
DOLPHIN PRODUCT FAMILY

User Manual

DOLPHIN*IQ*

DOLPHIN*4D*

DOLPHIN*MAX*

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Limited Warranty

Inspect the contents and the condition of the goods which are delivered within 14 days of receiving the goods, and immediately notify your supplier in the event that the shipment is incomplete or if the goods arrived with any damage.

Standard manufacturer warranty period for the Dolphin is 12 months, and for the probes and other accessories is 90 days. This warranty covers only malfunctions encountered during appropriate and normal use of the equipment. Damage caused by failure to follow instructions, misuse, improper maintenance, abuse or mishandling of the equipment, including mechanical damage to the product housing, is not covered by the warranty.

Warranty does not cover any damages, whether direct, consequential, incidental, financial or otherwise relating to performance or service issues of the system, including damages, data loss or loss of business profit.

Immediately contact your local distributor or a Viasonix service representative upon encountering a service problem. In the event that the product or any of its components should be returned to Viasonix, ensure that the product is well packaged with its' original packaging elements.

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Chapter 1 | Introduction

About Dolphin

The Dolphin product family includes the Dolphin/IQ, Dolphin/4D and Dolphin/MAX systems. The use of the term Dolphin in this manual relates to all systems, unless specifically stated otherwise.

Dolphin/IQ is an add-on Transcranial Doppler (TCD) system that needs to be connected to an external computer and display for operation, data display and storage. Dolphin/4D is a complete stand-alone system that includes an integrated computer and display. Dolphin/Max is similar to the Dolphin/4D system, except that it also has an internal rechargeable battery and an external power supply. All systems share identical indications for use, electronic boards, operation software, Doppler probes, and performance. The Dolphin systems are based on ultrasound Doppler technology for the purpose of measuring blood flow velocities.

The Dolphin must be operated only by trained personnel. For training instructions and schedules please contact your local distributor. Dolphin is intended for use only in adults and children, and should not be used under any conditions for fetal or neonatal examinations.

About this manual

This manual assumes that the reader is a trained professional, who is familiar with transcranial, peripheral and intraoperative vascular examinations. The use of the Dolphin for intraoperative examinations is not approved for use in the USA, and therefore all references in this manual to 16MHz probes or intraoperative applications are not applicable in the USA. The manual does not provide any instructions relating to the techniques or methods of acquiring clinical data. The sole intention of this manual is to provide detailed operation instructions of the Dolphin for optimal utilization of the device, as well as important warnings and cautions which are related to the safe use of the device.

Before turning on the Dolphin for the first time the user must read this manual thoroughly, and ensure that all of the issues that are related to the safe operation of the device are fully understood.

The Dolphin is designed for touch screen operation. The terms “click” or “press” that are used in this manual are used to indicate a user selection, which

can be performed either by clicking the selection with a computer mouse, touching the appropriate selection on the touch screen, or making the selection with the remote control or foot switch when applicable.

Indications for use (except in the USA)

The Dolphin systems are medical Doppler devices intended for noninvasive measurements of intracranial, extracranial and peripheral blood flow velocities. The 16 MHz probe is intended for intraoperative use.

Contraindications: The Dolphin is not intended to be used in fetal or neonatal applications, and except for the 16 MHz probe is not intended to be used inside the sterile field.

Note: The Dolphin is to be used only by trained medical personnel. The Dolphin systems can be used in hospitals, clinics and physician offices. The 16 MHz frequency is currently not available in the USA and Canadian markets.

Indications for use (only in the USA)

The Dolphin/IQ, Dolphin/4D and Dolphin/MAX are medical Doppler devices intended for noninvasive measurements of blood flow velocities in arteries and veins in adults and pediatric. The Dolphin systems can be used in hospitals, clinics and physician offices.

The Dolphin/XF robot accessory, when used with the Dolphin system, is a device which assists the user in the acquisition of cerebral blood flow velocity.

Contraindications: The Dolphin is not intended to be used in fetal or neonatal applications.

Note: The Dolphin is to be used only by trained medical personnel.

Patient Population

The Dolphin systems are intended for use in adults and pediatric populations.

Clinical Benefit

The clinical benefit of a transcranial Doppler system is to allow health care professionals with the diagnosis of transcranial pathology in patients.

Warnings and cautions



Warnings

- ⚠ Take care to carefully read the following section. Additional warnings and cautions also appear in other parts of this manual.
- ⚠ The 1.6 MHz, 2 MHz, 4 MHz and 8 MHz probes are intended only for non-invasive diagnosis in adult and pediatric populations. Do not use any of these probes intra-operatively or inside the sterile field. The device must be used only in accordance with the provided product labeling.
- ⚠ Only trained authorized medical personnel may operate the system. A new user must thoroughly read and understand the complete user manual. This device must be used in accordance with all instructions and labels.
- ⚠ Only authorized Information Technology (IT) personnel may configure the system connectivity to the Institute's network. IT personnel must follow the instructions in the Dolphin conformance statements, and validate proper network connectivity.
- ⚠ Warning: For USA only - Federal law in the USA restricts this device to sale by or on the order of a medical practitioner which is licensed by the law of the state in which they practice to use or order these devices.
- ⚠ Do not use or connect to the Dolphin any probes or other accessories that are not supplied by Viasonix for the Dolphin.
- ⚠ Immediately contact your local service representative or Viasonix when encountering problems with the Dolphin. Only trained and authorized personnel are permitted to service the system or open the casing. Do not attempt to repair the system or open the casing. Do not modify or make any changes to the Dolphin installation directory.
- ⚠ Electrical shock hazard. Do not remove casing cover. For service, contact an authorized service representative.
- ⚠ MR unsafe. The Dolphin devices and accessories are not suitable for use in a magnetic resonance imaging (MRI) environment.
- ⚠ Do not attempt to repair the power supply, repair cracked or broken cables, or to replace a fuse. For service, contact an authorized service representative.
- ⚠ Do not place ultrasound gel or probes during an examination over open wounds. Do not allow ultrasound gel or probes to come in contact with body fluids.
- ⚠ Turn off the power before performing maintenance activities. Do not clean the system with a wet cloth. Do not immerse the probes in water or other liquids.
- ⚠ Do not use the Dolphin for fetal or neonatal measurements.
- ⚠ Use only the power supply that is supplied with Dolphin. In the USA only, you can also power directly from the Cybernet medical grade CyberMed NB22 computer. Before turning the power on, make sure that all cables and connectors are properly connected.
- ⚠ Do not use the system near flammable conditions. Keep away from water or other liquids. Do not operate the system under non-approved environmental conditions.
- ⚠ Do not operate the system if the power cord or any other cable or connector is damaged.
- ⚠ Use the Dolphin only for valid medical reasons. According to the ALARA (As Low As Reasonably Achievable) principle, maintain the patient's examination time with ultrasound as short as possible. Maintain the Doppler insonation power during the examination as low as possible.
- ⚠ During ophthalmic measurements the Doppler insonation power is limited to 50 I_{SPTA,3}. Turning off the Ophthalmic Mode limits (this option not available in the USA) will allow the probes to transmit ultrasound power up to maximal allowed intensity for all vessels (ophthalmic vessels included). This higher power may damage the patient's eyes.
- ⚠ Use only the single-use 16 MHz probe that is supplied by Viasonix (not available in the USA). This probe is supplied sterile, and is designed only for single use. Do not try to sterilize this probe or use it more than once.

- ⚠ The 16 MHz probe is provided sterile for single-use only (not available in the USA). Do not use the 16 MHz probe inside the sterile field if the package or bag of the 16 MHz probe is torn or damaged in any manner prior to use, or if the sterilization date shown on the package has expired.
 - ⚠ Disposal of the rechargeable battery of the Dolphin/MAX should be only to recycled bins per institute guidelines and in accordance with local, state or applicable federal regulations.
 - ⚠ If the Dolphin/MAX rechargeable battery case is broken, avoid direct contact with internal components and do not use the rechargeable battery with Dolphin/MAX.
 - ⚠ Do not use the Dolphin/MAX rechargeable battery with Dolphin/MAX if it has been exposed to liquids, especially saltwater.
 - ⚠ Use only approved battery for the Dolphin/MAX. The Dolphin/MAX rechargeable battery is directional, and can only be inserted in the correct direction. Do not force it in.
 - ⚠ When transporting the Dolphin/MAX rechargeable battery follow the transportation instructions in this manual.
 - ⚠ Remove the Dolphin/MAX rechargeable battery whenever the system is not likely to be used for some time.
 - ⚠ Use only medically approved ultrasound gel for the Doppler probes.
 - ⚠ All external devices, including computers, printers, carts, or any other devices or components which may connect directly to the Dolphin or the Dolphin/IQ computer, must comply with IEC/EN 60601-1. It is the responsibility of the user to ensure compliance with patient isolation and IEC/EN 60601-1 requirements if equipment that is not supplied by Viasonix is used with the Dolphin.
- ⚠ Use only medically approved computers, printers and any other devices which may be used together with the Dolphin. Otherwise, use an approved isolation transformer to power up these devices. The Dolphin and all other external devices that are used in conjunction with the system should be placed out of reach of patients at a distance of at least 1.5 meters from the patient.
 - ⚠ Any wireless control devices that are used in conjunction with the Dolphin must comply with FCC/IC regulations, and comply with EU Directive RTTE. Any battery used with such device must comply with applicable device standards.
 - ⚠ When connecting the system or the computer to any external accessory both must be off the mains power supply.
 - ⚠ Do not perform any vasomotor reactivity procedures and do not administer CO₂ to patients with head injury or patients where the intracranial pressure may be elevated.
 - ⚠ Place the Dolphin only on a flat and hard surface. Ensure that the ventilation slots are free, and do not place the system on cloth, sponge or similar material.
 - ⚠ After each patient examination use only hospital approved cleaning agents to cleanse the surface of the probes. Immediately thereafter the probes must be wiped and completely dried.
 - ⚠ Never leave the patient unattended during the examination.
 - ⚠ Do not open the Dolphin casing. It does not contain parts that can be serviced by a technician. If the device is opened then warranty will be void.

! Cautions

- | | |
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| <ul style="list-style-type: none">! Turn off the power before connecting or disconnecting any probes or accessories. When re-connecting system components, make sure that you connect them in their proper location.! Turn off the power before cleaning. Clean the system only with a soft cloth or brush.! Do not attempt to repair the system. Do not attempt to change or modify the Dolphin software. Do not attempt to operate the system if you suspect that the system is not functioning properly. Contact immediately your local distributor.! Transferring a copy of the Dolphin installation program and/or the installation serial number to people or entities which did not purchase the Dolphin system is strictly prohibited.! Routinely create back-ups of all of the patient recordings. Ensure that the backup media is kept in a safe place for possible future restoration.! Never drop the system or any of its components. Take special care to prevent the sensors and Doppler probes from dropping or knocking on a hard surface in order to prevent mechanical damage. | <ul style="list-style-type: none">! Do not install or run any other applications on the computer when operating the Dolphin. Make sure all other applications are removed or turned off.! Never pull on the cables for disconnecting the probes or accessories.! Connect the Dolphin/IQ system only to a computer that meets the minimum requirements.! Make sure that the system is checked and serviced once a year on a routine basis by approved service personnel.! If Ground Bond Safety Test is performed on a Dolphin system, the Dolphin system must be powered off during the test.! Routine Preventive Maintenance or Calibration is not required. If local procedures require performing preventive maintenance, contact your local representative. |
|--|--|

The ALARA Principle

Pulse Wave (PW) Doppler is based on the transmission of a train of ultrasound bursts at a known frequency and at a given amplitude. These ultrasound bursts are reflected back to the probe from the target blood vessel or other reflecting element, and are received by the system during the period of time that the probe does not send bursts of ultrasound. While there are no known adverse effects related to Doppler ultrasound transmissions that are within FDA approved guidelines, it is still highly recommended to adhere to the ALARA principle to minimize any risks of exposure to ultrasound.

The ALARA principle states that using exposure to ultrasound insonation should be **As Low AS Reasonably Achievable**.

Ultrasound insonation level can be controlled in the Dolphin with any of the following controls:

Power: The Power setting in the Dolphin controls the magnitude of the pulse amplitude. Decreasing the Power will cause a decrease in the pulse amplitude, which in turn results in decreased transmitted ultrasound energy into the body. The Power setting can be displayed as either % of allowed FDA limits, or as absolute $I_{SPTA,3}$ parameter which is the derated spatial-peak temporal-average intensity in units of mW/cm^2 .

Scale: The Scale setting in the Dolphin represents the Pulse Repetition Frequency (PRF) of the ultrasound bursts. A higher PRF means more bursts per unit of time, hence higher ultrasound energy that is transmitted to the body. In addition, a higher Scale means that the duration between bursts is shortened, which causes the receiving duration to be shorter, and as a result the maximal Doppler penetration depth is decreased. Scale can be displayed in units of KHz or in Cm/sec.

Sample: The Sample setting stands for Sample Volume, which is a reflection of the length of each ultrasound burst (pulse duration), or the number of cycles composing each burst. The size of the Sample defines the effective length of the target segment from which reflections are received. Decreasing the Sample setting will result in decreased pulse duration, which in turn will result in less transmitted ultrasound energy into the body.

For additional important information about ALARA and Medical Ultrasound Safety refer to the supplied *Medical Ultrasound Safety* booklet by: **The American Institute of Ultrasound and Medicine (AIUM)**.

Residual Risks

The Dolphin is found to be safe and effective for use, and the clinical benefits of using the device outweigh the inherent residual risks that are associated with the use of the device. High frequency ultrasound energy delivered to healthy tissue is considered a residual risk accompanying the use of ultrasound devices.

Chapter 2 | Preparing the Dolphin

Dolphin/IQ Description

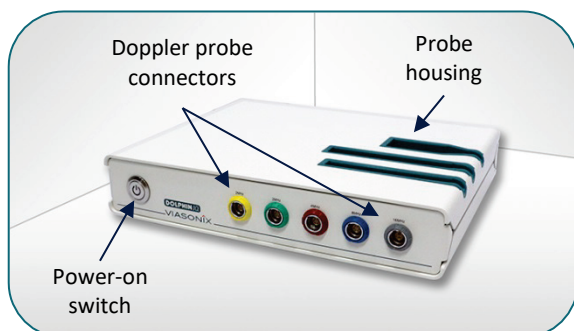
The standard **Dolphin/IQ** system may include the main console, Doppler probes, power supply, USB cable, remote control, foot switch, monitoring head gear and a user manual.

The cart, printer, personal computer, isolation transformer and any other accessories necessary for the Dolphin operation are typically supplied separately by the local distributor.

The Dolphin/IQ is a plug in module that requires to be connected via a USB cable to a computer for its operation. The computer is used for controlling system operation and for data display and storage. Check the USB cable connection to the computer if the program is not responding.

The Dolphin operates only with Doppler probes that are supplied by Viasonix.

A front view of the **Dolphin/IQ** is shown below:



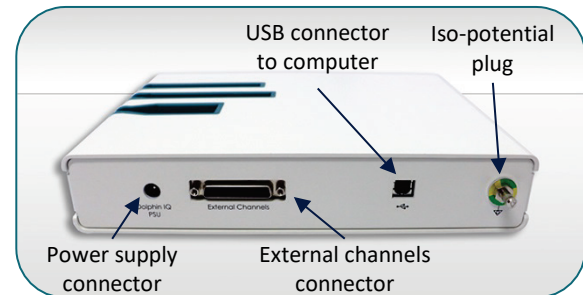
The front panel includes 5 color-coded connectors for the Doppler probes:

- Yellow for 2 MHz or 1.6 MHz
- Green for 2 MHz
- Red for 4 MHz
- Blue for 8 MHz
- Gray for 16 MHz

In addition, the front panel has a power on switch which is lit in green when the system is powered.

Note: the 16 MHz option is not available in the USA market.

A rear view of the **Dolphin/IQ** is shown below:



The back panel includes 3 connectors:

- Power inlet from the Dolphin/IQ power supply
- USB connector to connect the Dolphin/IQ to the host computer via the supplied USB cable
- D-type connector to allow input/output from external channels.

In addition, an iso-potential plug connector is located on the back panel. The purpose of this connector is to equalize potentials between the Dolphin/IQ and different metal parts. Connection is via a standard cable (Multi-Contact, part number POAG-KBT6DIN).

The Dolphin/IQ connects to an approved 12 V medical power supply (supplied with the system), which in turn connects to the mains power. In the USA only, the Dolphin/IQ can also receive 12 V power directly from the Cybernet medical grade CyberMed NB22 computer. All other supportive device components connect directly to the host computer. These may include: the receiver of an IR remote control, 3-pedal foot switch, keyboard, mouse, printer, USB camera, and any other similar USB device.

Dolphin/4D Description

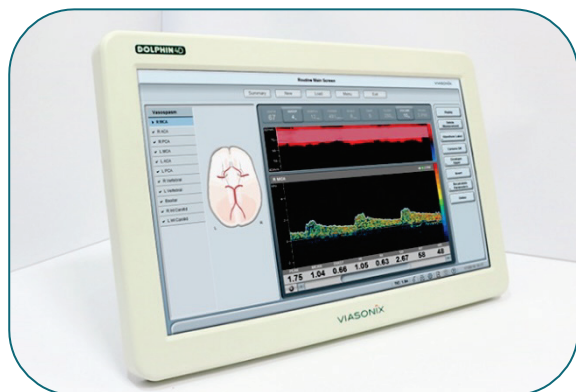
The standard **Dolphin/4D** system may include the main console, Doppler probes, remote control, foot switch, monitoring head gear and a user manual.

The cart, printer, isolation transformer and any other accessories necessary for the Dolphin operation are typically supplied separately by the local distributor.

The Dolphin/4D is a stand-alone system, which includes an integrated computer and display and a medical grade power supply which is necessary for complete operation.

The Dolphin operates only with Doppler probes that are supplied by Viasonix.

The **Dolphin/4D** is shown below:

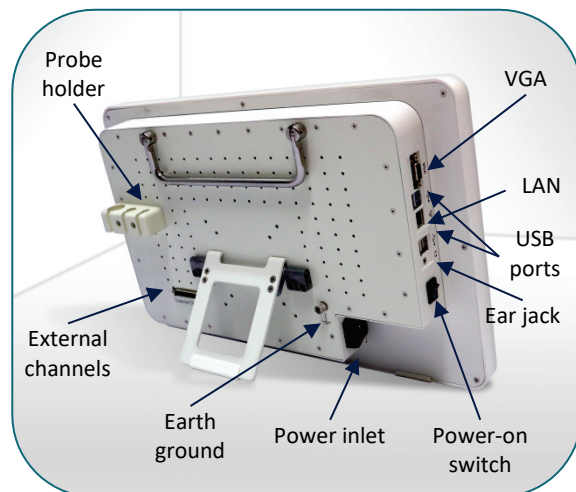


The right-side panel includes 5 color-coded connectors for the Doppler probes:

- Yellow for 2 MHz or 1.6 MHz
- Green for 2 MHz
- Red for 4 MHz
- Blue for 8 MHz
- Gray for 16 MHz

Note: the 16 MHz option is not available in the USA market.

A rear view of the **Dolphin/4D** is shown below:



The back panel includes the power inlet, the earth ground plug and the connector for the external channels as shown in the picture. The left side includes the power on switch, ear jack connector, 4 USB ports, and LAN and VGA connectors.

