supply to the backside of the speaker dock and to a hospital grade outlet that is easily accessible.

Note: The transceiver will only charge when the speaker dock is plugged into an outlet.

Place Transceiver into the Speaker Dock with the buttons facing outward. When the transceiver is properly connected, the speaker dock battery status bar LED illuminates in green.

- Green bar pulsing – Charging
- Four solid green bars – Charge Complete

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. The transceiver will not function when cradled in the speaker dock.

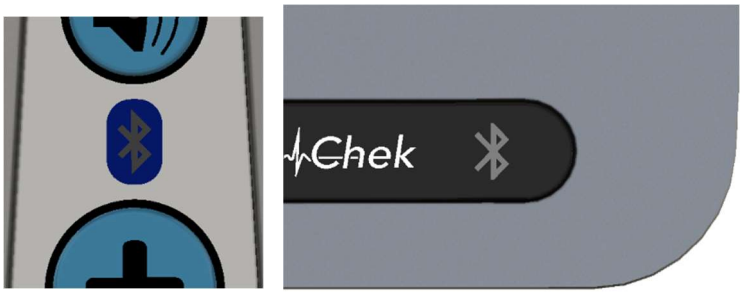
When placed in the speaker dock, the system provides isolation for two Means of Operator Protection (MOOP) through an AC/DC class II power supply. To isolate the speaker dock from AC mains, unplug from AC outlet. To minimize power consumption un-plug the speaker dock from outlet when not charging the Transceiver.

Pair and Connect the Transceiver to the Speaker Dock

1) To pair the transceiver to any speaker dock, ensure the speaker dock is turned ON and/or plugged in.
2) Place the transceiver into the speaker dock with the buttons facing outward.

Figure 3 – VascuChek® Transceiver Docked

- The connection indicator on the speaker dock and the transceiver should alternate blue-purple when pairing.
- Pairing is complete when the connection indicators are no longer illuminated.



3) A connection is automatically established when both the transceiver and paired speaker dock are turned ON. The connection indicator on both the transceiver and speaker dock will then illuminate blue.

Doppler Probe Connection

Doppler Probe Selection

CAUTION: Prior to use, inspect the Surgical or 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.

For surgical application use the Surgical Doppler probe.

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.

Surgical Doppler Probe with Sheath

1) Using aseptic technique, open the outer packaging and dispense the Doppler probe into the sterile field.

2) Remove the Doppler probe from remaining packaging and hold by its tip, with the open end ready to receive the transceiver. Note: Avoid gripping the Doppler probe's sheath as this will be deployed in future steps.

3) Transfer the transceiver into the sterile field by inserting it into the open end of the Doppler probe and pressing until it clicks into place.

4) Hold the tab marked "Pull" and pull steadily to extend the sheath completely over the transceiver.

5) Continue pulling to remove the tab and expose internal adhesive.

   CAUTION: The sterile field may be compromised if the sheath does not completely cover the transceiver or if anything else is allowed to touch the transceiver.

6) Press the sides marked “Seal” together to seal the transceiver within the sheath. Ensure a complete seal is established at the open end of the sheath.

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 directly on the vessel or other site to be evaluated, orienting the Doppler probe as shown in figure 2 below.

Adjust the angle between the Doppler probe and the vessel until the maximum audible signal is obtained.

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 Surgical probe may be immersed in water or other liquids. Applied Part is the 2.5 cm of the Surgical probe proximal to the patient)

