

Welch Allyn® Spot™ Vision Screener Model VS100



Directions For Use

Software version 3.1.XX

WelchAllyn®

Advancing Frontline Care™

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For information about any Welch Allyn product, contact Welch Allyn Technical Support: www.welchallyn.com/about/company/locations.htm.

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Introduction

About this document

This Directions for use manual is a comprehensive guide designed to help you understand the capabilities and operation of your Spot Vision Screener VS100. The information in this manual includes all options available with the Spot Vision Screener. The applicability of some sections of this manual depends on the configuration of your particular device. Read this manual thoroughly before attempting to use the device.

The vision screener is a hand-held instrument with a video display on the rear of the unit that provides subject visualization and alignment. Video display also provides user interface functionality for data input and display. The vision screener provides visual and audible cues to attract subject's attention and gaze. The device provides a fast data collect for easy evaluation of the most difficult pediatric subjects of limited compliance. Each screening provides simultaneous binocular assessment of the subject's refraction, pupil size and gaze.

Intended use

The Spot Vision Screener is intended to produce optical images that can help identify refractive errors and ocular misalignments by detecting special light reflexes from each eye during screening. The Spot Vision Screener evaluates these light reflexes from the retina to estimate refractive error. It also estimates pupil size, pupil distance and eye gaze deviation. It is intended for use on subjects six months of age through adults.

Indications for use

The Spot Vision Screener is indicated for use by healthcare professionals or under the direction of a healthcare professional to screen or evaluate individuals for potential refractive errors associated with poor vision. This type of photoretinoscopy device is intended to help the healthcare professional assess whether the subject should be referred to an eye care specialist for further evaluation or simply be monitored at future screenings. This screening is not intended to replace a full eye examination.

Contraindications

The Spot Vision Screener has no known contraindications.

Symbols

For information on the origin of these symbols, visit <http://www.welchallyn.com/symbolsglossary> for the Welch Allyn symbols glossary.

Documentation symbols



Consult directions for use (DFU). A copy of the DFU is available on this website. A printed copy of the DFU can be ordered from Welch Allyn for delivery within 7 calendar days.



WARNING The warning statements in this manual identify conditions or practices that could lead to illness, injury, or death.



Caution The caution statements in this manual identify conditions or practices that could result in damage to the equipment or other property, or loss of data. This definition applies to both yellow and black and white symbols.

Power symbols



Rated power input, DC



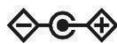
Rechargeable battery



Power on/off



USB



DC power input port, Center pin positive

Miscellaneous symbols

IPX0

Not protected against the ingress of water.



Non-ionizing electromagnetic radiation



Manufacturer



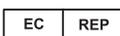
Reorder Number



Product Identifier



Serial Number



Authorized Representative in the European Community



Global Trade Item Number

User Interface Symbols

	Battery status/level indicator		Battery charging
	Wireless On/Off button		Connected to the wireless network
	No wireless network in range		No IP address assigned by the router
	Unknown network		Cannot connect to configured network
	Sound off		Sound on
	Continue		Back
	Exit		Print job in progress

Shipping, storing, and environment symbols

	This way up		Keep Dry
	Fragile		Humidity limitation
	Temperature limit		Atmospheric pressure limitation



Separate collection of batteries. Do not dispose as unsorted municipal waste.



Recyclable



Separate collection of Electrical and Electronic Equipment. Do not dispose as unsorted municipal waste.



Keep away from sunlight

Li-ion

Lithium ion battery

Warnings and cautions



WARNING The warning statements in this manual identify conditions or practices that could lead to loss of data, illness, injury, or death.



CAUTION The caution statements in this manual identify conditions or practices that could result in damage to the equipment or other property.



WARNING The Directions for Use (DFU) contains important instructions for successful and safe use, maintenance, cleaning, transport, storage, and operation of the device as well as a troubleshooting guide with additional support. Read instructions thoroughly and store the DFU for future reference. Contact Welch Allyn if any instructions are not understood.

Patient Safety



WARNING Photosensitivity risk. While this device is considered low risk according to IEEE 1789, Practices for Modulating Current in High-Brightness LEDs for Mitigating Health Risks to Viewers, this device uses flickering lights to attract patient attention. A very small percentage of individuals may experience epileptic seizures when exposed to certain light patterns or flashing lights. Apply clinical judgment when using this device.



WARNING Exposure to sound. This device uses sound cues to attract patient attention. If the sound creates discomfort for the patient, please mute the device in the settings.

Data and Performance



WARNING Risk of data loss. If a reboot is required during a system freeze, data loss, such as printer configuration and subject data, can occur.