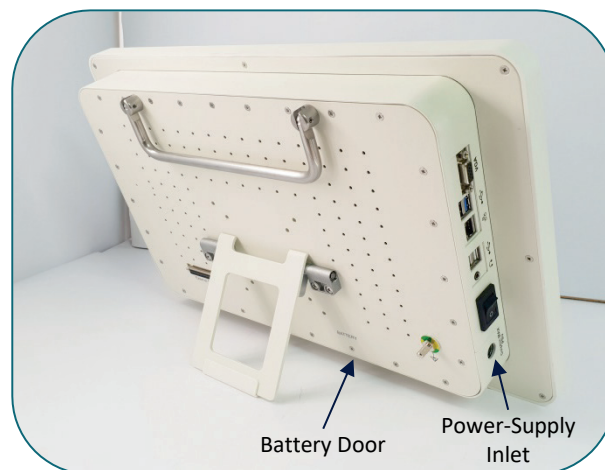
An approved power cord according to the destination market needs to be connected to the mains power through the power inlet on the back panel of the **Dolphin/4D**. All other supportive device components connect directly to the USB ports. These may include: the receiver of an IR remote control, 3-pedal foot switch, key-board, mouse, printer, USB camera, and any other similar USB device.

Dolphin/MAX Description

The **Dolphin/MAX** is similar to the **Dolphin/4D** system in all aspects, except that the **Dolphin/MAX** also includes a rechargeable internal battery for operation.

The back panel of the **Dolphin/MAX** is slightly different, and includes an inlet for the external power supply of the system, and a battery door located on the bottom panel that allows replacement of the internal rechargeable battery.

A rear view of the **Dolphin/MAX** is shown below:



The screen size, as well as all other connector inlets of the **Dolphin/MAX** are identical to the **Dolphin/4D**.

Unpacking and Installing the System

Refer to VS0617 Dolphin Installation and Service Manual and carefully read and follow unpacking and installation instructions.

The Dolphin software needs to be installed initially only for the Dolphin/IQ system, or for software upgrades for all Dolphin systems. Install the Dolphin software program to your approved personal computer. Note that software installation to the Dolphin/IQ computer must be done before the Dolphin/IQ is connected to the computer and turned on. It is mandatory to carefully follow all of the steps in the Software Installation Instructions that is supplied with the system when applicable.

The Dolphin program is designed to be viewed on a large wide screen display. The program is designed for touch screen operation.

The Doppler probes must be connected to the correct connectors as marked on the front panel (2 MHz, 1.6 MHz, 4 MHz, 8 MHz).

The single-use 16 MHz probe (not available in the USA) is inside the sterile package and should be opened only prior to use. The following is the only approved 16 MHz probe that can be used with the Dolphin systems: PW 16 MHz / 1.3 mm sterile single-use probe, by Medizintechnik Basler AG (CE₀₁₂₃ approved).

The identity of each probe is marked on the small label on the probe cable. Note that the red dot on the cable connector should be aligned to the top of the panel connector for the Dolphin/IQ, and aligned to the right on the Dolphin/4D and Dolphin/MAX side panel connector. Ensure that all probes are secured in place in the respective Doppler probe housing located either on the top panel of the Dolphin/IQ or the back panel of the Dolphin/4D and Dolphin/MAX.

Connect the power supply to the DC connector on the rear panel and to a hospital grade grounded power outlet (Dolphin/4D connects to mains power supply). Turn on the system using the power on switch on the front panel, and make sure that the switch lights up in green. Double click on the Dolphin icon to load the Dolphin program. The main screen or the patient details page of the program will appear on the computer screen. You may click on the **Next** button on the top right-hand side of the main screen in order to ensure that the software identifies the Dolphin.

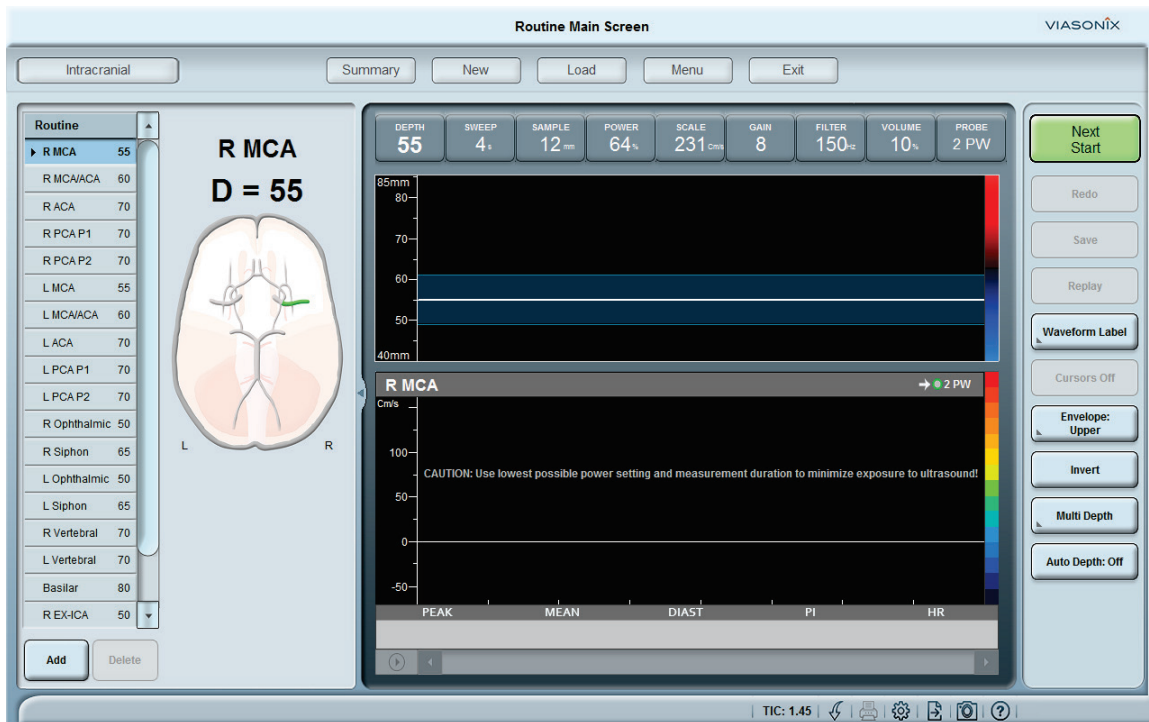
When using a wireless remote control, connect the remote control receiver to a USB slot in the computer. The receiver's led light is lit in red when connected. Point the remote control towards the receiver and randomly press the up/down arrow keys and observe the changes in the protocol list in the main screen display. If applicable, also connect the wired remote control and/or the foot switch to other USB slots, and randomly press the buttons or pedals to observe a response in the main screen.

When using the Dolphin/XF robot, connect each robotic element to a USB slot in the Dolphin/IQ computer or Dolphin/4D or Dolphin/MAX systems.

! Whenever transporting the system, computer, and all accessories make sure that all are secured in place without risk of falling. Make sure that there are no loose cables that might get tangled during the transportation.

Chapter 3 | Main Screen

This chapter is designed to allow the user to get familiar with the basic Dolphin **Main Screen** and system operation. A typical intracranial **Main Screen** display is shown below.



While there are many possible **Main Screen** display options, the general description below is applicable to all display options. There are many active regions in this screen as detailed below. Pressing the active regions provides a shortcut to the relevant options or screens, as will be explained in this chapter.

Main Bar

The **Main Bar** is the top row of the **Main Screen** display. This bar appears in almost every screen of the program.

The bar contains the full patient name and ID number on the left hand side, the Viasonix logo on the right hand side, and the name of the current screen display in the center. The display region of the patient name and ID is active, and clicking on it results in a shortcut to the **Patient Details** screen.

Main Options

The **Main Options** buttons are displayed in the central upper region of the **Main Screen**, below the **Main Bar**.

There are 5 main buttons in this region: *Summary*, *New*, *Load*, *Menu*, and *Exit*. These buttons always appear in the **Main Screen** and the **Summary Screen** displays.

However, when in the **Summary Screen**, the *Summary* button name changes to *Main*.

Summary / Main:

This button opens the **Summary Screen** display (from the **Main Screen**), or returns back to the **Main Screen** (from the **Summary Screen**).

New:

This button opens the **Patient Details** window. This button is typically used to start a new examination.

Load:

This button opens the **Load Patient** window. This button is typically used to load an examination for offline review.

Menu:

This button opens the **Main Menu** window. Through this button the user can get access to all Dolphin features and configuration options, including setting up preferred settings.

Exit:

This button is used to close the Dolphin program. Before shutting down a message box will appear requiring the user to confirm this action. Pressing the *OK* button will then close the program (or pressing the *Cancel* button to keep the program open).

Protocol Region

The **Protocol Region** is located at the left-hand side of the **Main Screen**. This region is composed of 3 separate parts: The **Protocol Selection** button to the left of the **Main Options** buttons at the top, the **Protocol List** on the left-hand side, and the corresponding **Schematic Picture** to the right. A *Splitter* option is available by touching the right border of this region. By dragging the splitter to the left, the user can hide either just the **Schematic Picture**, or all of the **Protocol Region**. Moving the splitter to the right will re-display the hidden section back again.

Protocol Selection:

This button displays the selected protocol. By clicking on it, a drop-down list opens with all available protocol options, and the user may select another protocol, or enter the **Edit Protocols** screen. When selecting another protocol, the **Protocol List** and the **Schematic Picture** change accordingly.

Protocol List:

This region displays a list of all of the sites that are defined in the current protocol, according to the examination order. The user may select at any time any other site (that is not in the measurement order) simply by touching the site name. The respective graph area will change accordingly. If the list is long, a scroll bar will appear to the right of the list in order to allow scrolling the list down. When a site is measured, a checkmark will appear next to the site name.

Under the Protocol List, there are two control buttons:

Delete: This button allows deleting a measurement directly from the Main Screen. By marking the selected site from the protocol list on the left and pressing this button the measurement will be deleted.

Add: This button allows adding an additional measurement from the same blood vessel but at a different depth. The site name will be marked with M1, M2, M3, etc., according to the number of measurements performed for the same vessel.

Schematic Picture:

This region displays the appropriate schematic picture for the current protocol. When a vessel is selected in the protocol list, the corresponding segment in the schematic picture will be highlighted in green. Once the measurement of the vessel is completed, the segment in the picture will be highlighted in red.

Graph Region

The Graph Region is located in the center of the Main Screen. The main focus of this region is the Spectrum Region and its corresponding M-Mode display. The Doppler controls and the measured parameters are displayed next to the Spectrum and M-Mode regions. The relative position of the M-Mode and the parameters in relation to the Spectrum Region is configurable, by clicking to the left of the M-Mode scale or on the parameters region and selecting the *Display Location* option. Above the spectrum region is a header bar that includes the name of the vessel, the selected Doppler probe, and an arrow indicating the direction of the flow (towards or away from the probe). Below the spectrum is a Scroll Bar to allow scrolling the measured waveform. There is a splitter between the Spectrum and M-Mode displays that allows changing the respective display area of each.

When the Multi-Depth or Bilateral options are selected, the **Graph Region** will be reproduced according to the number of selected spectrums for display. Each spectrum will have its own header, which will now also include in its center the Depth (in mm) at which each spectrum is measured. The Doppler controls will apply only to the selected spectrum, which is marked with a blue colored frame.

Spectrum Region:

In this region the Doppler spectrum is displayed. The Y axis on the left side is an active region, and the user may touch this region to configure some spectrum display options. The white horizontal *Zero Line* is shown across the Display Region, and can be dragged up or down to relocate the spectrum accordingly. To the right of the Display Region is the spectrum color scale that is sensitive to the power of the received spectra. Clicking on this scale allows selecting a different color scale.

Graph Header:

This region is located just above the **Spectrum Region**. The site name is displayed in the left side of the header. This is an active region, and by clicking on the site name at any time, online or offline, a drop-down list opens with all of the possible sites for this test, and the user may select another name from the list. The right-hand side of the header bar displays the Doppler icon and the selected Doppler frequency for the current measurement. The arrow to the left of

the Doppler icon indicates if the spectrum is displayed with the flow towards or away from the probe. The central part of the header is used if additional information is required, such as the Depth (during multi-Depth measurements) or the sweep time in the summary screen.

Signal Scroll Bar:

This scroll bar is located below the spectrum display region. The right and left arrows on the bar will scroll the signal in the time axis, accordingly. Alternatively, the user can simply drag the scroll bar box to any time location along the bar. A *Play* icon is shown on the left corner of the scroll bar. By pressing it, the user can replay the captured signal. Alternatively, signal replay can also be performed with the *Replay* button in the right-hand buttons. The *Play* icon changes to a *Freeze* icon after activation, and the user can freeze the signal at any time.

M-Mode Region:

This region displays the M-mode, color coded in colors of red and blue. Red indicates flow towards the probe while blue represents blood flow away from the probe. The location of this region can be configured to be above, below, or to the right or left of the Spectrum region. In addition, the start and end depths of the Y axis can be configured. The display also includes a horizontal line or region that represents the depth along the ultrasound beam, or the sample volume, from which the Doppler spectrum is measured and displayed.

Signal Control Buttons:

These buttons appear at the top of the screen above the **Signal** and/or **M-Mode Display Regions**, and they are used to control the Doppler signals and display. The buttons show the name of the feature that they control and the corresponding current value. In all cases, touching a button will open a drop-down list with all possible options for the selected control. During a measurement, up/down buttons will appear allowing to modify the current setting. The main control buttons are:

Depth

This parameter displays the current depth, in mm, from which the PW Doppler receives the data for spectrum processing.

Sweep

This parameter controls the X axis time scale, shown in seconds (s) or minutes (m).

Sample

This parameter controls the length of the ultrasound bursts, or the Sample Volume. The sample volume represents the length, in mm, along the ultrasound beam from which the Doppler reflections are used to generate the Doppler spectrum.

Power

This parameter controls the amplitude of the ultrasound bursts, which in turn affects the insonation power. It can be represented either in units of % relative to the maximal allowed power, or in units of ISPTA.3, which is the derated spatial peak pulse wave intensity in W/cm^2 . When selecting an Ophthalmic artery, the maximal ISPTA.3 power is limited by default to a maximum of $50 mW/cm^2$ (the software does not allow to use 1.6 MHz probe for ophthalmic measurements).

Scale

This parameter controls the pulse repetition frequency (PRF) of the ultrasound bursts. It can be displayed in units of KHz or velocity (cm/s).

Gain

This parameter controls the spectrum gain, and affects the color scale with which the spectrum is displayed.

Filter

This parameter controls the “thump filter”, or the level of the high pass filter in units of Hz. It helps to filter out the low frequencies near the zero line in the Doppler spectrum.

Volume

This parameter controls the magnitude of the sound level. The user can also select *Mute* from the drop-down list to mute all sound.

Probe

This button shows the selected Doppler probe. The drop-down list displays all other options that are possible for selection.

Parameters Display Region:

This region displays the measured parameters. The location of this region can be configured to be above, below, or to the right or left of the Spectrum region. The respective value of each parameter is shown below the parameter name. The parameters are displayed according to the selected peak envelope (upper, lower, both or none). For upper envelope display the parameters are calculated only for the spectrum above the zero line, and vice versa for a lower envelope display. The parameters calculated for the spectrum below the zero line are marked with the “minus” sign.

The main Doppler parameters available for display are:

Peak

This parameter represents the maximal systolic velocity/frequency during a cardiac cycle, in units of cm/sec or KHz.

Mean

This parameter represents the time-average value of the envelope (maximal velocity/frequency) over one cardiac cycle. It is in units of cm/sec or KHz, corresponding to the mean blood flow velocity/frequency.

Diast

This parameter represents the minimal diastolic velocity/frequency during a cardiac cycle, in units of cm/sec or KHz.

PI

This parameter, which is unit-less, represents the Gosling Pulsatility Index, and is calculated based on the peak envelope as: (peak systolic velocity – minimal diastolic velocity) / mean velocity.

RI

This parameter, which is unit-less, represents the Pourcelot Resistance Index, and is calculated based on the peak envelope as: (peak systolic velocity – minimal diastolic velocity) / peak systolic velocity.

S/D

This parameter, which is unit-less, represents the systolic to diastolic flow ratio, and is calculated based on the peak envelope as: (peak systolic velocity / minimal diastolic velocity).

RT

This parameter, in mili-seconds, represents the rise time from end-diastole to peak systole.

HR

This parameter represents heart rate in beats (number of cardiac cycles) per minute.

Right Side Buttons

The region dedicated for the **Right-Hand Buttons** appears at the right side of most Dolphin screens. This region houses all of the buttons that are relevant for controls and operations that are related to the specific screen that is open.

Next:

The *Next* button is the most important button during a protocol examination. It appears for online modes at the top right-hand side in green. The *Next* button allows the user to complete the patient examination with this single button. The function of the *Next* button is to guide the user, step by step,

through the protocol. Each next step is specified in text inside the button, such as guiding the user to the next site, starting or freezing the probe, or any other action that is required for the current protocol. When a message box open, pressing *Next* will result in approval of the message, similar to pressing the *OK* button.

Freeze/Redo:

This button, located below the *Next* button, toggles between *Freeze* and *Redo*. During online measurement, the button shows *Freeze*, to allow the user to stop the measurement at any time even in the middle of a test. Once in *Freeze*, the button shows *Redo*, to allow the user to repeat the measurement for the current site. Note that pressing the Redo button will automatically delete the measurement that was already made.

Replay:

This button allows replaying the measured Doppler spectrum after freeze. The replay includes the spectral sound. The vessel being replayed will blink in the schematic picture. This option is similar to the *Play* icon on the left-hand side of the signal scroll bar.

Waveform Label:

This button allows adding a label to the Doppler measurement. By selecting this option, a DDL opens which allows selecting a label from a predefined list of labels, adding a new label, or configuring the list of predefined labels. Once a label is selected, the DDL will also show an option to delete the selected label. When making a selection, the selected waveform label will appear at the top center inside the spectrum region.

Cursors:

This button allows placing 2 vertical and 2 horizontal cursors in the spectral window after freeze for more detailed analysis. The time and velocity/frequency difference between each pair of cursors is displayed in the center of the graph.

Envelope:

This button allows toggling the display of the peak envelope: only Upper or only Lower Envelope (above or below the zero line), both Upper and Lower or none. The selection of the Envelope display also determines the display of the parameters shown next to the graph region.

Invert:

This button defines the direction of the blood flow relative to the probe, either towards the probe or away from the probe. Pressing this button results in inverting the Doppler spectrum display, and changing the direction of the little arrow to the left

of the Doppler icon in the graph header. An arrow pointing towards the circle icon means flow towards the probe, and vice versa.

Multi Depth:

This button allows to simultaneously display on screen different spectrums from up to 8 different depths. The Depth of each spectrum is shown in the center of the corresponding header bar. By pressing the vessel name in each header bar, a new name can be selected from the corresponding DDL. The selected spectrum is marked with a highlighted blue frame. Simply touch any other spectrum to replace the selection.

Auto Depth:

This button assists in quickly finding a signal by identifying a proper signal along the ultrasound beam within the selected M Mode range.

Recalculate Parameters:

This option allows recalculating the Doppler parameters after freeze. The DDL that opens allows to either manually type a new value for a selected parameter, or to recalculate specific parameters by placing the corresponding cursors at the appropriate locations. For example, for velocity measurements the 3 horizontal cursors need to be placed at the estimated diastolic, mean and peak velocities. Once the cursors are placed select either the **Recalculate** or the **Cancel** buttons on the right-hand side. The parameters that are recalculated are displayed with the "(m)" sign next to them. Once recalculation was performed, the DDL also shows an option to reset the calculated parameters.

Online:

This button is applicable only during offline review modes. By selecting *Online* the program automatically turns to online mode with the currently reviewed patient details, and is ready to proceed with a new examination.

Information Bar

The **Information Bar** is located at the bottom of all Dolphin screens. The **Information Bar** is divided into 3 main regions.

Dolphin Messages:

The left-hand side is dedicated to Dolphin messages that indicate from time to time either status or guiding instructions.