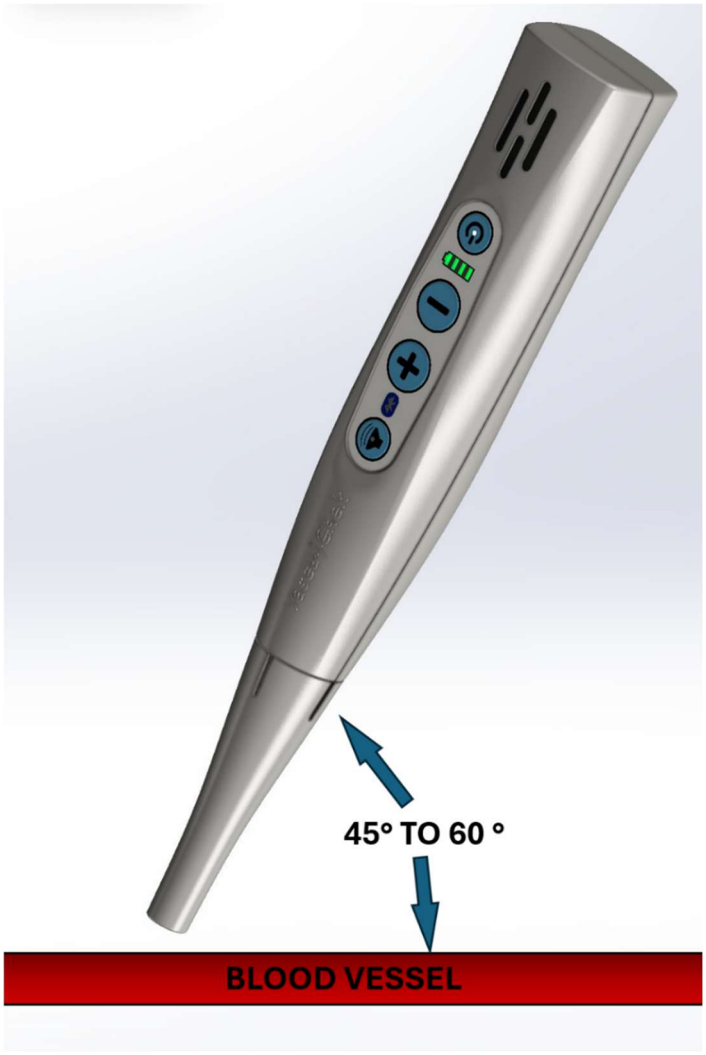


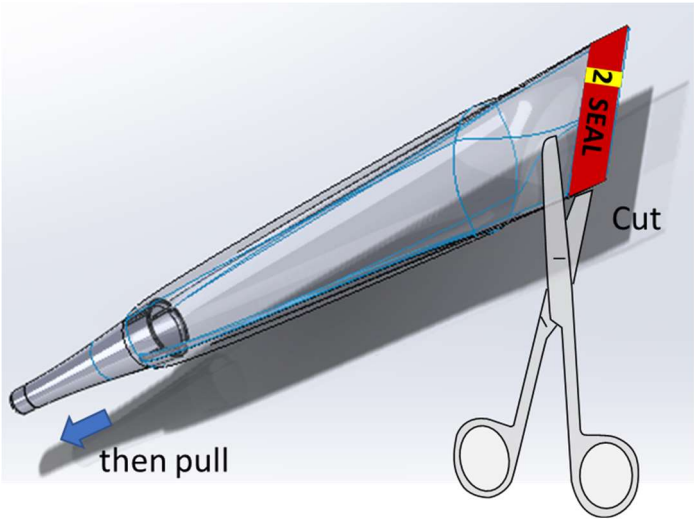
Figure 4 – VascuChek® is typically held between 45° and 60° relative to the vessel being tested

Probe Removal

Surgical Doppler Probe

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

Remove the device from the sterile field and cut the sheath near the seal with scissors as needed. Hold the device by the transceiver with clean hands and slowly pull the open end of the sheath up towards the probe so that the sheath is pulled inside-out trapping any blood or hazardous contamination in the sheath.



Pull 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.

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.

Cybersecurity Information

Bluetooth Connection: The VascuChek® uses Bluetooth® (version 5.4) Low Energy (BLE) radio via Out-of-Band (OOB) pairing for encrypted communication and streaming of audio between the Transceiver and Speaker Dock. The VascuChek® Transceiver and Speaker Dock may only connect to devices in which a secure connection is enabled via the OOB pairing connection process. BLE radio communications are implemented by an FCC-certified module on each of the Transceiver and Speaker Dock. Use of this connection is not required to use the Transceiver and may be disconnected at any time.

Communication Ports: The VascuChek® Transceiver and Speaker Dock include a physical UART connection port that sends and receives device data and which function to initiate the OOB BLE connection.

Secure Device Configurations and Firmware Updates: The VascuChek® Transceiver and Speaker Dock are provided in their secure configuration. The VascuChek® Transceiver and Speaker Dock firmware is fixed and cannot be updated by the user. Any unauthorized modification to the firmware may increase cybersecurity risk.

End of Support: The VascuChek® Transceiver and Speaker Dock firmware is fixed and cannot be updated by the user. As firmware components age, the original manufacturer may no longer provide support for these components. Use of devices when following end of support may increase cybersecurity risk. Remington Medical will inform customers about the transition period for any firmware components approaching their end of support date and any changes in cybersecurity risk associated with use of the device beyond this date.

Software Bill of Materials (SBOM): Remington Medical will provide a copy of the SBOM upon request. Please visit www.remmed.com or contact Remington Medical at 800-989-0057or Quality@remmed.com for additional information.

Cybersecurity Event Recording and Incidents: VascuChek® maintains an internal log of cybersecurity events including identification of connected devices and time / date information for initiation and discontinuance of OOB BLE component connections. This log may be used by Remington support staff to monitor and diagnose potential cybersecurity incidents. If the VascuChek® Transceiver and Speaker Dock are not behaving as expected and you anticipate a cybersecurity incident has occurred, stop use of the device immediately. Contact Remington Medical for instructions about returning and replacing your device.