Date/Time:

The right-hand side shows the date and time. During **Online**, the display shows the current date and time. During **Offline** review modes the display is grayed out, and shows the date and time that the examination under review was

conducted. The *Date/Time* region is active, and by clicking on it the standard MS Windows date and time screen opens, to allow modification of these parameters.

Shortcut Icons:

To the left of the *Date/Time* region are 7 icons that represent: *Help*, *Camera*, *Export*, *Setup*, *Print*, *Battery Status* and *Minimize*. These icons are shortcuts to various options that could be relevant for the current screen display. The *Help* icon opens the general **Help Menu**. The Camera icon allows taking a picture which will be automatically placed in the *Write Report* window. The *Export* icon allows to export to file either a screen capture of the current screen, generate a movie, the examination report in PDF format, the measurement signals in Excel format, the examination file in VDL format (Viasonix Dolphin format), or the raw data file for the current measurement (only during online measurements). The *Setup* icon provides a shortcut to all configuration options that are relevant to the current screen that is now displayed. These configuration options can also be accessed through the main **Menu Screen**. The *Print* icon provides a shortcut to the **Print Preview** or **Print** options. The battery icon is applicable only for the Dolphin/Max, and it displays the battery status. The icon displays the current remaining battery capacity, the charging indicator, and in case that the battery is about to be depleted then the icon will be displayed in red and blinking. The *Minimize* icon minimizes the program display and allows access to the computer desktop.

Monitoring Examination

To begin a **Monitoring** measurement, select either a **Unilateral Monitoring** protocol (left or right side) or **Bilateral Monitoring** protocol (both sides simultaneously, with the aid of the monitoring head gear).

Use the **Next** button to begin a monitoring examination. Once a stable signal is acquired, press the **Next** button again to begin recording. While the examination is in recording mode, the **Trends** window in the graph region continuously records and displays parameters of detected cardiac cycles. The Trends window also displays relevant event markers such as predefined markers, automatic markers, HITS/Artifacts and others. In case **HITS Detection** is enabled for this test, the Trends window also displays a counter of total HITS and Artifacts identified during the test.

While in **Freeze** stage, use the Trends window to scroll the continuously stored spectral display and use Zoom controls on the bottom to change the time scale of the Trends display. Each event

marker can be selected by clicking on its icon in the Trends window or by selecting it from the event markers list. The event markers can be filtered using the drop-down list that is located above the event markers list.

The following buttons on the right panel can be used:

Pause/Resume Recording

The examination can be paused or resumed at any time using the Pause Recording and Resume Recording button.

Predefined Event Markers

Select text event markers to add either from a predefined events list or type in a new text event marker that can also be permanently stored in the predefined events list.

Set Delta Mean Baseline

Press to set a baseline for the Delta Mean marker. Once pressed, a new parameter DM% is added and shows the relative change between current mean velocity and baseline mean velocity.

Manage Event Markers

Press to delete an event marker, rename a text event marker, and mark HITS as Artifact (and vice versa).

Bilateral/Unilateral toggle

Quickly toggle the protocol from bilateral to unilateral mode and vice versa.

HITS Analysis

Access HITS Analysis screen to review each HITS or Artifact event individually.

Ophthalmic Measurements

The transorbital approach through the eye is used to insonate the ophthalmic artery. Measurement through the eyes requires that the insonation power will be as low as possible, because the eye has no bone or other protection from emitted ultrasound as it is a fluid filled structure.

When selecting an Ophthalmic vessel, the limits of the insonation power are automatically set to a maximum of $I_{SPTA,3}$ of 50 mW/cm². The Ophthalmic vessels can be measured only with the 2 MHz, 4 MHz and 8 MHz probes (not the 1.6MHz probe).

In special cases, when the examiner decides that the examination requires higher power settings, the Ophthalmic Mode option may be turned off to allow higher insonation power settings similar to all the other vessels (this option is not available in the USA). When the Ophthalmic Mode is turned off, the display of the selected power will be shown in red when the selected power exceeds the default ophthalmic power limits. In addition, a message is displayed on screen to emphasize to the user that the Ophthalmic mode is Off.

Patent Foramen Ovale (PFO) Test

To begin a **PFO** measurement, select a **PFO** protocol. The PFO protocol can be performed either unilaterally (left/right side) or bilaterally (both sides simultaneously).

Use the **Next** button to begin the PFO examination. Once a stable signal is acquired, press the **Next** button again to begin recording. While the examination is in recording mode, the graph on the bottom is continuously updated with spectral and envelope data.

During recording, multiple sessions can be added using the Session button below the PFO Summary Table. Within a session, a user can mark key events such as injection and Valsalva maneuver using the event keys below the PFO Summary Table.

While in **Freeze** stage, use the spectral graph on the bottom to scroll the continuously stored spectral display. To continue with another session, press Next/Resume button. Finally, the PFO Sessions Table shows the results per each PFO session that was conducted. For reporting purposes, sessions can be renamed or deleted using buttons below the PFO Sessions Table.

The following buttons on the right panel can be used:

Bilateral/Unilateral toggle

Quickly toggle the protocol from bilateral to unilateral mode and vice versa.

HITS Analysis

Access HITS Analysis screen to review each HITS or Artifact event individually.

High Intensity Transient Signal (HITS) Analysis – Advanced Layout

In PFO and Monitoring examinations, press the HITS Analysis button on the right panel to review each identified HITS/Artifact individually. Dolphin software will open a dedicated screen with events list, high resolution power M Mode display, complex & energy graphs, spectral display, and HITS distribution charts. For PFO there will be an additional spectral display of the entire measurement and for monitoring there will be an additional cardiac cycle parameters trends display. Select a HITS/Artifact event from the list and the screen will update to display relevant information.

The following buttons on the right panel can be used:

Next/Event

Select the next HITS/Artifact event from the list.

Close

Close the HITS Analysis screen and go back to main screen.

To List Layout

Switch to the alternative List Layout (detailed in the following section)

Replay Sound

Replay of the audible sound around the HITS/Artifact event.

Mark as HITS/Artifact

Mark the currently selected HITS event as artifact and vice versa.

Delete Event

Delete the current HITS/Artifact event.

Full Screen

Enlarge the power M Mode, complex & energy graphs, and spectral display.

Distribution Charts

Show/hide the distribution charts on the right side.

Settings

General settings related to this screen functionality.

High Intensity Transient Signal (HITS) Analysis – List Layout

This alternative layout provides a simpler interface with data required to analyze each HITS and Artifact that were detected. Each event is displayed as a single row in a list of events.

The following buttons on the right panel can be used:

Next/Event

Select the next HITS/Artifact event from the list.

Close

Close the HITS Analysis screen and go back to main screen.

Replay Sound

Replay of the audible sound around the HITS/Artifact event.

Mark as HITS/Artifact

Mark the currently selected HITS event as artifact and vice versa.

Delete Event

Delete the current HITS/Artifact event.

Exclude from Report

Do not show the selected event in the report

Sort

Change the events sort mode according to the chosen criteria.

Settings

General settings related to this screen functionality.

Keyboard Shortcuts

Opens an explanation message for the keyboard keys that can be used to control this screen.

Vasomotor Reactivity (VMR) Test

To begin a **VMR** measurement, select a **VMR** protocol (to be performed without an external Capnograph) or a **VMR + Capnograph** protocol (to be performed with an external dedicated Capnograph).

Use the **Next** button to begin the VMR examination. If an external Capnograph is used, the data from the Capnograph is displayed in the external channels window. Once a stable signal is acquired, press the **Next** button again to begin recording. When ready, press the **Next/Start VMR** button and perform the VMR protocol. Measurement results are presented on the left panel.

While the examination is in recording stage:

- The **Trends** window in the graph region continuously records and displays parameters of detected cardiac cycles.
- The entire measurement spectral graph continuously records and displays spectral and envelope data.

While in **Freeze** stage, use the Trends window to scroll the spectral display and use the Zoom controls on the bottom to change the time scale of the Trends display.

The following buttons on the right panel can be used:

Recalculate Parameters

Recalculate Velocity, Rise Time and Heart Rate parameters for each VMR cursor: Control, Min and Max.

Set Baseline/Min/Max Location

Press to modify the location of the VMR cursors.

Bilateral/Unilateral toggle

Quickly toggle the protocol from bilateral to unilateral mode and vice versa.

Breath Holding Test

To begin a **Breath Holding** measurement, select a **Breath Holding** protocol.

Use the **Next** button to begin the BH examination. Once a stable signal is acquired, press the **Next** button again to begin recording. When ready, press the **Next/Start BH** button and perform the Breath Holding protocol. Timer is displayed on the left panel to indicate breath holding time until **Next/Stop BH** is pressed. Measurement results are presented on the left panel.

While the examination is in recording stage:

- The **Trends** window in the graph region continuously records and displays parameters of detected cardiac cycles.
- The entire measurement spectral graph continuously records and displays spectral and envelope data.

While in **Freeze** stage, use the Trends window to scroll the spectral display and use the Zoom controls on the bottom to change the time scale of the Trends display.

The following buttons on the right panel can be used:

Recalculate Parameters

Recalculate Velocity, Rise Time and Heart Rate parameters for each BH cursor: Control and Stop BH.

Set Start/Stop BH Location

Press to modify the location of the breath holding cursors.

Bilateral/Unilateral toggle

Quickly toggle the protocol from bilateral to unilateral mode and vice versa.

Cognitive Response Test

To begin a **Cognitive Response** measurement, select a **Cognitive Response** protocol.

Use the **Next** button to begin the Cognitive Response examination. Once a stable signal is acquired, press the **Next** button again to begin recording. When ready, press the **Next/Start Stimulation** button and perform the Cognitive Response protocol. Timer is displayed on the left panel to indicate stimulation time until

Next/Stop Stimulation is pressed. Measurement results are presented on the left panel.

While the examination is in recording stage:

- The **Trends** window in the graph region continuously records and displays parameters of detected cardiac cycles.
- The entire measurement spectral graph continuously records and displays spectral and envelope data.

While in **Freeze** stage, use the Trends window to scroll the spectral display and use the Zoom controls on the bottom to change the time scale of the Trends display.

The following buttons on the right panel can be used:

Recalculate Parameters

Recalculate Velocity, Rise Time and Heart Rate parameters for each Cognitive Response cursor: Control and Stop Stimulation.

Set Start/Stop Stimulation Location

Press to modify the location of the Cognitive Response cursors.

Bilateral/Unilateral toggle

Quickly toggle the protocol from bilateral to unilateral mode and vice versa.

Sickle Cell and Vasospasm Tests

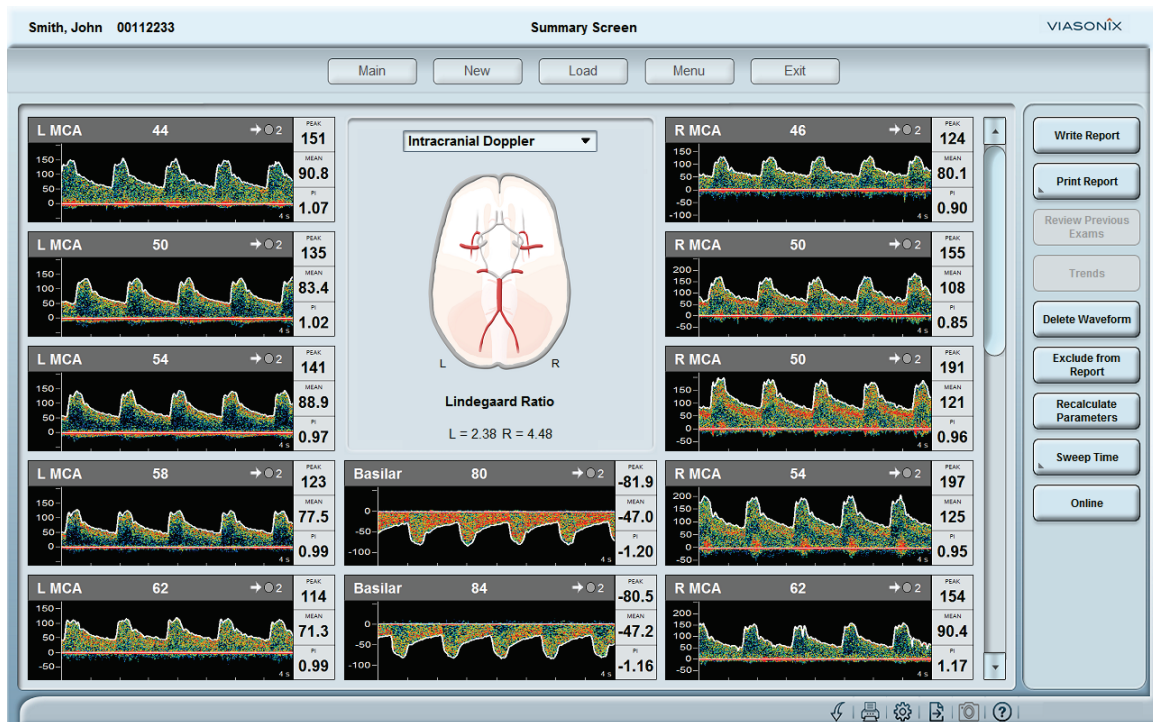
To begin a **Sickle Cell** or **Vasospasm** measurement, select a **Sickle Cell** or **Vasospasm** protocol. Use **Next** button to perform the protocol measurements. When a report is generated, the software will use the special report layout for **Sickle Cell** or **Vasospasm** protocol.

Intraoperative Test

To begin an **Intraoperative** measurement, select the **Intraoperative** protocol (not available in the USA). Use the **Next** button to perform a measurement. Once completed, use the **Next/Add Measurement** button to add another measurement to the protocols list. Then, press **Next/Start** to begin the new measurement. Use **Rename Vessel** button to label the vessel that was used for the measurement.

Chapter 4 | Summary Screen

This chapter is designed to allow the user to get familiar with the Dolphin summary screens and the examination report options.



In general, the **Summary Screen** summarizes all of the examination measurements that were conducted for the patient under review. The **Summary Screen** can be accessed at any time with the *Summary* button in the **Main Screen**, either during an online examination or during offline review. When loading an examination file for review, the **Summary Screen** automatically opens. Whenever the display is that of the **Summary Screen**, the *Summary* button (from the **Main Options Buttons** at the top of the screen) changes to *Main*, and by pressing it the display returns to the **Main Screen**.

Summary Preview

The **Summary Preview** screen always appears when there are several different summary display options. If there is only one summary display option, then the display will automatically display that screen without passing through the preview screen. A schematic representation of each summary display option is separately shown. These additional display options are usually related to specialty tests or monitoring. By touching any of these specific regions, the corresponding **Summary Screen** display will open. Alternatively, the user can choose the

required summary display by selecting the preferred option from the drop-down list that opens when touching the *Summary Preview* title in the summary title region.

Summary Screen Display

This screen summarizes all of the measurements and basic results for the examination under review. The title of the display is shown in the field located in the center of the screen, above the schematic picture. To toggle between the different summary screen options, if available, the user can select the preferred display through the drop-down list that opens when touching the summary title region.

In most display options, the relevant schematic picture will be shown in the center, and the measured Doppler spectrums will be displayed on both sides of the picture according to the left/right vessel orientation. The Basilar artery will be displayed in the center, below the schematic picture. If the Lindegaard Ratio (LR), defined as the Mean MCA velocity divided by the Mean ICA velocity, is selected to be displayed, the LR will be shown below the schematic picture.

The regions of the graphs are active. Therefore, touching any specific graph which is displayed in the **Summary Screen** will result in opening the corresponding measurement in the **Main Screen**. If the number of graphs displayed on the screen exceeds the maximum allowed, then a scroll bar will appear on the right side to allow the user to scroll down the summary screen display.

Each measured Doppler spectrum is displayed with its' specific header, that includes information about the site name, the insonation Depth, and the Doppler probe icon with the direction arrow. The selected Sweep time is shown on the bottom right hand of each graph. The measurement parameters that are selected to be displayed appear in the parameter boxes to the right of each Doppler spectrum.

Configuration Options:

The Print Layout Configuration allows also determining the display in the Summary Screen. Several configuration options are also available through the *Setup* icon in the **Information Bar**. An example of such options includes:

Spectrum Display

Allows configuring the display and print options with or without the Doppler spectral information.

Waveforms/Page

Allows selecting the maximum number of graphs displayed per page.

Lindegaard Ratio

Allows selecting to show or hide the Lindegaard ratio. If shown, it will appear below the schematic picture.

Select Parameters

This option allows selecting which parameters will be displayed in the Summary Screen and printed in the patient report. The selected parameters are marked with a checkmark.

Right Hand Buttons:

The buttons on the right hand allow various controls related to the **Summary Screen**. These buttons include:

Write Report

Allows access to the **Write Report** screen for preparation of the examination report.

Print Report

This button also allows to select a Print Preview option, which displays the print layout on the screen display, or to send the examination report to the printer.

Review Previous Exam, Trends

Allows to select a display of Summary Screens from past measurements performed for the same patient, or to review measurement Trends for the same patient based on past measurements for the same vessels.

Delete Waveform

Opens a list of waveforms that can be deleted. Check the waveforms to be deleted and press the Ok button. Note that deleted waveforms cannot be recovered.

Exclude from Report

Opens a list of waveforms that can be excluded from the report. Check the waveforms to be excluded and press the Ok button. Excluded waveforms will not appear in the report. It is possible to change the exclusion state at any time.

Recalculate Parameters

Opens a list of waveforms that can be used for batch manual recalculations.

Sweep Time

When pressing this button, a drop-down list opens, and allows the user to select a different sweep time for the display of all graphs in the summary screen. The newly selected *Sweep Time* will also remain when returning to the **Main Screen**.

Send to PACS

This option shows only if the DICOM option is turned *On* through the main **Menu** screen. By clicking on this button, the patient report, as printed, is sent to the PACS server.

Complete Exam

This button appears only during online mode. It is an optional button to close an examination and open the Patient Details screen in order to input data for a new examination.

Online

This button appears only during offline review modes. When pressing this button, the **Main Screen** opens with the currently reviewed patient name, ready to immediately begin a new examination.

Examination Report:

To prepare a written report for the current examination (whether online or offline), the user needs to press the *Write Report* button in the **Summary Screen**. The **Write Report** screen that opens includes the main text region on the left, various standard text editing and formatting options below that region, a list of *Entries*, and a list of previously prepared report templates.

Writing a Report

To write a report, simply start typing the text in the designated text region. Most text processing options are available for selection through the specific buttons below the text region. The user needs to mark the text to be formatted, and then simply click on the appropriate button, such as bold, underline, italic, etc. In addition, when writing the report, the user can receive additional quick assistance from the list of entries, by simply clicking on the entry of interest, and then selecting the required parameter from the drop-down list for that entry. The parameter will appear in the body of the text within < >, but when the report is printed the actual value of the parameter will be printed. For example, the user can write: "on <EXAM_DATE> <PATIENT_NAME> was admitted for routine examination". The examination date and the current patient name will be printed in the corresponding text locations when the report is printed.

In addition, the user can import a template report that was previously prepared. The template can be imported to any section in the written text, and be modified thereafter. To import a template either double-click on the selected template name, or mark the template name and click on the *Load Template* button from the right-hand side. The user can also import text files with RTF format with the *Import from *.RTF* button on the right-hand side. The *Insert Table* button on the right-hand side allows the user to create and configure a reporting table with as many rows/columns as needed.

Another option that is available to the user is to incorporate a picture in the report, for example a picture taken of a certain patient wound. This option can be accessed by selecting the *Camera* button on the right-hand side. The camera will become activated, and the picture will fill the screen display. To reduce the picture size that will be taken, press the *Picture Size* button on the right-hand side and select the desired size. After pressing the *OK* button, the current picture displayed will be added to the examination report.

After writing the report, the user can press the *OK* button to approve and save the text report with the current examination. The text report will always be printed at the end of the examination printout. The report can be later viewed and modified during offline review. The user can also select to export the text report to a file with the *Export to *.RTF* button from the right-hand side. The *Save As* window will open to save the file in the selected folder.

Report Template

The user can prepare as many report templates as needed. The report templates can always be incorporated into the text report as explained above. To prepare a report template, simply write the required template in the text region as explained above, and press the *Save as New Template* button on the right-hand side when done. After pressing this button, a new field opens at the top of the template list, and the user needs to type the name of the new template and press the *OK* button. To rename the template, the user can press the *Rename Template* button from the list on the right at any time, and input the new name. To delete a template, simply mark the appropriate template and press the *Delete Template* button from the right-hand side, and then confirm the deletion by pressing *OK*.

Chapter 5 | New Examination

This chapter describes the process of starting a new patient examination.

Always when starting the Dolphin, the **Patient Details** screen opens and the program is in online mode and ready to start an examination with default settings. Starting a new examination can be done by simply pressing the *New* button at the top of the screen, or by selecting the *New* option from the **Patient** list in the main **Menu** screen. In all cases the **Patient Details** screen opens. To start a new examination with default patient details and settings when the program is in offline review mode, the user can simply press the *Online* button.

Patient Details:

This section includes basic information about the patient. The fields of *ID* and *Last Name* are marked with “*”, as they must be filled in order to continue. The ID number is unique, and the program does not allow having any 2 patients with the same ID numbers. When pressing the *Gender* field, a drop-down list will show allowing the user to select *Male* or *Female*. The *Date of Birth (DOB)* field does not have to be filled. However, when it is filled, the *Age* field will automatically show the patient age. Alternatively, the user can type the age without entering the DOB.

Contact Information:

The fields in this section are used for entering the required contact details of the patient, such as home and mobile telephone numbers, fax number, home address, and email address.

Contact Person:

This section is designed for identifying a contact person in addition to the patient. The *Relation* field identifies the relationship between the contact person and the patient.

Physician:

This section is designed to include the names of the patient’s primary physician, the referring physician, reading physician and the name of the examiner performing the current examination.

Insurance/Exam:

This section is designed to input the insurance information which is relevant for the current examination. Alternatively, an *Exam* display can replace the Insurance fields, displaying DICOM Worklist related fields.

Patient Picture:

A picture of the patient can be added to this screen in the dedicated picture frame. In order to acquire the patient’s picture, a standard USB camera must be connected to the Dolphin/4D or Dolphin/MAX, or to the computer of the Dolphin/IQ.

In order to acquire a picture, the user can either click on the empty picture field, or click on the *Camera* button on the right-hand side. Point the camera toward the patient's face, and view the large display in the center of the screen. The user can *Acquire* a picture, *Reset* the picture to acquire again, or *Delete* the acquired picture, with the aid of the right hand buttons. After pressing *OK* the picture will show in the **Patient Details** screen. Alternatively, if the picture of the patient is available in file, the user can select the *Add Picture from File* button on the right-hand side, and load the picture to its' designated display region on the screen.

Medical History

Additional details regarding the current patient can be entered with the aid of the *Medical History* button on the right-hand side of the **Patient Details** screen. The **Medical History** screen has 3 main sections: *Patient Status*, *Risk Factors* and *Indications*.

Patient Status:

This section is designed to input various patient status details, such as the patients' weight and height. The Body Mass Index (*BMI*) is automatically calculated. The user can select a different set of units for the weight and height by pressing the *Units* button on the right-hand side. The fields in this section are configurable, either through the main **Menu** screen, or through the shortcut *Setup* icon at the bottom of the screen. The user can rename the fields, add new fields, remove fields, and determine the display order.

Risk Factors:

This section is designed to mark various risk factors that apply to the patient. The fields in this section are configurable, either through the main **Menu** screen, or through the shortcut *Setup* icon at the bottom of the screen. The user can rename the fields, add new fields, remove fields, and determine the display order.

Free Text:

This section is designed for free text typing. The user can add additional free text fields, and give each field a dedicated name. The fields in this section are configurable, either through the main **Menu** screen, or through the shortcut *Setup* icon at the bottom of the screen. The user can rename the fields, add new fields, remove fields, and determine the display order.

Indications

Further additional details regarding the patient indications and physical examination can be entered in the **Indication** screen, which can be accessed by pressing the *Indications* button in the **Patient Details** or the **Medical History** screens on the right-hand side.

The **Indications** screen has 4 main sections:

Current Symptoms, *Additional Fields*, *Physical Examination- Pulses* and *Diagnosis Codes*.

These fields are configurable, either through the main **Menu** screen, or through the shortcut *Setup* icon at the bottom of the screen. The user can rename the fields, add new fields, remove fields, and determine the display order.

Current Symptoms:

This section is designed to mark various patient symptoms as detailed in the list.

Additional Fields:

This section is designed to allow the examiner to input any other related patient information.

Physical Examination:

This section is designed to mark the results of a physical examination of the pulses (on a scale of 0 to 3) and the existence of bruits.

Diagnosis Codes:

This section is designed to mark applicable diagnosis.

Vitals / Event Log

Further additional details regarding patient surveillance can be entered in the **Vitals / Event Log** screen, which can be accessed by pressing the *Vitals / Event Log* button in the **Patient Details**. This screen has 2 main sections: *Daily Vitals* and *Events Log*.

These fields are configurable, either through the main **Menu** screen, or through the shortcut *Setup* icon at the bottom of the screen. The user can rename the fields, add new fields, remove fields, and determine the display order.

Daily Vitals:

This section is designed to manually input external measurements for documentation.

Event Log:

This section is designed to document relevant events that occurred during a patient's stay.

Returning Patient

The user can select the patient details information of a returning patient with the aid of the *Patients List* button at the right-hand side of the **Patient Details** screen. The **Select Patient** screen is opened. The screen displays a list of all of the patients previously examined that are on the computer database, including their names (last name and first name), ID number, DOB (Date of Birth) and date of last visit.

When a patient is returning for a new examination, there is no need to retype his/her personal details. The user simply needs to mark the returning patient in the list that is displayed in the **Select Patient** screen, and double click on the name or press *OK*. The **Patient Details** screen will open, with the available patient details already filled in the respective fields. Note that the Physician and Insurance fields are empty and should be re-filled by the user. There are several methods to search for a particular patient or a group of patients. The *Reset Search* button on the right-hand side will reset the search and return to the full list.

Patient Name:

By starting to type the patient's last name in the *Name* field, the patient list narrows according to the typed text.

Patient ID:

By starting to type the patient's ID number in the *ID* field, the patient list narrows according to the typed digits or text.

Date:

By typing a specific date in the *Date* field, the patient list shows only patients examined on that particular day.

Search Filters/Quick Search:

By clicking on the *Search Filters* button on the right-hand side, the **Quick Search** screen opens.

By clicking on a field, a drop-down list with previously entered data is displayed, and the user can select a string from the list. In addition, the *Date* and the *Age* fields allow the user to set limits for the search. The user can conduct the search based on more than one search parameter. The *Reset Search* button on the right resets the search parameters.

Search Filters/Advanced Search:

The *Advanced Search* button is located on the right-hand side of the **Quick Search** screen. By selecting it, the **Advanced Search** screens opens. The user can increase the search process by entering limits into the *Patient Status* fields, or by marking the relevant *Risk Factors*.

DICOM Work List/ HL7 Orders

These buttons will be displayed only if either the *DICOM* or *HL7* interfaces are *On*. The buttons are located on the right-hand side of the **Patient Details** Screen. To use these options the Dolphin needs to be connected to the institute's patient server. With this option the user can view the list of patients that are scheduled to come for an examination at a particular date (current date as default). To view the list of patients, press the *Query* button on the right-hand side. By selecting a patient and clicking *OK* (or double clicking on the patient name) the **Patient Details** screen opens with the details of the patient already incorporated. The user can modify or add any of the details, and continue the examination as scheduled.

Chapter 6 | Load Examination

This chapter describes the process of loading a patient examination for offline review.

The screenshot shows the 'Load Patient' interface. At the top, it says 'Fisher, Linda 15975523' and 'Load Patient'. Below this is a table of patients:

Name	ID	Date	Protocol
Cross, Bill	15957345	17/08/2016	Intracranial
► Fisher, Linda	15975523	16/08/2016	Intracranial
Aurbach, Jonathan	379842133		VMR Test
Smith, Lesly	6542167542		
Goren, David	735156742		
Davenport, Elliot	78745212		
Frank, Jim	853135154		
Heinz, Carl	89654576		

To the right of the table is a brain diagram with a red line indicating the examination area. Below the diagram are 'OK' and 'CANCEL' buttons. On the far right is a vertical toolbar with buttons: 'Search Filters', 'Reset Search', 'Delete Patient', 'Delete Exam', 'Delete Filters', 'View Details', 'Review Previous Exams', 'Trends', and 'Patient List'. The bottom status bar shows '17/08/16 10:17'.

To load a file for review the user needs to press the *Load* button at the top of the screen. Alternatively, the user can select the *Load* option from the main **Menu** screen. In both cases, the **Load Patient** screen (shown above) opens.

The main region of the **Load Patient** screen includes a list of all of the patients in the database (name and ID numbers). A preview of the marked examination is shown to the right of the patient list, and various control buttons are available on the right-hand side of the screen.

To review a specific examination, simply mark a patient from the list and press the *OK* button. The corresponding **Summary Screen** will open, and the user will be able to select a measurement for review in the **Main Screen**, and to perform almost all of the functions that are available during online as explained in the previous chapters, except new data acquisition.

Note - Offline review through the *Load* option does not require connection to the Dolphin system. Thus, the review process can be performed on any workstation with licensed Dolphin software.

The patient list normally includes all of the patients in the database with a valid examination.

However, in some examinations the user may input the patient details, but for some reason the examination will not be performed or valid measurements will not be available. The *Patient List* button on the right allows the user to include or exclude from the list patients with empty data records. Note that patients with empty data records will show in the patient list with “(empty)” next to the patient name.

Search Patient

There are several options to search for a specific patient or for a group of patients.

According to patient name or ID:

By starting to type the patient details in the *Name* or *ID* fields above the list, the patient list starts to narrow down according to the typed character string.

Search Filters:

By clicking on the *Search Filters* button on the right-hand side, the **Quick Search** screen opens. By clicking on a field, a drop-down list with previously entered data is displayed, and the user can select a string from the list. In addition, the *Date* and the *Age* fields allow the user to set limits for the search. The user can conduct the search based on more than one search parameter. The *Reset Search* button on the right resets the search parameters.

Search Filters/Advanced Search:

The *Advanced Search* button is located on the right-hand side of the **Quick Search** screen. By selecting it, the **Advanced Search** screens opens. The user can increase the search process by entering limits into the *Patient Status* fields, or by marking the relevant *Risk Factors*.

Examination Preview

The preview section is composed of 2 regions to the right of the patient list, and is active only when a patient from the list is marked.

Examination List:

The top region includes a list of all of the examination dates for the selected patient, and the examination protocols that were made on those dates. A scroll bar is available whenever the list is longer than the dedicated space.

Examination Preview:

This region, located below the examination list, shows a schematic display and results of the protocol measurements that were performed. The user can mark another protocol from the list and the display will update accordingly.

Delete Options

There are 2 delete options: delete a patient from the list, or delete a specific patient examination. Both options can be accessed from the corresponding buttons on the right-hand side of the screen.

Delete Patient:

To delete all patient examinations from a specific patient database, the user needs to mark the selected patient from the list, and then press the *Delete Patient* button. A message window will open and request to confirm the deletion.

Delete Exam:

An exam is defined as all of the protocol measurements that were performed on the patient on a specific date. To delete an exam, simply mark the exam in the preview region, and press the *Delete Exam* button. A message window will open and request to confirm the deletion. Note that the patient details will still be available in the database when selecting to view the patient list with empty patient records.

Delete Filters:

This option allows deleting a group of patients, including those with empty patient records. By selecting the *Delete Filters* button, the **Quick Search** and the **Advanced Search** screens can be accessed. The user can define the search parameters as explained previously, and the result will be a patient list according to the search parameters, that are candidates for permanent deletion from the database. Note - pressing the *OK* button will permanently delete those patients.

Quick Review

Besides the standard offline review, the user can quickly review the patient details and the various examinations that were performed.

View Details:

Once selecting a patient, the user can press the *View Details* button in order to review the patient details. The user can add input or modify existing fields, but will be request to confirm the changes when closing the window.

Previous Exams:

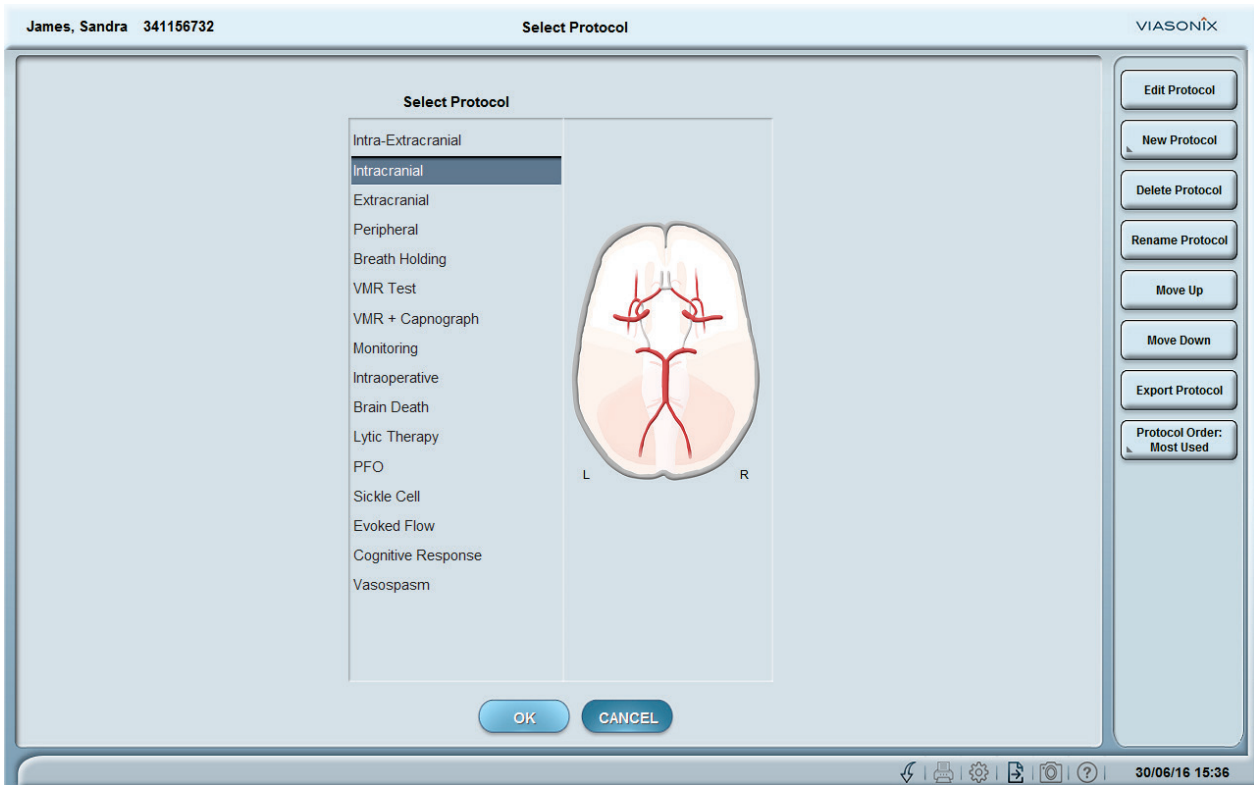
The *Previous Exams* button is used to preview measurements and compare measurement trends for the selected patient. Selecting this button opens a screen with the **Summary Screens** which correspond to different examination dates are displayed for review. The examination date appears above the summary preview, and the user can touch the date field to open a drop-down list with additional examination dates. By selecting a different date, the corresponding summary preview will be displayed.

Trends:

The Trends button shows a graphical display, which compares the changes in the Doppler parameters, ratios, and/or manually input parameters, as a function of the examination date.

Chapter 7 | Protocol Management

This chapter describes the concept and management of examination protocols.



By definition, an examination protocol defines all of the sites and probes that are used during the examination, and their corresponding order and Doppler settings. The user can define as many protocols as required, and use several different protocols during the examination process. Different protocols can be configured per the required patient examinations, and/or defined for different examiners, etc.

The selected protocol is shown during *Online* mode in the field on the top left part of the **Main Screen**. By clicking on the *Protocol* field, a drop-down list opens which allows the user to select the appropriate protocol for the current examination. The Protocol list on the left shows the order of sites to be measured. The schematic picture shows the current vessel in green, and vessels that were already measured are displayed in red.

Select Protocol

The simplest way to select a protocol is from the drop-down list of the protocol field in the **Main Screen**. An alternative method is through the **Select Protocol** screen (shown below), which is also the gate to protocol management and configuration.

There are 2 ways to enter that screen:

- Selecting the **Edit Protocols** option at the bottom of the protocol drop down list in the **Main Screen**, or
- Entering the main **Menu Screen** and selecting the *Select Protocol* option.

The main area of the screen displays a list of all of the defined protocols, and a corresponding schematic picture which defines the marked protocol. By marking a different protocol from the list, the schematic picture updates accordingly. To select a protocol for the current examination, simply mark the desired protocol and press *OK*. The order of display of the protocols can be managed with the aid of the buttons on the right-hand side.

Rename Protocol

To rename a protocol, simply mark the target protocol, and select the *Rename* button on the right side of the **Select Protocol** screen. The protocol name field becomes editable, and the user can type any other name. Note that renaming a protocol does not change the protocol configuration.

Export Protocol

This option allows exporting a single protocol that is marked in the list on the left as a VDL file.

Protocol Order

The user can define with the *Protocol Order* button on the right-hand side of the **Select Protocol** screen, the order of the protocols in the protocol list. A drop-down list opens when pressing the button, allow selecting from 4 different order options:

- ABC Order* is the standard alphabetical name order
- Most Used* displays the protocols by order of the frequency used. The most frequently used protocol will be the first in the list, and so on
- Recently Used* displays the protocols by the order used. The last protocol used will be the first in the list, and so on
- Customized option allows the user to configure any preferable order. Simply touch a protocol name and drag and drop it in the preferred order location.

New Protocol

To configure a new protocol, simply select the *New* button on the right side of the **Select Protocol** screen, and then select the type of examination to be configured in the protocol. A new field will open at the top of the protocol list, allowing the user to enter the desired new protocol name. By pressing *OK* the **Edit Protocol** screen, as defined below, will open and allow the user to start the configuration process of the new protocol.

Edit Protocol

To edit and configure a protocol, simply mark the target protocol, and select the *Edit* button on the right side of the **Select Protocol** screen. The **Edit Protocol** screen, shown below, will open and allow the user to configure or modify the protocol.

The main area of the screen is a table describing the order and details of the sites to be measured. All of the entries in the table open a drop-down list when touched to allow a selection from available options. The *Start Depth* and *End Depth* fields mark the default range of the M-Mode display.