System Block Diagram

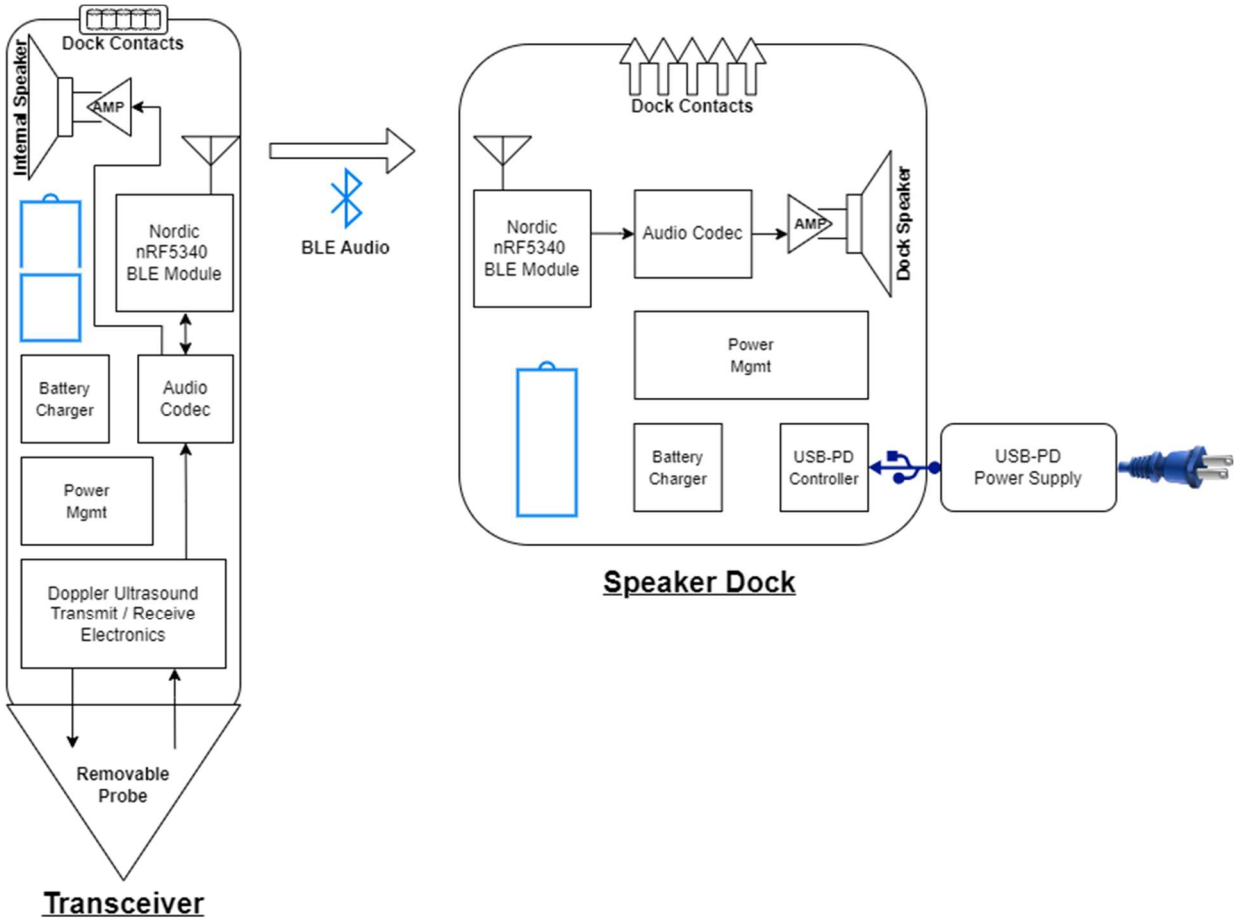


Figure 3 – System Block Diagram

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 for its internal function of ultrasound transmission and reception, as well as a Bluetooth Low Energy (BLE) radio for communication and streaming of audio between the Transceiver and Speaker Dock. RF emissions associated with ultrasound transmission and reception should be very low and not likely to cause interference in nearby electronic equipment. BLE radio communications are implemented by an FCC-certified module on each of the Transceiver and Speaker Dock, abiding by the Bluetooth Low Energy standard for frequency bands use, channel usage, modulation and limitations on transmitted power and RF emissions. The frequencies used and transmitted power are summarized below: • Radio protocol: Bluetooth Low Energy (BLE) • Frequency band: 2.4GHz ISM Band (2.402 - 2.480 GHz Utilized) • Channels: 40 channels with 2MHz spacing (3 advertising channels/37 data channels) • Channel Usage: Frequency-Hopping Spread Spectrum (FHSS) • Modulation: GFSK • Transmit power: 0dBm
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 60601-1-2:2020 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 Speaker Dock 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 +/-15 kV have damaged the AC to DC supply. Consult Remington Medical for help if a severe ESD event occurs that prevents the speaker dock from powering on.
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 speaker dock. The speaker dock should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the speaker dock LED should be observed to verify normal operation while charging. The speaker dock 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® Speaker Dock is connected. 4. Consult Remington Medical for help.
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	100% dip in U_T for 0.5 cycle.	100 V / 60 HZ: 100% dip 0.5 cycle 240 V / 50 HZ: 100% dip 0.5 cycle	Mains power quality should be that of a typical commercial or hospital environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
power supply input lines. **IEC 61000-4-11**	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 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	
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 Speaker Dock: 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
*A*aprt	= -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
*I*pa,α	= ATTENUATED PULSE-AVERAGE INTENSITY	IEC 62359, 3.5
I_{pi}	= PULSE-INTENSITY INTEGRAL	IEC 62359, 3.32
*I*pi,*α*	= ATTENUATED PULSE-INTENSITY INTEGRAL	IEC 62359, 3.6
*I*spta	= 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
*P*α	= ATTENUATED OUTPUT POWER	IEC 62359, 3.3
$P_{r,}\alpha$	= 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

Symbol	Term	Reference
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)

All Variables

CW Mode			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			0.05	0.19		1.15		0.89
Associated Acoustic Parameters	Pr.a@zMI	(MPa)						
	W0	(mW)		6.93		6.93		6.93
	W1x1	(mW)		6.93		6.93		
	zs	(cm)			0.89			
	zb	(cm)					0.89	
	zMI	(cm)	0.89					
	Zpii.a	(cm)	0.89					
	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)	418					
	Ispta @ Zpii	(mW/cm^2)	692					
	pr @ zpii	(MPa)	0.16					

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.