Edit Protocol

VIASONIX

Protocol Name: Intracranial

#	Side	Vessel	Probe	Depth	Sample	Power	Scale	Gain	Zero	Start Depth	End Depth	Direction	Envelope
1	R	MCA	2 PW	55	12	64%	231	8	30%	40	85	Towards	Upper
2	R	MCA/ACA	2 PW	60	"	"	"	8	50%	40	85	Towards	Both
3	R	ACA	2 PW	70	"	"	"	8	70%	50	90	Towards	Lower
4	R	PCA P1	2 PW	70	"	"	"	8	30%	50	90	Towards	Upper
5	R	PCA P2	2 PW	70	"	"	"	8	70%	50	90	Towards	Lower
6	L	MCA	2 PW	55	"	"	"	8	30%	40	85	Towards	Upper
7	L	MCA/ACA	2 PW	60	"	"	"	8	50%	40	85	Towards	Both
8	L	ACA	2 PW	70	"	"	"	8	70%	50	90	Towards	Lower
9	L	PCA P1	2 PW	70	"	"	"	8	30%	50	90	Towards	Upper
10	L	PCA P2	2 PW	70	"	"	"	8	70%	50	90	Towards	Lower
11	R	Ophthalmic	2 PW	50	6	6.9%	231	2	40%	20	70	Towards	Upper
12	R	Siphon	2 PW	65	12	3.6%	231	8	50%	40	90	Towards	Upper
13	L	Ophthalmic	2 PW	50	6	6.9%	231	2	40%	20	70	Towards	Upper
14	L	Siphon	2 PW	65	12	3.6%	231	8	50%	40	90	Towards	Upper
15	R	Vertebral	2 PW	70	12	64%	231	7	40%	40	85	Towards	Lower
16	L	Vertebral	2 PW	70	"	"	"	7	40%	40	85	Towards	Lower
17		Basilar	2 PW	80	12	53%	192	10	60%	50	110	Towards	Lower
18	R	EX-ICA	2 PW	50	12	14%	231	8	70%	40	85	Towards	Lower

OK CANCEL

Add Line

Delete Line

Move Up

Move Down

Import Protocol

Multi Depth

Bilateral: Off

Vessels

Fixed Text Report

Edit Waveform Labels

Edit Custom Trends

Set Report Title

In order to modify an existing protocol, simply press on the entry to be changed, and select a different option from the drop-down list. In addition, by marking a protocol line, additional modifications can be made with the aid of the buttons on the right, such as moving the marked row up or down with the *Move Up* and *Move Down* buttons, or deleting the row from the protocol with the *Delete Line* button. An alternative way to move protocol lines up or down is to simply drag and drop the line in the preferred location. The *Add Line* button adds a new row with empty fields below the current marked location, and the user can start inserting the entries as desired.

The user can select the same site as many times as required for measurement in the same protocol. The site will then be marked with the letter M next to it, with the corresponding number indicating the measurement cycle number.

The user can also add a complete previously configured protocol to the current protocol by selecting the *Import Protocol* button (when applicable). A drop-down list with all available protocol names shows, and by selecting one of them that whole protocol is added at the end of the current protocol. In addition, a shortcut to the vessel configuration screen is available through the *Vessels* button. This option allows renaming the vessels or changing their display order in the drop-down list.

The *Bilateral* button duplicates the vessel that is currently marked for right/left simultaneous bilateral measurements. Note that the line number is now marked with the same number and with *a* and *b* to indicate bilateral measurements. The button changes to *Unilateral* when a bilateral line is marked, to allow separating the 2 measurements.

Chapter 8 | Main Menu and Setup

This chapter describes the various setup features that are available through the main menu screen.



The **Menu Screen** (shown above) is accessed through the *Menu* button in the **Main Screen** or **Summary Screen**. Through the options available in this screen the user can configure, manage and access practically all of the Dolphin's software features.

The Menu Screen is divided into the main software categories: *Patient*, *Protocols*, *Setup*, *Database*, *Research* and *Help*. Under each of these categories is a list of relevant buttons, which in turn open a drop-down list for continued selection, open a configuration window, or perform the requested action. Buttons which open a DDL are marked with a small side arrow, and options which open a configuration window are marked with "...". Note that all of the selections that are made through the Menu screen are automatically accepted when pressing the *Close* button.

All of the main menu categories are discussed in other chapters. This chapter focuses on the options available under the *Setup* category.

Print

Pressing the *Print* button opens a drop-down list with several options: Select Printer, Configure Printer, Hospital Logo, and Layout Configuration.

Select Printer:

This option shows a list of all printers that are configured and recognized by the computer. To select a printer from the list simply mark the selected option.

Configure Printer:

This option opens that standard MS Windows printer configuration window. The user can configure here various printer options, such as paper type, print layout, printout colors, etc.

Header:

The printed reports can include in the report header various institute details. Such as institute name and department name. Additionally, the header appearance can be modified with options such as font size.

The Header screen also allows switching to advanced Header editing mode. This advanced mode allows a more flexible layout using a drag & drop editor.

Footer:

This screen allows editing the page footer using a drag & drop layout printed reports can include in the report footer various details. The logo in the center of the footer is locked and cannot be changed.

Page Contents

Page Contents opens the Print Layout screen which allows configuring a wide range of print options. The examination report will be printed according to the selections made in this screen.

The *Print Preview* button on the right-hand side allows previewing the selected configuration for quick evaluation.

The Screen is composed of 2 main columns.

The first is the *Select Item* column, which allows selecting the main display groups such as patient details or any of the special examination modes.

The second column, *Select Settings*, is divided into 2 parts: the left side contains a list of the categories and sub-categories for display, and the right side includes an active field for each sub-category, that allows configuring the desired display setting. A drop-down list opens for each of the display setting fields. The categories and sub-categories in the second column change according to the group selection in the *Select Item* column.

Custom Worksheets

This screen allows generating custom reports using drag & drop editor. The created worksheets/diagrams can then be printed, reviewed in summary screen, and be sent to PACS.

Custom Patient Trends

This screen allows defining custom trends graphs for a protocol. The custom trends can include different data collected for a patient including examination results, ratios, and manual input values. The custom trends will appear in Trends screen and in the reports, when relevant data is available.

Fixed Text Report

This screen allows setting up fixed text report for a protocol that will act as a default free text report. The default report can be edited at any time using the Write Report screen. The default/edited free text report will be included in the generated reports.

Reference Values

This screen allows adding reference table with user defined thresholds to the report.

Report Waveforms Order

Select the order of the waveforms display, for example, according to measurement order or a completely customized order.

Tests Configuration

This option represents the main configuration option that allows configuring all preferred Doppler, general display, and specialty test settings.

Pressing the *Tests Configuration* button opens the main setup screen. The setup screen is composed of 2 main columns: the *Select Item* column, which allows the user to select the main group category for configuration, and the *Select Settings* column, for selection of the preferred system setting. The *Select Settings* column is divided into 2 parts: the left side contains a list of general categories and their respective sub-categories, and the right side includes an active field for each sub-category, that allows configuring the desired setting. A drop-down list opens for each of the setting fields. The categories and sub-categories in the second column change according to the test selection in the *Select Test* column.

Doppler

This category, which appears at the top of the *Select Item* list, is used to configure all of the main options and settings that are related to the Doppler spectrum, controls and measurements. Some of the main categories for configuration include:

Workflow:

This category allows configurations that directly affect the workflow of the examination, the method of saving waveforms to summary screen and the functionality of Next button

Spectrum:

This category allows configurations that affect the spectrum display, its velocity scale and color palette.

Doppler Controls and Gain:

This category allows configurations related to the Doppler controls display and their options. The Power Booster to enable higher insonation levels (within regulatory limits); the Power Display units, as percentage of maximal power or as ISPTA.3 which is the derated spatial-peak temporal-average intensity in units of mW/cm²; and the Ophthalmic Mode (not available in the USA), on or off, which allows to limit the maximal power level for the ophthalmic vessels below regulatory limits. When Ophthalmic mode is off, the display of the power steps above the recommended power limits are displayed in red.

Misc.

This category allows configuration of general items, such as Sound Level (standard or attenuated), Schematic Picture display (show or hide), and Grid lines (show or hide).

Depth Step

This category allows configuration of the depth steps for each Doppler probe frequency each time the Depth parameter is changed.

Insonation Angle

This category allows configuration of the insonation angle for each Doppler frequency that is used. The angle directly affects the measured Doppler velocity according to the Doppler equation.

Thermal Indices

This category allows configuration of the on screen display of the thermal indices of soft tissue (TIS), cranium (TIC) or bone (TIB). Each index can be selected to always be displayed, or only per regulatory requirements.

Velocity Profile & 4D Velocity Scan

This category allows configuration related to the 4D velocity scan and velocity profile special graphs.

Routine and Monitoring Examinations

This category, which appears in the *Select Item* list below Doppler, is used to configure all of the main options and display settings that are related to the 2 main examination modes: routine and monitoring modes. Some of the main categories for configuration include:

Main Screen Display

This category allows setting the main display elements visibility. Conditional visibility can also be configured in this category.

M Mode:

This category allows configuring M Mode related settings such as the *M Mode Location* display relative to the spectrum display (above, below, to the right or left of the spectrum); The *M Mode Depth Line* display as a line located at the selected depth, or as a region highlighting the sample volume range.

Side Spectrums:

This category allows setting the visibility and configuration of optional side spectrums graphs.

Parameters Configuration:

This category allows to configure the location of the measured Doppler parameters (above, below, to the right or left of the spectrum) through the *Parameters Location* option; and to select separately to *Show* or *Hide* from the main screen display each of the measured Doppler parameters.

Trend's Parameters:

This category allows configuring the color of each parameter that is selected for display in the monitoring trend window.

Split Trends Display:

This category allows determining whether the trend waveforms for right and left sides during bilateral measurements will be displayed in separate trend screens or in a single screen. Likewise, the user can determine whether to display trend waveforms for parameters with different scales in the same screen or in separate screens for each scale group.

Trends Y Scale:

This category allows configuring the Y scale display for each parameter group. The options include automatic adaptive scales for the entire measurement or only for the zoomed and displayed region, or to manually set the Y scale region.

Trends Display:

The trends screen has an option to highlight the zoomed area (out of the entire measurement region). When selecting to show the zoomed area, the Doppler spectrum screens will update accordingly when selecting this area and moving it to the left or right.

Actions on Alert:

Alert configuration can be performed primarily for monitoring operation modes. When an alert is activated, the configuration can include having a "beep" sound display the parameter in red on the screen, or automatically adding an event marker.

Event Markers:

This category allows configuring event markers which are applicable in monitoring operation modes. The user can select an automatic time marker to be added every selected time, display the pre-configured even list in the main screen, Display predefined markers or when freeze is activated with a complete vertical line in the trends screen, or display the Delta Mean marker.

Specialty Tests

This category, which appears as the long list in the bottom of the *Select Item* list, is used to configure all of the main options and display settings that are related to each specific specialty test. Most of the configuration categories for each specialty test are similar to routine and/or monitoring modes and have been described above. In addition, some specialty tests have specific categories that are unique to the test.

BHI:

This option is available only for the Breath Holding test. The Breath Holding Index (BHI) can be configured to be calculated either according to the peak or mean velocities.

In addition to the setting configurations described above, the user can configure a list of predefined waveform labels, markers or alerts to be applicable to each specific test or examination mode.

To set the labels, markers or alerts simply select the corresponding button from the list on the right-hand side of the configuration screen. A respective configuration screen opens, that allows creating new entries, changing their display order, or removing an entry from the list. When an alert is added, a special window opens that allows selecting for each parameter when to activate the alert: if the measured parameter is greater than or less than a given value.

External Channels

The Dolphin allows receiving data for display from an external unit (input) or exporting a waveform for display on an external unit (output). Pressing the External Channels button opens a drop-down list for selecting of input or output channels for configuration.

Selecting any option opens a special screen that allows configuring the external channels for each examination test. For each examination test selection from the column on the left-hand side, a number of external channels can be configured. In general, there are analog and digital channels for selection, as well as 2 “fixed” input channels: a display of the peak Doppler envelope, and a display of the CO2 data from a supported USB Capnograph.

For each external channel various settings can be configured from the column on the right-hand side of the screen. The primary option is to enable or disable the selected channel. Then various display and calibration settings can be configured, including the channel label, color display, units, Y scale settings, and calibration settings.

Additional information regarding external channels can be found in the Dolphin installation and service manual, section “External Channels Specifications”.

Controls

This option allows the user to configure the function of the configurable pedals/keys in the various control accessories. When selecting this option, the *Setup Controls* screen opens, and allows setting up the function of each pedal/key. The 3 main groups are the *Remote Control*, *Foot Switch* and *Keyboard*.

Remote Control:

There are 3 configurable keys in the remote control: F1, F2, and F3. The user can configure the function of each of these keys from the available drop-down list.

Foot Switch:

There are 3 configurable pedals in the foot switch: Left Pedal, Middle Pedal, and Right Pedal. The user can configure the function of each of these pedals from the available drop-down list.

Keyboard:

The user can configure the function of the F4-F11 keys in the key-board from the available list.

Language

This option allows selecting a different operating language for the Dolphin program. When selecting this option, a drop-down list opens with a choice of various languages. Note that after selecting a different language from the list, the program should be closed, and then re-started. Text strings that are not translated will appear in the original English text. In order to return to *English*, the user must remember the relative location of the *Menu* button and the corresponding *Language* button in the **Menu Screen**.

Chapter 9 | Database

This chapter describes the various available database and patient file management options, such as exporting measurements in various formats, importing files for review, database backup, and restoring files from backup for review. The *Database* section includes also networking and connectivity options as well as data management. All of these features can be accessed through the *Database* section in the main **Menu Screen**. The export options are available also through the shortcut icon at the bottom of all of the screens.

Export

Pressing the *Export* button opens a drop-down list with several export options as well as an option to setup several target export locations. There is also a shortcut to the various export options through the *Export* icon at the bottom right of all screens (on the information bar).

Screen Capture:

This feature allows the user to save the current measurement screen, such as the **Main Screen** or the **Summary Screen**, in most standard picture formats.

Report (PDF):

This feature allows the user to save the patient report for the currently opened examination in PDF format.

Excel:

This feature allows the user to Doppler data such as envelope, Parameters, and HITS in Excel format.

Examination (VDL):

This feature allows the user to save the current patient examination in VDL (Dolphin) format. This option is very useful, for example, when the user wishes to send a specific patient examination to a colleague for review on a Dolphin review station. The VDL files allow a complete examination review that is similar to loading a file from the database. To review a VDL file, simply double click on the file, and the Dolphin program will open with the loaded patient file.

Assistance File:

This feature allows the user to export an assistance file for diagnostics purposes.

Raw Data:

This feature allows the user to save the current raw data measurement in DAT format. This option is very useful primarily for research purposes, where the researcher can manipulate the data and reproduce the measurements according to the research requirements. To be able to review the DAT files contact your Viasonix representative.

Movie:

This feature allows the user to create a movie file. After selecting the file name and location and pressing OK, a movie file is created which is composed of all of the activity that is performed with the Dolphin program and is displayed on the screen. To end the movie capture press the F12 key on the key board or press the Pause icon on the bottom right hand side of the screen.

Setup Locations:

Use this screen to prepare a predefined list of locations to quickly export to or import from.

Default File Name Template:

Use this screen to predefine a template of a file name for exported files. Use <TAGS> from the list of TAGS as placeholders to be substituted with actual data when exporting.

Import Examination

The *Import Examination* button is designed to load and review examination files in DOL format. These files can be imported into any computer review station, and therefore the Dolphin does not have to be connected to the computer. The imported examination file is loaded into the Dolphin and added to the database, and the user can perform a complete offline review of the examination.

Backup

The *Backup* button is designed to perform routine backups of the patient examination database to an external media.

! Note: It is very important to perform routine backup of the patient examination database, to avoid losing patient data due to computer failure or other uncontrolled events. It is important to keep the backup media in a safe and protective environment, away from the location of the Dolphin system.

Backup can be performed to an external USB storage media, a DVD, or to a network folder.

The program automatically identifies the different options that are connected to the computer, and allows the user to select the target backup media. In addition, there are 2 different backup options: *Move* and *Copy*.

Selecting *Move* results in moving all of the examination files from the computer to the backup media, hence the computer database will be empty. This is equivalent to deleting the entire database from the computer and relying only on the backup media. Selecting *Copy* results in copying all of the examination files to the backup media, while also maintaining those files on the original computer. However, this action will result in quickly filling up the space on the computer hard disk, so eventually the user will have to free up some hard disk space for additional examinations.

Before beginning the backup process, the **Backup Information** window opens, which provides the user with a summary of the requested backup, including the expected disk size and the number of patients files to be backed up. In addition, the user can add free text comments in the *Comments* field to describe the specific backup or to describe where the backup is placed, or any other free text. This information will appear in the backup history review screen.

There are three different backup options that are available to the user when clicking the *Backup* button. In addition, the backup history can be reviewed. A drop-down list opens with the following options:

Delta from Last Backup:

This option is useful when performing routine backups every certain period of time. With this option the program will automatically backup all of the examination files that were added to the database since the last performed backup.

By selecting this option, a drop-down list opens to allow the user to select the target backup media that is recognized by the system, followed by the selection of the backup method: *Copy* or *Move*. The **Backup Information** screen opens, and by pressing *OK* the backup process starts.

Search Patients:

This option allows the user to backup only selected patient files. For example: backup only patients that were referred by a certain physician. After selecting *Search Patients*, a drop-down list opens to allow the user to select the target backup media that is recognized by the system, followed by the

selection of the backup method: *Copy* or *Move*.

Then the **Quick Search** screen opens, and allows the user to search for a specific group of patients according to specific search criteria.

Excluding the *Date* and *Age* fields where the user needs to input the search range, all other fields automatically open a drop-down list with all available options for these fields based on the current database. The user can further extend the search options with the *Advanced Search* button on the right, which allows to further search patients by status or risk factors. After approving the search criteria, the **Backup Information** screen opens, and by pressing *OK* the backup process starts. If the search criteria do not identify any patients, a message will appear indicating that the backup for the search patients option is aborted.

All Patients:

This option is useful to backup all of the patients that are currently in the database, regardless of previous backup history. By selecting this option, a drop-down list opens to allow the user to select the target backup media that is recognized by the system, followed by the selection of the backup method: *Copy* or *Move*. The **Backup Information** screen opens, and by pressing *OK* the backup process starts.

Backup History:

This option allows the user to review that history of backups that were performed, including additional information such as the backup id, date, location, size, method, type, and comments that were added by the user.

Network Backup:

This option allows the user to setup network locations for backup, such as shared folders.

Automatic Backup:

Setup automatic backup to schedule a backup to a network shared folder. Each time the automatic backup runs, all new exams since last backup are copied to the shared folder.

Restore

The *Restore* button is designed to restore patient examination files from a backup media to the Dolphin program for review and analysis. To restore, choose a detected media or a network folder from the drop-down list. The restore feature will restore only files that are currently not in the database.

Network Restore:

This option allows defining locations such as network shared folders to restore from.

Storage

This option allows several special configuration options related to the database.

Save Configuration:

Options to configure the specific data to be stored for each type of test, for offline review.

Delete Raw Data Files:

Option to free up disk space by deleting raw data portion of examinations either manually or automatically (periodically). This is only relevant when Raw Data storage is turned on under Save Configuration. Once the raw data portion is deleted, it is no longer possible to post process waveforms.

Recovery Bin:

Option to setup the recovery bin that can be used to restore waveforms deleted by mistake.

HIPAA:

Option to perform privacy related functions such as periodically deleting old exams or de-identifying them.

Examination Database Storage Mode:

Option to store a locked PDF report instead of the complete data.

Predefined Import/Export Locations:

This option allows configuring several local and networking target locations that will appear whenever the *Export* or *Import* options are used. Simply press the *Add* button and browse to the target location. The *Delete* button is used to delete a previous target location.

Predefined Backup to Network Locations:

This option allows configuring network target locations that will appear whenever *Backup* is used. Simply press the *Add* button and browse to the target location. The *Delete* button is used to delete a previous target location.

Default Export File Name Template:

This option allows configuring the default file name template for the various exported file options. By pressing on one of the <tabs> inside the template, a list opens on the right-hand side which allows to add any parameter that is selected to be used in the name template.

Automatic PDF Report Export:

This option allows to automatically save the generated PDF reports to a configured target local or network directory. The report template file name can be also configured by pressing inside the *File Name Template* field and creating a new template.

Examination Database Storage Mode:

This option allows saving the entire patient examinations only in PDF format rather than in DOL format. Note: Saving in PDF format allows saving a lot of disk space, but the examination cannot be reviewed or modified after the examination is closed.

Network

This option is designed for network communication with the institute's server.

! Only certified Information Technology personnel are authorized to configure the Dolphin for network connections. A password is required to enter the different configuration screens.

Some of the screens under this menu are password protected. Please contact your local representative if you require access to any of these screens.

DICOM, HL7 or GDT

The comprehensive DICOM, HL7 or GDT connectivity and specifications are detailed separately in the respective conformance documents.

After entering the correct password, the respective configuration screens open, with several configurable fields. The primary field is to determine whether the *DICOM/HL7/GDT Server Interface* is *On* or *Off* and whether the local or remote SQL server is connected. If *Off* (or *Internal* for SQL) is selected, then all of the associated buttons in the **Patient Details** or **Load** screens are hidden, and the **DICOM/HL7/GDT** configuration fields are inactive. To continue with the configuration, select *On* for the *Interface* field, which allows the user to fill all of the respective connectivity fields. A *Test Connection* button at the bottom of the screen allows testing the connectivity to the institute's server.

PDF, Excel, Videos, and Email

These screens allow automatic export of PDF or Excel, or transmission of email at the end of an examination. The export is triggered when the user starts a new examination, loads another examination, presses Complete Exam button on Summary Screen, or exits the software.

Review Station, Trends Sync

Both Review Station and Trends Synch are meant to share data with other stations. While Review Station shares the complete examination, the Trends Synch option shares only the numerical data that is required to present trends for returning patients.

Chapter 10 | Research

This chapter describes the various options available for research and information purposes.

Statistics

When selecting the *Statistics* option, the *Statistics* window opens. A list of various parameters is displayed on the left side, and a bar or graph display is shown in the center. By marking any of the items in the list, the graphical display updates according to the information in the current patient database on the computer hard disk.

Selecting the Advanced X&Y option from the list allows displaying in an X-Y axis format the results from the patient database. Two drop down field for each axis allow selection of the preferred parameters for display.

The *Search Filters* button on the right allows narrowing down the database on which the statistics is performed according to different patient or examination criteria. The search filters can be reset with the *Reset Search* button at any time. All of the patient and examination details related to the selected database can be exported to an excel file with the *Export To Excel* button on the right.

Anonymous Output

The *Anonymous Output* option allows printing or exporting a patient file without the identification details of the patient. This option is useful for research purposes.

Print

When this option is selected, the examination report will print without the patient name and identification number.

Export to PDF

When this option is selected, the PDF examination report will be saved to the selected directory without including the patient name or ID number.

Chapter 11 | Help

This chapter describes the various help and information options that are available to the user, and various support issues regarding Dolphin operation.

About

When pressing the *About* button a new window opens with details of the Dolphin software version number, and basic computer hardware information.

Dolphin

The *Dolphin* button opens the main **Help Screen**. This screen includes explanations about most of the features and options available in the program. The left hand side includes a list of major categories, and each major category further divides into several main sub-categories. The user can select any category or sub-category, and read the detailed explanations that appear in the text window in the center. In addition, to search for a particular feature or item the user can use the *Search* option. When entering a text string in the search field and pressing the *Search* button, the first time the string appears is marked in the text. By pressing *Search* again the next corresponding string will be marked. The string search is not limited only to the currently displayed category, and will continue searching the complete help database.

License

Open the License screen to view the current Dolphin software license details, or enter a new license key.

Hotkeys

This button opens the **Hotkeys** window, which is designed as a table which details the specific function of each hotkey or pedal in the remote control, foot switch and keyboard. This page can be printed with the button on the right hand side.

Troubleshoot

This feature provides quick troubleshooting options. The user needs to mark the problem that was encountered from the list on the left (if identified in the list), and the corresponding troubleshooting instructions will appear in the central text region.

Service

This section is available only for service personnel. There are several main categories:

Diagnostics

This option is designed for performing basic Dolphin diagnostic testing.

Assistance

This option is designed to allow remote connection to the Dolphin computer or to save and send a file to Viasonix.

Password Protection

This option is designed for adding various password (PW) protections to the program. This option can be accessed only by authorized institute personnel that have access to the entrance PW. After inserting the access PW, the Password Protection screen opens. A specific login password can be configured, which will allow only authorized Dolphin users to start the program. In addition, the authorized institute representative can protect the system from changes by Dolphin users in the following options: Delete Patient/Exam, Modify Protocols, Modify Patient Details, Modify Examination Results. If protected, the authorized entrance PW will need to be typed in order to allow the change.

Export

This option is used to export the configured protocols or the complete Dolphin settings. The exported file is in VDL format, and is to be used in order to load the protocols or settings to another computer.

Control Panel

This option provides quick shortcuts to main operating system screens and options, as well as service related Tools.

Options

This option provides to customize the *Startup* display when starting the program for the first time. The program can open either with the *Patient Details* screen or the *Main* screen. In addition, all system messages, which have been selected to be hidden, can be automatically restored. Network allows disabling the automatic retry functionality when a document could not be sent over the network.

Viasonix

This option is PW protected, and is designed for the sole use of Viasonix personnel.

Profile Settings

Allow setting a separate profile for multiple users.

Translation Tool

This option is PW protected, and is designed to provide an option for efficient translation of the Dolphin program into a new language.

Chapter 12 | Control Options, Accessories

The standard method to use the software and control the Dolphin system is with the use of a mouse or touch screen to make program selections, and a keyboard to type text and enter data. To help and simplify system operation, however, the Dolphin supports additional options to aid in rapid selections, free the hands, or allow operation away from the system: remote control, foot switch, and key-board. In addition, a standard USB camera can be connected to the computer for the purpose of adding the patient's picture to the database or to add a picture to the patient report.

Remote Controls

The remote controls are designed for management of the most important Dolphin functions and features that are used during an examination. Do not use a remote control that is not supplied with the Dolphin. There are two remote controls that can be used with Dolphin system:

Wireless Remote Control:

The wireless remote control is IR based and comes with a USB IR receiver which connects to the computer. Make sure that the receiver USB cable is firmly connected, and that its led lights are lit. The remote control needs to be pointed towards the receiver when operated.

Dolphin Wireless Remote Control



Wired Remote Control:

The wired remote control connects to the computer via USB cable. The cable connector on the remote control end is fixed and cannot be detached. Make sure that the USB cable is firmly connected to the computer.

Dolphin Wired Remote Control



The remote control allows the user to operate away from the system, and by the patient's bed. The remote control includes dedicated keys for most of the main functions, as well as some user defined

keys. In general, there are four groups of keys in the remote control, as shown below: Signal Control Keys, Main Keys, Next and Arrows, and Configurable Keys.

Signal Control Keys:

The remote support 8 signal control functions, each divided into 2 keys to allow to increase (+) or decrease (-) the value of the corresponding function. The 8 standard functions are: *Power, Sample, Scale, Depth, Volume, Gain, Zero* and *Sweep*.

Main Keys:

The 8 main keys include: *Freeze/Redo, Save, Channel, Envelope, Print, Invert* and *Mute*. The wireless remote control includes additional Probe button and the wired remote control includes an additional Delete button. These are standard functions that support performing an examination.

Next and Arrows:

The *Next* button, which is the main online examination button, is colored differently and is larger in size. Most online steps can be performed through this button. In addition there are 2 sets of arrows in the remote control: up/down and right/left. The main function of the right/left arrows is to scroll the waveforms after freeze, while the main function of the up/down arrows is to scroll along the protocol list during *Freeze* or to change the *Depth* during online measurement.

Configurable Keys:

There are 3 configurable keys in the remote control: F1, F2, and F3. The wired remote control supports an additional F4 configurable key. The user can assign to these keys any desired function from the list of available options through the *Setup/Controls* option in the main **Menu Screen**.

Foot Switch

The Dolphin supports the use of a three-pedal foot switch that allows performing 3 main system functions by using the foot, hence freeing the hands completely and allowing the examiner to focus on the patient. The 3 pedals can be configured by the user through the *Setup/Controls* option in the main **Menu Screen**. The user can assign to these pedals any desired function from the list of available options. It is recommended, however, that one of these functions will be *Next*, which is the most important key during a routine examination. If one of the pedals is stuck or has some sort of mechanical interference, disconnect the USB connector of the foot switch from the computer and contact your authorized service representative.

Keyboard

The main function of the keyboard is to write text. However, the keyboard also supports hot keys, which also allow to perform many standard and routine functions of the program and to simplify system operation for the user. There are two groups of hot keys: keys with configurable functions, and keys with fixed functions. The configurable hot keys are the F4 through F11 keys. These keys can be configured by the user through the *Setup/Controls* option in the main **Menu Screen**. The user can assign to these keys any desired function from the list of available options.

The hot keys with the fixed functions are detailed in the table below. In general and whenever possible, the hot key is the first letter of the function.

Hot Key	Function	Hot Key	Function
Space Bar	<i>Next</i>	ESC	<i>Cancel</i>
F	<i>Freeze/Redo</i>	M	<i>Mute</i>
T	<i>Waveform Label</i>	N	<i>New examination</i>
S	<i>Summary</i>	L	<i>Load examination</i>
P	<i>Print</i>	X	<i>Exit</i>
W	<i>DICOM Worklist</i>	O	<i>Online</i>
E	<i>Envelope</i>	I	<i>Invert</i>
Z	<i>Toggle Probes</i>	R	<i>Replay</i>
G	<i>Grid toggle</i>		
Up/down Arrows	<i>Scroll Lists</i>	Right/Left Arrows	<i>Scroll waveforms</i>
<	<i>Scroll signal left</i>	>	<i>Scroll signal right</i>

Monitoring Head Set

The Dolphin offers a monitoring head set, shown on the right, that can be used during TCD monitoring. The head set allows unilateral or bilateral monitoring. It is fixed and tightened over the patient head with the knob located in the front of the head set. Single use pads from biocompatible material are attached from the inside of the headset to the front and back parts. The monitoring probes are inserted through the probe fixation sub-unit and enable to adjust the position of the probes in the X, Y, and angular directions. One screw helps to lock the sub-unit in the X-Y direction, and another helps to lock the probe angular position within the sub-unit, to ensure continuous stable measurements from the same location.

Dolphin Monitoring Headset



External Channel Box

The Dolphin supports optional connection to analog and digital external channels. The connection can be performed optionally through the External Channel Connection Box.

The box has the option to connect up to 8 channels of analog input, 4 channels of analog output, and 2 channels each for digital input and output.

The box is connected to the back panel of the Dolphin through a D-Type connector. Connection to external devices is through the standard RCA connectors.



16 MHz Transformer (not available in USA)

The Dolphin supports a sterile single-use 16 MHz probe for use inside the sterile field for intraoperative measurements of blood flow velocities. The 16 MHz probe is not connected directly to the Dolphin. It connects to the Dolphin through a dedicated safety transformer. The dedicated transformer is located outside of the sterile field, and connects directly to the 16 MHz port in the Dolphin.

Chapter 13 | Dolphin/XF Robot

The **Dolphin/XF Robot** is a Dolphin accessory which can be used with any of the Dolphin TCD models. It allows scanning of the cerebral circulation in order to assist in the acquisition of cerebral blood flow velocity.

Note: In the event that the robot does not assist in finding a cerebral blood flow velocity, try using the standard monitoring headset.

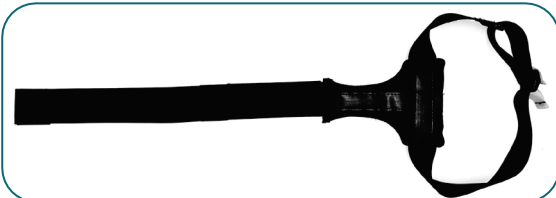
The Dolphin/XF robot is a mechanical enclosure that houses a standard Dolphin monitoring probe which is inserted into the Dolphin/XF enclosure, and can be removed for cleaning purposes. The robot has the ability to control the direction of the probe in 2 angular movements, that generate a region that can be scanned by the probe for the availability of Doppler waveforms.

The Dolphin/XF robot can be used either unilaterally or bilaterally. Each robotic element is marked with either a Green or Yellow label. The USB cable coming out of each robotic element needs to be properly connected to a USB slot in the Dolphin system or Dolphin/IQ computer. In addition, each Doppler monitoring probe that is used with the robotic element is also marked with a corresponding Green or Yellow label, and should be connected accordingly to the corresponding green or yellow 2MHz probe ports in the Dolphin system. The robot elements are situated on each side of a dedicated headset.

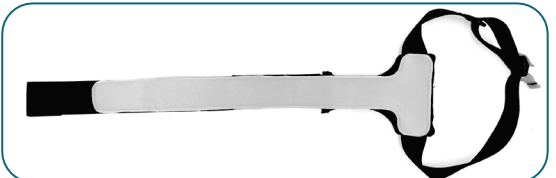
Preparing the Dolphin/XF Headset

The dedicated Dolphin/XF headset has a disposable pad that comes in contact with the head. To replace a pad, follow these steps (pad is shown in gray for illustration only):

- a) Open the top strap of the headset



- b) Attach the disposable monitoring pad to the Velcro along the main strap



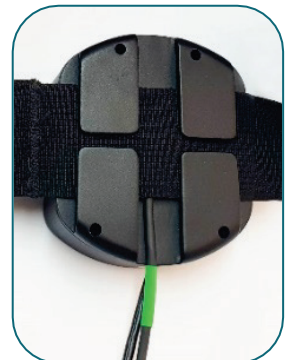
- c) Wrap the top strap around the back strap as shown



- d) Alternatively, use the disposable Dolphin/XF headset. This headset is for single-patient use only, and should be replaced before each new examination. This headset is tightened or loosened by 2 straps that are located in the front part of the headset.

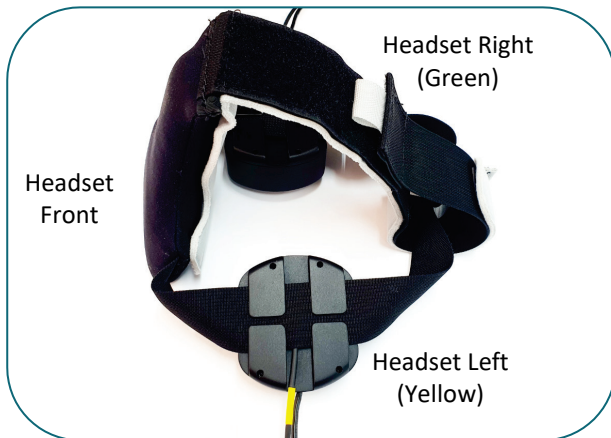


- e) Carefully insert the headset strap into the back panel of the Dolphin/XF Robot unit.
- f) Begin with inserting the strap under the top flaps and then the bottom flaps, taking care not to pull and break the flaps. The probe head should be pointing towards the inside of the headset.



- g) Repeat this action on each side, connecting both Dolphin/XF Robot units to the headset.

Note: When using the Bilateral Dolphin/XF Robot, it is recommended to connect the Dolphin/XF Robot Unit which is marked with a Green circle to the right side of the headset and the one marked with a Yellow circle to the left side.

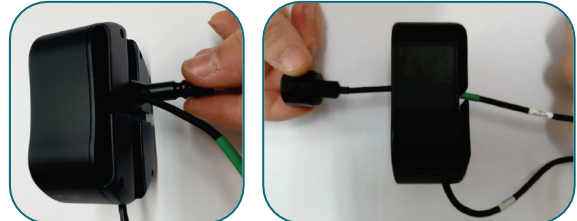


- h) Place the complete headset assembly on the patient's head. Make sure that the headset's front with the cushion is placed on the patient's forehead, and that the robot units are placed in the region of the temporal window.
- i) Adjust the top Velcro strap to roughly fit the patient's head just enough to make sure that the headset does not slip towards the neck or cover the eyes. Do not tighten the strap too much to allow the Dolphin/XF Robot units to be placed in the correct position
- j) Adjust the headset's circumference by pulling on the gray tabs on the back, or on the front straps in the disposable headset. Pull the right tab while holding the left side of the strap to tighten the headset. Make sure that the headset is not too tight on the head.



Preparing the Dolphin/XF Unit

- a) To remove the probe from the robot housing for cleaning or other purposes, use the monitoring probe handle as shown. Place it to fit the back side of the probe, and lightly push the probe out of the front of the Dolphin/XF Robot unit. Carefully pull out the probe followed by the probe cable.



- b) To insert the probe back in place, insert first the probe connector through the front panel as shown, and pull it from the back. Lightly push the probe head until it is fixed in place. Do not apply significant force.

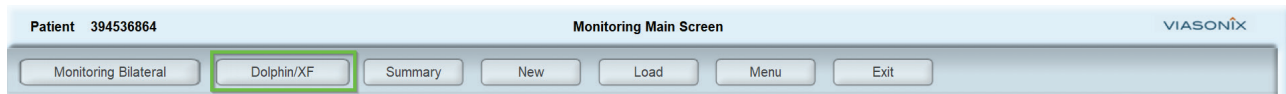


- c) The Dolphin/XF has a disposable silicon "cup" that is used to collect the ultrasound gel. Remove the used cover from the probe and replace with a new cover on top of the probe head as shown without applying any force.



Using the Dolphin/XF Software

The Dolphin/XF is automatically identified by the software when connected to the Dolphin system. Once identified, a Dolphin/XF button appears on the top bar as shown below.



To toggle between robot display and a standard Dolphin display on the main screen, press the Dolphin/XF button. For bilateral robot use, a bilateral protocol needs to be selected.

When pressing the Dolphin/XF button, a dedicated robot display area will open as shown in the figure below. Each robot has a separate control and display area which is marked accordingly.



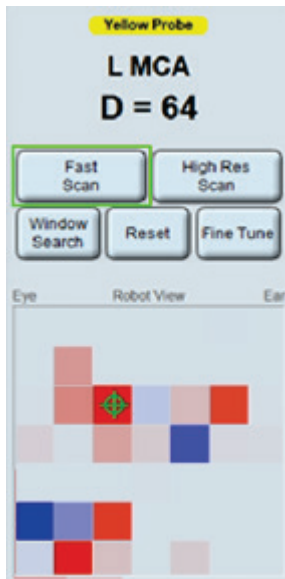
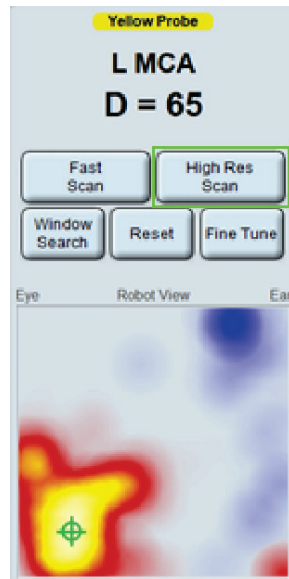
The main robot display region is the Heat Map, which is located below the robot control buttons. The Heat Map displays the current position of the probe in the scanned region, and it also maps the identified intensity level and direction of the Doppler spectrums at each position and presents it in a color scale of red and blue colors, where red indicates flow towards the probe and blue indicates flow away from the probe. Pressing anywhere on the heat map will move the position of the probe to that manually selected position.

The Dolphin/XF has several operation buttons for control of the robot.

Fast Scan – This option performs a quick low-resolution scan at the current Dolphin/XF location in order to identify a cerebral waveform. During the scan the patient should be instructed not to

move or talk. The “heat map” display region will be highlighted with red and blue color gradients as an indication of signal strength and direction. The position of the probe is marked on the heat map with a green target icon.