	Transceiver may be defective. Contact Remington Medical, Inc.

Symptoms	Possible Problems & Solutions
"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.
Speaker Dock does not power on.	Ensure the power supply and cable are connected to the speaker dock and outlet.
Transceiver fails to pair when inserted to the Speaker Dock. The VascuChek Logo on the Speaker Dock may flash.	Inadequate or interrupted connection between Transceiver and Speaker Dock during pairing. Remove and carefully re-insert the transceiver into the dock. If issue persists, power off and unplug the AC adapter from speaker dock, then reattach.

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 and speaker docks 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 Speaker Dock should be disposed of properly at life end as it contains a magnet.

Transceiver Reprocessing

The transceiver requires little maintenance. Keep it clean and free of dust. It is recommended that the transceiver be checked after each use for any sign of damage or wear. The exterior may be cleaned and disinfected using the following steps:

1) Check the transceiver for any organic material.

Cleaning:

2) Wipe the Transceiver with a dry soft cloth to remove gross contamination.
3) Flush each difficult to clean area, such as speakers and seams, with 60mL of cold tap water two (2) times using a 60mL syringe.

4) Using a soft-bristled brush dipped in cold tap water and a lint-free cloth wetted with cold tap water, clean the device until there is no visible soil. Pay close attention to the speakers, seams, and labels. If applicable, re-wet the soft-bristled brush or lint-free cloth as needed.
5) After brushing/wiping the device, flush each difficult to clean area, such as speakers and seams, with 60 mL of cold tap water two (2) times using a 60 mL syringe.
6) Wipe the device with a dry lint-free cloth to remove any moisture prior to initiating the disinfection process.
7) Inspect the device for residual soil. If found, repeat steps 2 – 7.
NOTE: If visible soil still remains or if damage, degradation, or residual contamination of any time is observed, notify Remington Medical.

Disinfection:

8) Wipe the device with a fresh PDI Super Sani Cloth Germicidal wipe for approximately three (3) minutes using two (2) wipes.
NOTE: Do not squeeze the cloth directly on the Transceiver.
9) Rinse the device by flushing the difficult to clean areas such as speakers and seams, with 60 mL of cold tap water two (2) times using a 60 mL syringe.
10) After cleaning, wipe the Transceiver with a lint-free cloth dampened with deionized (DI) water for approximately one (1) minute two (2) times using a fresh cloth for each wiping session.
11) Allow to air dry before use.
12) Check the Transceiver for any residual organic material. If any is present, remove it and disinfect the Transceiver again.

The transceiver should not contact mucus membranes, blood, or compromised tissue. Always utilize the sheath while inside the sterile field.

Speaker Dock Reprocessing

Wipe the speaker dock with a dry soft cloth

Accessories & Parts

Item	Catalog Number
VascuChek® Kit	VC-KIT-02
VascuChek® Transceiver	VC-TRX-02
VascuChek® Surgical Probe	VC-SP-01
VascuChek® Clinical Probe	VC-CP-01
VascuChek® Speaker Dock	VC-SD-01

Remington® MEDICAL

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