High Res Scan – This option performs a high-resolution scan at the current Dolphin/XF location in order to identify a cerebral waveform. This scan takes longer to complete compared to the Fast Scan option. During the scan the patient should be instructed not to move or talk. The “heat map” display region will be highlighted with red and blue color gradients as an indication of signal strength and direction. The position of the probe is marked on the heat map with a green target icon.

Fast Scan**High Resolution Scan**

Reset - Pressing this button will reset the probe position back to the center position.

Window Search - This option is designed to assist in the initial quick search for a signal in the current robot position, for the purpose of selecting the position of robot placement. The robot continuously performs a quick scan of the current Dolphin/XF position in an attempt to find a potential window.

Fine Tune - Pressing this button will rescan the close vicinity of the current Dolphin/XF position in an attempt to find the optimal signal around the current position.

Go to Pos - Pressing this button will move the robot to the position of maximal signal intensity of the positive flow (direction towards the probe).

Go to Neg - Pressing this button will move the robot to the position of maximal signal intensity of the negative flow (direction away from the probe).

Chapter 14 | General Information

Cleaning and Disinfection

- ! Turn off the mains power before performing any maintenance activity. Do not clean the system with water or a wet cloth.

The exterior parts of the Dolphin and its' probes should be cleaned on a routine basis as necessary and between uses. Before cleaning, the system must be turned off and disconnected from the mains power supply. It is important to take all necessary precautions to eliminate the possibility of exposing patients, physicians, technicians or third parties to hazardous or infectious materials. Use universally accepted precautions when cleaning the system and probes.

Start cleaning by removing surface particles from the system or probe surface. Use a clean gauze pad or lint-free cloth, slightly moistened with tap water, to wipe the surface of the system. Ensure that these areas are free of gel and any other visible residue. Be sure that the cleaning solution does not seep through the enclosure holes of the system. Cleaning around the system ports or connectors can be accomplished using a clean soft brush. After cleaning is completed, allow adequate time for drying and then reconnect the system power cable.

Disinfection of Doppler Probes (1.6, 2, 4, and 8 MHz)

Prior to starting a new patient examination, all of the Doppler probes and their cables should be disinfected. It is recommended to use Protex Ultra disinfectant wipes (or equivalent wipes) and follow the manufacturer instructions for use. These wipes were tested for material compatibility. Wipe hard non porous surface with wipe until surface is visibly wet. Allow surface to remain wet for 4 minutes per the manufacturer instructions. Permit surface to air dry. If surfaces are extremely dirty, clean first with another wipe before disinfecting.

- ! After each cleaning or disinfection of the probes perform visual inspection of the probes to ensure that the probe is not physically damaged, and is without any cracks or tears.
- ! DO NOT sterilize, heat, or autoclave any of the probes.
- ! DO NOT immerse the system or any of the probes in water or any other liquids.

Dolphin/MAX Rechargeable Battery Handling and Disposal

Only service personnel are allowed to replace the rechargeable battery. The battery is directional, and can be inserted into the battery compartment only in a specific direction. To replace a battery, carefully open using a screwdriver the battery door on the bottom panel of the Dolphin/MAX, remove the rechargeable battery and close the battery door. Do not try to force it in when replacing.

Given normal storage and usage, the battery delivers 80% or more of its initial capacity after 300 charge/discharge cycles.

Store extra Dolphin/MAX rechargeable batteries in a cool, well-ventilated, with smoke and/or heat detection area, away from ignition sources.

Lithium Ion batteries contain elements that may pose health risks to individuals if they are allowed to leach into the ground water supply. In some countries, it may be illegal to dispose of these batteries in standard household waste. Therefore, Dolphin/MAX batteries must be disposed to recycled bins per institute guidelines and in accordance with local, state or applicable federal regulations.

When disposing a battery, to render the battery safe apply tape over any exposed connectors to prevent the accidental shorting of the positive and negative terminals of the battery during transport. Place each rechargeable battery into its own plastic bag, seal the bag, and deposit the battery into the recycling container. NEVER dispose of the battery in a fire or incinerator, as the battery may catch fire and explode.

General System Specifications

The basic Dolphin specifications are listed below.

Weight: Dolphin/IQ approx. 2 kg, Dolphin/4D and Dolphin/MAX approx. 6 kg.

Dimensions: Dolphin/IQ 26.5 x 20.5 x 5.5 cm, Dolphin/4D and Dolphin/MAX 47 x 30 x 7 cm

Mains Power: 110-220 V, 50-60 Hz

Power Rating: Dolphin/4D 100-240V, 50/60 Hz, 1.5A max. Dolphin/IQ 12VDC, 5A. Dolphin/MAX External 15VDC, 9.6A or internal battery.

Battery Operating Time: at least 3 hours of routine examination (applicable only to Dolphin/MAX)

Doppler Frequencies: 2 MHz, 1.6 MHz, 4 MHz, 8 MHz, 16 MHz (not in the USA)

Summary Screens: Interactive

Examination Reports: Configurable, with user defined templates

Report Headers: Configurable, support institute name and logo

Optional Accessories: Monitoring head set, Dolphin/XF robot, External Channel connection box

Control Accessories: Remote control, foot switch, keyboard, touch screen

Doppler Controls: Depth, Sample Volume, Gain, Power, Scale, Volume, Gain, Sweep, Zero Line, Insonation Angle, Thump Filter, Color Palette, Units

Save: Automatic, configurable duration

Signal/Spectrum Replay: Yes, full audio for Doppler

Spectrum Colors: 16, configurable

Cursors: Yes

Display Grid: Yes

Print Configuration: Yes

Protocol support: Yes, unlimited, user configured

Networking: DICOM (including SR), HL7, GDT, SQL

Display splitters: Available

Patient Details: Advanced, including medical history, indications and patient status

Review Workstations: Yes, unlimited

Doppler Parameters: peak velocity, mean velocity, diastolic velocity, pulsatility index, resistance index, systolic to diastolic ration, rise time, heart rate

Velocity Units: Cm/sec or KHz

Database Search: Advanced, based on patient and examination details

Export: Screen capture, waveforms (excel), reports (PDF), examination file (VDL), Movie (MP4), Protocols

Backup: All database, only examinations that were not previously backed up, or according to advanced search criteria.

Doppler parameters accuracy: +/- 10%

Operating system: Windows 7, 8.1, 10, 11

Storage temperature: -20°C to 60°C (18°C to 25°C for 16 MHz probe)

Operating temperature: 10°C to 40°C (18°C to 25°C for 16 MHz probe)

Storage humidity: 8% to 80% relative non-condensing (20% to 70% for 16 MHz probe)

Operating humidity: 15% to 80% relative non-condensing (20% to 70% for 16 MHz probe)

Storage atmospheric pressure:
500 hPa to 1060 hPa

Operating atmospheric pressure:
700 hPa to 1060 hPa

Minimum hardware requirements:

CPU: Quad Core 1 GHz

RAM: 4 GB or higher

Hard Drive: 256GB or higher

Display size: 15" Wide Screen

At the end of service life of the device or its accessories, dispose them according with local regulations.

Probe Specifications

The Dolphin probes are used for both adult and pediatric use.

Characteristic	1.6MHz PW	2 MHz PW	2 MHz PW Monitoring	4MHz PW/CW	8MHz PW/CW	16MHz PW
Frequency (MHz)	1.6 ±5%	2 ±5%	2 ±5%	4 ±5%	8 ±5%	16 ±5%
Focal Area (mm)	49 ±5	49 ±5	49 ±5	26 ±4	11 ±3	Non-focused
Crystal Diameter (mm)	16	16	16	8	5	0.8
Outside Diameter (mm)	21 ±0.3	21 ±0.3	20 ±0.3	11.3 ±0.2	8.6 ±0.2	1.3
Length of probe housing (mm)	60 ±2	60 ±2	29 ±2	97 ±0.5	86.5 ±0.5	2.5 m cable

Maximal Transducer Temperatures. Maximal temperature rise at the tip of the transducers, while the transducers transmit Doppler ultrasound at maximal power for at least 30 minutes. Still Air is while the transducer tip is in open air, and Simulated Use is while the transducer tip is attached to the skin.

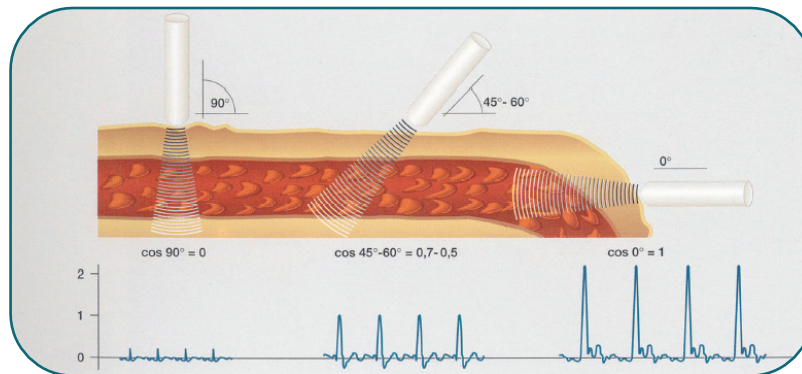
Probe Frequency	Still Air Temperature (°C)	Simulated Use Temperature (°C)
1.6 MHz	33.2 (TR=8.0)	36.5 (TR=2.4)
2 MHz	33.3 (TR=8.1)	36.8 (TR=2.3)
2 MHz Monitoring	33.0 (TR=7.7)	36.6 (TR=1.9)
4 MHz	30.0 (TR=5.0)	35.9 (TR=1.5)
8 MHz	30.3 (TR=5.0)	36.3 (TR=1.5)
16 MHz	26.3 (TR=1.1)	34.7 (TR=0.5)
Probe Frequency	Still Air Temperature (°C)	Simulated Use Temperature (°C)

TR: Temperature rises above initial ambient state (°C).

List of Dolphin Accessories / Part Numbers

	Part No.	Description
Dolphin Systems	PVC0227	Dolphin/MAX Transcranial Doppler System
	PVC0201	Dolphin/4D Transcranial Doppler System
	PVC0200	Dolphin/IQ Transcranial Doppler System
Dolphin Probes	PVC0160	2 MHz Probe
	PVC0161-G	2 MHz Monitoring Probe Green - 2m Cable
	PVC0161-Y	2 MHz Monitoring Probe Yellow - 2m Cable
	PVC0161-G-5m	2 MHz Monitoring Probe Green - 5m Cable
	PVC0161-Y-5m	2 MHz Monitoring Probe Yellow - 5m Cable
	PVC0072	4 MHz Probe
	PVC0073	8 MHz Probe
	PVC0166	1.6 MHz Probe
	PVC0313-G	Dolphin 1.6 MHz Monitoring Probe Green - 2m Cable
	PVC0313-Y	Dolphin 1.6 MHz Monitoring Probe Yellow - 2m Cable
	PVC0162	16 MHz Single Use Sterile Probes (Pack of 5)
	PVC0163	Connector for 16 MHz Single Use Probes
Dolphin Remote Controls	PVC0221	Dolphin Wired Remote Control
	PVC0190-R	Dolphin Wireless Remote Control + Receiver
	PVC0190	Dolphin Wireless Remote Control
	PVC0191	Dolphin Wireless Remote Control Receiver
	PVB0076	3 Pedal Foot Switch
Dolphin Monitoring Headset	PVC0202	Dolphin Monitoring Headset
	PVC0283-50	Pads for Dolphin Monitoring Headset (Pack of 50)
Dolphin/XF Robot Accessories	PVC0263-Y	Dolphin/XF Robot Unit Yellow
	PVC0263-G	Dolphin/XF Robot Unit Green
	PVC0308	Dolphin/XF Robot Monitoring Headset
	PVC0314	Dolphin/XF Disposable Monitoring Headset
	PVC0310	Dolphin/XF Robot Casing
	PVC0309-50	Pads for Dolphin/XF Robot Monitoring Headset (Pack of 50)
	PVC0264-8-100	Dolphin/XF Robot Disposable Gel Rubber (Pack of 100)
Additional Dolphin Accessories	PVC0249	Dolphin External Channels Connection Box
	PVB0107	Replacement Battery for Dolphin/MAX
	PVA0396	Stand for Dolphin/4D and Dolphin/MAX
	PVC0167	Probe Holder for Dolphin/4D and Dolphin/MAX Back Panel
	PVB0093	Dolphin/IQ External Power Supply

Basics of Doppler Measurements



The magnitude of the Doppler signal is directly related to the Cosine of the angle between the ultrasound beam and the blood flow direction inside the blood vessel. Therefore, in order to obtain a good Doppler waveform it is required that the angle between the beam and the vessel be as small as possible (see picture above).

Contact your service provider if during a measurement unexpected noise spikes or other forms of irregular noise signals appear in the Doppler spectrum.

In obtaining TCD waveforms, the 3 main “windows” through which insonation is possible are:

- The Transtemporal window, for access primarily to the Middle Cerebral Artery (MCA), Anterior Cerebral Artery (ACA), Posterior Cerebral Artery (PCA), the MCA/ACA bifurcation, and the terminal portion of the Internal Carotid Artery (ICA).

- The Suboccipital window, for access primarily to the Basilar (BA) and Vertebral (VA) arteries.
- The Transorbital window, for access primarily to the Ophthalmic Artery (OA) and the Carotid Siphon.

There are numerous reports in the literature regarding appropriate TCD insonation and clinical applications. Two recommended such guidelines include:

- Vascular Technology Professional Performance Guideline, Transcranial Doppler (Non-Imaging), *Society for Vascular Ultrasound*, 2003.
- Assessment: Transcranial Doppler Ultrasonography. Report of the Therapeutics and Technology Assessment, Subcommittee of the American Academy of Neurology, *M.A. Sloan, A.V. Alexandrov et al., Neurology 2004; 62: 1468-1481.*

Acoustic Information

Glossary:

MI	the Mechanical Index.
TIS_{scan}	the Soft Tissue Thermal Index in an auto-scanning mode.
$TIS_{non-scan}$	the Soft Tissue Thermal Index in a non-autoscanning mode.
TIB	the Bone Thermal Index.
TIC	the Cranial Thermal Index.
A_{aprt}	the area of the active aperture (square centimeters).
$p_{r.3}$	the derated peak rarefactional pressure associated with the transmit pattern giving rise to the value reported under MI (megapascals).
W_o	the ultrasonic power, except for TIS_{scan} , in which case it is the ultrasonic power passing through a one centimeter window (milliwatts).
$W_{.3(z1)}$	the derated ultrasonic power at axial distance $z1$ (milliwatts).
$I_{TA.3(z1)}$	the derated spatial-peak temporal-average intensity at axial distance $z1$ (milliwatts per square centimeter).
z_1	the axial distance corresponding to the location of $\max[\min(W_{.3(z)}, I_{TA.3(z)} \times 1 \text{ cm}^2)]$, where $z^3 z_{bp}$ (centimeters).
z_{bp}	$1.69 \times \text{SQRT}(A_{aprt})$ (centimeters).
z_{sp}	For MI, the axial distance at which $p_{r.3}$ is measured. For TIB, the axial distance at which TIB is a global maximum (i.e., $z_{sp} = z_{B.3}$) (centimeters).
$d_{eq}(z)$	the equivalent beam diameter as a function of axial distance z , and is equal to $[(4/p)(W_o/I_{TA}(z))]^{0.5}$ where $I_{TA}(z)$ is the temporal-average intensity as a function of z (centimeters).
f_c	the center frequency (MHz). For MI, f_c is the center frequency associated with the transmit pattern giving rise to the global maximum reported value of MI. For TI, for combined modes involving transmit patterns of unequal center frequency, f_c is defined as the overall range of center frequencies of the respective transmit patterns.
Dim. of A_{aprt}	the active aperture dimensions for the azimuthal (x) and elevational (y) planes (centimeters).
PD	the pulse duration (microseconds) associated with the transmit pattern giving rise to the reported value of MI.
PRF	the pulse repetition frequency associated with the transmit pattern giving rise to the reported value of MI (Hz).
$p_r@PII_{max}$	the peak rarefactional pressure at the point where the free-field, spatial-peak pulse intensity integral is a maximum (megapascals).
$d_{eq}@PII_{max}$	the equivalent beam diameter at the point where the free-field, spatial-peak pulse intensity integral is a maximum (centimeters).
FL	the focal length, or azimuthal (x) and elevational (y) lengths, if different (centimeters).
$I_{PA.3}@MI_{max}$	the derated pulse-average intensity at the point of global maximum reported MI (Watts per square centimeter).

Operating Conditions for all measurements: Maximal insonation power.

Acoustic measurement uncertainties:

Power:	$\pm 28\%$
Pressure:	$\pm 14\%$
Intensities:	$\pm 28.07\%$
MI:	$\pm 15\%$
Center Frequency:	$\pm 1.25 \%$

2 MHz - Acoustic output reporting table according to FDA Track 3 requirements:

Transducer: 2 MHz, PVC0160
 Operation Mode: Pulse Wave Doppler
 Applications: Transcranial Doppler

Index label			MI	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					A < 1 cm ²	A > 1 cm ²		
Global Maximum index value			0.42	N/A	N/A	N/A	2.01	
Associated acoustic parameters	Pr.3 [MPa]		0.59					
	W ₀ [mW]			N/A	N/A		128.8	
	Min[W.3(Z ₁),I _{TA.3} (Z ₁)]					N/A		
	Z ₁ [cm]					N/A		
	Z _{bp} [cm]					N/A		
	Z _{sp} [cm]		4.77				N/A	
	d _{eq} (Z _{sp}) [cm]						N/A	
	F _c [MHz]		2.00	N/A	N/A	N/A	N/A	2.00
	Dim of A _{aprt}	X [cm]		N/A	N/A	N/A	N/A	1.60
Y [cm]			N/A	N/A	N/A	N/A	1.60	
Other information	PD [μSec]		12.59					
	PRF [Hz]		6000					
	Pr @P _{II} _{max} [MPa]		0.82					
	d _{eq} @P _{II} _{max} [cm]						N/A	
	Focal Length	FLx [cm]		N/A	N/A	N/A		N/A
		Fly [cm]		N/A	N/A	N/A		N/A
I _{PA.3} @M _I _{max} [W/cm ²]		7.62						
Operating control conditions								

2 MHz - Acoustic output reporting table according to FDA Track 3 requirements:

Transducer: 2 MHz, PVC0160
 Operation Mode: Pulse Wave Ophthalmic Mode Doppler
 Applications: Transcranial Doppler

Index label			MI	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					A < 1 cm ²	A > 1 cm ²		
Global Maximum index value			0.20	N/A	N/A	N/A	0.11	
Associated acoustic parameters	Pr.3 [MPa]		0.29					
	W ₀ [mW]			N/A	N/A		N/A	
	Min[W.3(Z ₁),I _{TA.3} (Z ₁)]					N/A		
	Z ₁ [cm]					N/A		
	Z _{bp} [cm]					N/A		
	Z _{sp} [cm]		4.77				N/A	
	d _{eq} (Z _{sp}) [cm]						N/A	
	F _c [MHz]		2.00	N/A	N/A	N/A	N/A	
	Dim of A _{aprt}	X [cm]		N/A	N/A	N/A	N/A	1.60
		Y [cm]		N/A	N/A	N/A	N/A	1.60
Other information	PD [μSec]		12.59					
	PRF [Hz]		6000					
	Pr @P _{II} _{max} [MPa]		0.40					
	d _{eq} @P _{II} _{max} [cm]						N/A	
	Focal Length	FLx [cm]		N/A	N/A	N/A		N/A
		Fly [cm]		N/A	N/A	N/A		N/A
	I _{PA.3} @M _I _{max} [W/cm ²]		0.66					
Operating control conditions								

1.6 MHz - Acoustic output reporting table according to FDA Track 3 requirements:

Transducer: 1.6 MHz, PVC0166
 Operation Mode: Pulse Wave Doppler
 Applications: Transcranial Doppler

Index label			MI	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					A < 1 cm ²	A > 1 cm ²		
Global Maximum index value			0.56	N/A	N/A	N/A	2.05	
Associated acoustic parameters	Pr.3 [MPa]		0.71					
	W ₀ [mW]			N/A	N/A	N/A	131.2	
	Min[W.3(Z ₁),I _{TA.3} (Z ₁)]				N/A			
	Z ₁ [cm]				N/A			
	Z _{bp} [cm]				N/A			
	Z _{sp} [cm]		3.87			N/A		
	d _{eq} (Z _{sp}) [cm]					N/A		
	F _c [MHz]		1.60	N/A	N/A	N/A	1.60	
	Dim of A _{aprt}	X [cm]		N/A	N/A	N/A	N/A	1.60
Y [cm]			N/A	N/A	N/A	N/A	1.60	
Other information	PD [μSec]		12.64					
	PRF [Hz]		6000					
	Pr @P _{II} _{max} [MPa]		0.88					
	d _{eq} @P _{II} _{max} [cm]					N/A		
	Focal Length	FLx [cm]		N/A	N/A	N/A		N/A
		Fly [cm]		N/A	N/A	N/A		N/A
I _{PA.3} @M _I _{max} [W/cm ²]		7.59						
Operating control conditions								

4 MHz - Acoustic output reporting table according to FDA Track 3 requirements:

Transducer: 4 MHz, PVC0072
 Operation Mode: Pulse Wave Doppler
 Applications: Peripheral Vascular Doppler

Index label			MI	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					A < 1 cm ²	A > 1 cm ²		
Global Maximum index value			0.47	N/A	1.43	N/A	N/A	
Associated acoustic parameters	Pr.3 [MPa]		0.94					
	W ₀ [mW]			N/A	75.2		N/A	
	Min[W.3(Z ₁),I _{TA.3} (Z ₁)]					N/A		
	Z ₁ [cm]					N/A		
	Z _{bp} [cm]					N/A		
	Z _{sp} [cm]		1.64				N/A	
	d _{eq} (Z _{sp}) [cm]						N/A	
	F _c [MHz]		4.00	N/A	4.00	N/A	N/A	
	Dim of A _{aprt}	X [cm]		N/A	0.80	N/A	N/A	N/A
		Y [cm]		N/A	0.80	N/A	N/A	N/A
Other information	PD [μSec]		3.24					
	PRF [Hz]		24000					
	Pr @P _{II} _{max} [MPa]		1.18					
	d _{eq} @P _{II} _{max} [cm]					N/A		
	Focal Length	FLx [cm]		N/A	N/A	N/A		N/A
		Fly [cm]		N/A	N/A	N/A		N/A
	I _{PA.3} @M _I _{max} [W/cm ²]		7.41					
Operating control conditions								

4 MHz - Acoustic output reporting table according to FDA Track 3 requirements:

Transducer: 4 MHz, PVC0072
 Operation Mode: Pulse Wave Ophthalmic Mode Doppler
 Applications: Peripheral Vascular Doppler

Index label			MI	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					A < 1 cm ²	A > 1 cm ²		
Global Maximum index value			0.22	N/A	0.12	N/A	N/A	N/A
Associated acoustic parameters	Pr.3 [MPa]		0.45					
	W0 [mW]			N/A	6.53		N/A	N/A
	Min[W.3(Z1),lTA.3(Z1)]					N/A		
	Z1 [cm]					N/A		
	Zbp [cm]					N/A		
	Zsp [cm]		1.64				N/A	
	deq(Zsp) [cm]						N/A	
	Fc [MHz]		4.00	N/A	4.00	N/A	N/A	N/A
	Dim of Aaprt	X [cm]		N/A	0.80	N/A	N/A	N/A
Y [cm]			N/A	0.80	N/A	N/A	N/A	
Other information	PD [μSec]		3.24					
	PRF [Hz]		24000					
	Pr @PII _{max} [MPa]		0.57					
	deq @PII _{max} [cm]						N/A	
	Focal Length	FLx [cm]		N/A	N/A	N/A		N/A
		Fly [cm]		N/A	N/A	N/A		N/A
	lPA.3 @MI _{max} [W/cm ²]		0.64					
Operating control conditions								

4 MHz - Acoustic output reporting table according to FDA Track 3 requirements:

Transducer: 4 MHz, PVC0072
 Operation Mode: Continuous Wave Doppler
 Applications: Peripheral Vascular Doppler

Index label			MI	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					A < 1 cm ²	A > 1 cm ²		
Global Maximum index value			0.08	N/A	1.43	N/A	N/A	
Associated acoustic parameters	Pr.3 [MPa]		0.16					
	W ₀ [mW]			N/A	75.2		N/A	
	Min[W.3(Z ₁),I _{TA.3} (Z ₁)]					N/A		
	Z ₁ [cm]					N/A		
	Z _{bp} [cm]					N/A		
	Z _{sp} [cm]		1.64				N/A	
	d _{eq} (Z _{sp}) [cm]						N/A	
	F _c [MHz]		4.00	N/A	4.00	N/A	N/A	
	Dim of A _{aprt}	X [cm]		N/A	0.80	N/A	N/A	N/A
		Y [cm]		N/A	0.80	N/A	N/A	N/A
Other information	PD [μSec]		NA					
	PRF [Hz]		NA					
	Pr @P _{II} _{max} [MPa]		0.20					
	d _{eq} @P _{II} _{max} [cm]					N/A		
	Focal Length	FLx [cm]		N/A	N/A	N/A		N/A
		Fly [cm]		N/A	N/A	N/A		N/A
	I _{PA.3} @M _I _{max} [W/cm ²]		7.41					
Operating control conditions								

8 MHz - Acoustic output reporting table according to FDA Track 3 requirements:

Transducer: 8 MHz, PVC0073
 Operation Mode: Pulse Wave Doppler
 Applications: Peripheral Vascular Doppler

Index label			MI	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					A < 1 cm ²	A > 1 cm ²		
Global Maximum index value			0.33	N/A	1.32	N/A	N/A	N/A
Associated acoustic parameters	Pr.3 [MPa]		0.93					
	W ₀ [mW]			N/A	34.6		N/A	N/A
	Min[W.3(Z ₁),I _{TA.3} (Z ₁)]					N/A		
	Z ₁ [cm]					N/A		
	Z _{bp} [cm]					N/A		
	Z _{sp} [cm]		0.75				N/A	
	d _{eq} (Z _{sp}) [cm]						N/A	
	F _c [MHz]		8.00	N/A	8.00	N/A	N/A	N/A
	Dim of A _{aprt}	X [cm]		N/A	0.50	N/A	N/A	N/A
		Y [cm]		N/A	0.50	N/A	N/A	N/A
Other information	PD [μSec]		1.78					
	PRF [Hz]		16000					
	Pr @P _{II} _{max} [MPa]		1.14					
	d _{eq} @P _{II} _{max} [cm]						N/A	
	Focal Length	FLx [cm]		N/A	N/A	N/A		N/A
		Fly [cm]		N/A	N/A	N/A		N/A
	I _{PA.3} @M _I _{max} [W/cm ²]		20.2					
Operating control conditions								

8 MHz - Acoustic output reporting table according to FDA Track 3 requirements:

Transducer: 8 MHz, PVC0073
 Operation Mode: Pulse Wave Ophthalmic Mode Doppler
 Applications: Peripheral Vascular Doppler

Index label			MI	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					A < 1 cm ²	A > 1 cm ²		
Global Maximum index value			0.16	N/A	0.11	N/A	N/A	
Associated acoustic parameters	P _{r.3} [MPa]		0.45					
	W ₀ [mW]			N/A	3.01		N/A	
	Min[W. _{.3} (Z ₁),I _{TA.3} (Z ₁)]					N/A		
	Z ₁ [cm]					N/A		
	Z _{bp} [cm]					N/A		
	Z _{sp} [cm]		0.75				N/A	
	d _{eq} (Z _{sp}) [cm]						N/A	
	F _c [MHz]		8.00	N/A	8.00	N/A	N/A	N/A
	Dim of A _{aprt}	X [cm]		N/A	0.50	N/A	N/A	N/A
Y [cm]			N/A	0.50	N/A	N/A	N/A	
Other information	PD [μSec]		1.78					
	PRF [Hz]		16000					
	Pr @P _{II} _{max} [MPa]		0.56					
	d _{eq} @P _{II} _{max} [cm]					N/A		
	Focal Length	FLx [cm]		N/A	N/A	N/A		N/A
		Fly [cm]		N/A	N/A	N/A		N/A
	I _{PA.3} @M _I _{max} [W/cm ²]		1.75					
Operating control conditions								

8 MHz - Acoustic output reporting table according to FDA Track 3 requirements:

Transducer: 8 MHz, PVC0073
 Operation Mode: Continuous Wave Doppler
 Applications: Peripheral Vascular Doppler

Index label			MI	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					A < 1 cm ²	A > 1 cm ²		
Global Maximum index value			0.06	N/A	1.32	N/A	N/A	
Associated acoustic parameters	Pr.3 [MPa]		0.16					
	W ₀ [mW]			N/A	34.6		N/A	
	Min[W.3(Z ₁),I _{TA.3} (Z ₁)]					N/A		
	Z ₁ [cm]					N/A		
	Z _{bp} [cm]					N/A		
	Z _{sp} [cm]		0.75				N/A	
	d _{eq} (Z _{sp}) [cm]						N/A	
	F _c [MHz]		8.00	N/A	8.00	N/A	N/A	
	Dim of A _{aprt}	X [cm]		N/A	0.50	N/A	N/A	N/A
		Y [cm]		N/A	0.50	N/A	N/A	N/A
Other information	PD [μSec]		NA					
	PRF [Hz]		NA					
	Pr @P _{II} _{max} [MPa]		0.19					
	d _{eq} @P _{II} _{max} [cm]						N/A	
	Focal Length	FLx [cm]		N/A	N/A	N/A		N/A
		Fly [cm]		N/A	N/A	N/A		N/A
	I _{PA.3} @M _I _{max} [W/cm ²]		20.2					
Operating control conditions								

16 MHz - Acoustic output reporting table according to FDA Track 3 requirements (not available in USA):

Transducer: 16 MHz, PVC0162
 Operation Mode: Pulse Wave Intraoperative Mode Doppler
 Applications: Intraoperative Doppler

Index label			MI	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					A < 1 cm ²	A > 1 cm ²		
Global Maximum index value			0.05	N/A	0.018	N/A	N/A	N/A
Associated acoustic parameters	Pr.3 [MPa]		0.20					
	W ₀ [mW]			N/A	0.24		N/A	N/A
	Min[W.3(Z ₁),I _{TA.3} (Z ₁)]					N/A		
	Z ₁ [cm]					N/A		
	Z _{bp} [cm]					N/A		
	Z _{sp} [cm]		0.059				N/A	
	d _{eq} (Z _{sp}) [cm]						N/A	
	F _c [MHz]		16.00	N/A	16.00	N/A	N/A	N/A
	Dim of A _{aprt}	X [cm]		N/A	0.13	N/A	N/A	N/A
Y [cm]			N/A	0.13	N/A	N/A	N/A	
Other information	PD [μSec]		1.24					
	PRF [Hz]		16000					
	Pr @P _{II} _{max} [MPa]		0.21					
	d _{eq} @P _{II} _{max} [cm]						N/A	
	Focal Length	FLx [cm]		N/A	N/A	N/A		N/A
		Fly [cm]		N/A	N/A	N/A		N/A
I _{PA.3} @M _I _{max} [W/cm ²]		3.78						
Operating control conditions								

EMC Information

The Dolphin complies with Class B EMC requirements. The Dolphin uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

When using the Doppler functions of the Dolphin in the vicinity of other electronic devices, interference signals might be heard and observed on the Doppler screen. This interference is common to all Doppler devices, and will be obvious to the user. It is the responsibility of the user to discriminate between normal and noisy signals, and ignore or delete the erroneous signals.

Do not allow the use of cellular telephones in the vicinity of the Dolphin.

If interference persists, try to identify the source of interference and remove it. Alternately, try relocating the Dolphin to a different location. If the problem persists, contact your local service representative.

Electrical fast transient bursts on the power input and output may interrupt the program. If the program does not start automatically again, try to turn the system power off and on again, and then continue with the measurement process.

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 Dolphin/IQ, Dolphin/4D and Dolphin/MAX systems, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The use of accessories or replacement parts, other than those sold/specified by the manufacturer may result in increased emissions or decreased immunity of the Dolphin.



Use of the Dolphin adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.



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.



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 Dolphin, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

List of cables, transducers and accessories of Dolphin/IQ: 2 MHz handheld probe, 2 MHz monitoring probe, 1.6 MHz probe, 4 MHz probe, 8 MHz probe, 16 MHz single use probe (not available in USA), USB IR receiver and remote control, wired remote control, USB footswitch, USB cable, External medical power supply, monitoring head set, XF robot, external channel box.


List of cables, transducers and accessories of Dolphin/4D: 2 MHz handheld probe, 2 MHz monitoring probe, 1.6 MHz probe, 4 MHz probe, 8 MHz probe, 16 MHz single use probe (not available in USA), USB IR receiver and remote control, wired remote control, USB footswitch, mains power cable, monitoring head set, XF robot, external channel box.

List of cables, transducers and accessories of Dolphin/MAX: 2 MHz handheld probe, 2 MHz monitoring probe, 1.6 MHz probe, 4 MHz probe, 8 MHz probe, 16 MHz single use probe (not available in USA), USB IR receiver and remote control, wired remote control, USB footswitch, External medical power supply, monitoring head set, XF robot, external channel box, internal rechargeable battery.

Guidance and manufacturer's declaration – electromagnetic Emissions

Declaration – electromagnetic emissions		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group1 Class B	The Dolphin 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.
Harmonic emissions IEC 61000-3-2	Class B	The Dolphin 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.
Voltage Fluctuations And Flicker IEC 61000-3-3:2013	Complies	

Declaration – electromagnetic immunity			
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	8 kV contact 2, 4, 8, 15kV air	8 kV contact 2, 4, 8, 15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	2 kV for power supply lines 1 kV for input/output lines	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	1 kV line(s) to line(s) 2 kV line(s) to earth 2 kV Signal input/output) to earth	1 kV line(s) to line(s) 2 kV line(s) to earth 2 kV Signal input/output) to earth	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	0% UT; 0.5cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle	0% UT; 0.5cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Dolphin requires continued operation during power mains interruptions, it is recommended that the Dolphin be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 (A/m)	30 (A/m)	Power frequency 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.			

Declaration – electromagnetic immunity			
IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3V, 6V	3V, 6V	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Dolphin, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{12}{V_2} \right] \sqrt{P}$ $d = \left[\frac{12}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{23}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.</p> <p>D Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
Radiated RF IEC 61000-4-3	10V/m	10V/m	
	10V/m from 0.15 to 80MHz; 10V/m from 0.15 to 80MHz and 80% AM at 1kHz	10V/m from 0.15 to 80MHz; 10V/m from 0.15 to 80MHz and 80% AM at 1kHz	
	10V/m from 80MHz to 2.7GHz	10V/m from 80MHz to 2.7GHz	

Recommended separation distances between portable and mobile RF communications equipment and the Dolphin				
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m			
	150 kHz to 80 MHz outside ISM bands $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = \left[\frac{12}{V_2} \right] \sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{12}{E_1} \right] \sqrt{P}$	800 MHz to 2,5 GHz $d = \left[\frac{23}{E_1} \right] \sqrt{P}$
0.01	0.12	0.2	0.4	1
0.1	0.37	0.64	1.3	2.6
1	1.17	2	4	8
10	3.7	6.4	13	26
100	11.7	20	40	80

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment							
Test frequency (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation ^{b)}	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)	Compliance level (V/m)
385	380 –390	TETRA 400	Pulse modulation ^{b)} 18 Hz	1.8	0.3	27	27
450	430 – 470	GMRS 460, FRS 460	FM ^{c)} ± 5 kHz deviation 1 kHz sine	2	0.3	28	28
710	704 – 787	LTE Band 13, 17	Pulse modulation ^{b)} 217 Hz	0.2	0.3	9	9
745							
780							
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation ^{b)} 18 Hz	2	0.3	28	28
870							
930							
1720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation ^{b)} 217 Hz	2	0.3	28	28
1845							
1970							
2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ^{b)} 217 Hz	2	0.3	28	28
5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation ^{b)} 217 Hz	0.2	0.3	9	9
5500							
5785							
NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.							
^{a)} For some services, only the uplink frequencies are included.							
^{b)} The carrier shall be modulated using a 50 % duty cycle square wave signal.							
^{c)} As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.							

Cybersecurity Guidelines

- !** Read the Cybersecurity guidelines section in this user manual and follow the instructions carefully. Failure to do so may expose the system to Cybersecurity attacks and potentially cause loss of availability, integrity and confidentiality.

The following guidelines are important to assure Dolphin system functionality and safety with regards to Cybersecurity threats:

- Local institution IT must be consulted regarding Cybersecurity requirements for Dolphin system.
- Unapproved additional 3rd party applications must not be installed. However, it is allowed to use a corporate version antivirus or firewall according to “**Windows Updates, Antiviruses and Firewalls**” in VS0617 Dolphin Installation and Service Manual.
- On routine use, the system must not be connected to the Internet.
- Cybersecurity controls provided by Microsoft Windows such as Windows Firewall, Windows Defender, User Account Control, etc. must **not** be turned off.
- When accessing the system using a USB storage device (for example, to update software), make sure the USB device was scanned with an updated antivirus prior to plugging it into the system.
- Windows Updates on Dolphin computer must follow “**Windows Updates, Antiviruses and Firewalls**” in VS0617 Dolphin Installation and Service Manual.
- If Dolphin system needs to be connected to internal network for routine use, it must be connected to a controlled network supervised by local institution IT.
- Wired network is preferable over wireless network connection. Wireless network connection should only be used if there is no wired alternative and in that case, it must be properly secured according to local institution IT protocols.
- If Domain network connection is required, the Domain connection must be secured according to local institution protocols.
- If domain network is not applicable, it is advised to manually password protect the active user accounts on the Dolphin computer. Strong passwords are preferable. Passwords must not be publicly exposed.
- It is advised to password protect the BIOS component of the PC and configure the BIOS to prevent a USB boot. The password must remain confidential.
- It is advised to work in a restricted user account on routine use.
- Providers and institute IT are advised to have each end user aware of the following:
 - a. Avoid leaving the computer unattended without logging off first.
 - b. Avoid using an administrator account.
 - c. The importance of using a relatively strong login password.
 - d. Avoid publicly exposing their login password
 - e. The importance of periodically changing their login password.
 - f. Avoid installing third party software.
 - g. Avoid changing critical system settings.
- Avoid connecting the Dolphin computer to an unsecured wireless network.








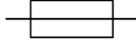












Serious Incident Reporting

To report any incident, contact your local distributor or service representative.

Make sure to provide the following information: Complete serial number of the system that appears on the product label on the back panel; Date of incident; Detailed description of the incident, including information if any on patient or user impact or injury. Add pictures if available; Your contact information, including name and address of facility, contact name, title, and telephone number / email address.

Labels and Symbols

The following labels are used with the Dolphin systems:

	Refer to instruction manual / booklet		Type CF applied part
	Consult instructions for use		Manufacturer
	Type BF applied part		Date of manufacture
	Warning		Fuse
	Caution		Recycling Symbol (For Dolphin/MAX)
	Dispose of this product according to local regulations.		MR unsafe. MRI not compatible.
	Do not re-use. Disposable.		Restricted device. Prescription Required.
	Serial Number		Part Number
	Unique Device Identification		Authorized representative in the European Community
	Medical Device		CE mark including notified body number.