WARNING Use only accessories approved by Welch Allyn. Visit www.welchallyn.com. The use of any other accessories can result in inaccurate subject data, can damage the equipment, and can void your product warranty.



WARNING Subject injury risk. Verify subject identity on the device after manual entry and before printing or transferring subject records.



WARNING False positive and false negative results may occur in a healthcare screening. Vision screening does not replace a complete eye examination by an ophthalmologist or optometrist.



WARNING The use of screening results for recommending therapy is reserved exclusively for eye care professionals.



WARNING The screening results of this autorefractor are not to be used directly for the prescription of corrective eyewear.



WARNING If the pupils are too small, the vision screener notifies you on screen. You may want to adjust the lighting in the room.



CAUTION HIPAA and GDPR requires healthcare providers to protect patient data from unauthorized viewing and use. Use of lock screen and other data security protections available on this device are recommended.



WARNING The VS100 transmits patient data as read-only PDFs. Nevertheless, the possibility of security breaches cannot be completely excluded. Verify that patient data matches the correct record and that it has not been altered prior to making treatment decisions.



CAUTION Product security exploits can cause the device or device data to become unavailable or cause data security breaches. Avoid inserting uncontrolled or unsecured USB drives into the USB port or connecting to a wireless network with incomplete security.



WARNING Patient Risk - selecting "hide recommendation" causes the device to not show Pass/Refer messages during screening.



WARNING Patient Risk - When performing repeated measurements, use the first reading (and referral) for most accurate results.



WARNING Device System Date is used in Pass/Refer determination. Insure that the System Time is correct to prevent incorrect referrals



WARNING Risk of false positive and false negative results. Modification of referral criteria should be performed only by a vision specialist.

Electrical and Fire



WARNING Risk of electric shock. All signal input and output (SIP/SOP) connectors are intended for connection of only other medical devices, medical systems or non-medical devices complying with IEC 60601-1, or other IEC standards appropriate to the device. For example, a printer connected via USB must comply with IEC 60950. Connecting additional unapproved devices to the device might increase chassis or subject leakage currents.



WARNING Risk of electric shock. No modification of this equipment is allowed. Do not open the device or attempt repairs. The device has no user-serviceable internal parts. Only perform routine cleaning and maintenance procedures specifically described in this manual. Inspection and servicing of internal parts shall only be performed by qualified service personnel. Attempt to modify this device may result in bodily harm and will voids product warranty.



WARNING Risk of electric shock. Do not allow the subject to make contact with accessible conductive parts (DC adaptor output connector, power input connector and USB port). Additionally, you should not make contact with the subject and any accessible conductive parts at the same time.



WARNING To avoid a possible explosion, do not use the device in the presence of flammable anesthetics: mixtures containing air, oxygen, or nitrous oxide.



WARNING Lithium ion battery. Risk of fire, explosion, and burns. Do not handle or disassemble the battery pack.



WARNING Injury risk and equipment damage risk. When charging the device, properly secure all DC transformer cords to minimize trip hazards.



WARNING The power cord set may not be used with any other equipment other than the Welch Allyn Spot Vision Screener VS100.



WARNING Electric shock hazard. Before cleaning the vision screener, disconnect the DC power cord from the power outlet and the vision screener.



WARNING Changes or modifications not expressly approved by Welch Allyn could void the user's authority to operate the equipment.



WARNING Risk of shock, burn or fire. If device is dropped, subjected to impact, or other damage resulting in exposed internal parts or excessive heating - unplug the device, turn off, and do not use device. Return to Welch Allyn for service.

Storage and Handling



CAUTION The device contains high-quality, fragile parts. Do not subject it to physical shock.



CAUTION Do not use the wrist strap as a means to carry the device; it is not designed to carry the weight of the device.



CAUTION The device is not waterproof. If you accidentally drop it into liquid or liquid is spilled on the device, contact Welch Allyn Technical Support immediately. If minor water droplets are found on the device, wipe off with a soft dry cloth.



CAUTION Do not store the device in the foam or case while the DC power adapter is plugged in; this may cause damage to the power cord and to the device.



CAUTION Do not leave the device in excessive heat or in direct sunlight. High temperatures can cause the device to malfunction.



CAUTION When plugging the DC power connector into the device, do not force the power connector into the device. Using force can damage the device and voids the warranty. The power connector on the power supply easily inserts into the vision screener.



CAUTION Do not push or scratch the touchscreen display with stiff or rigid objects. This may cause damage to the device. A stylus is acceptable for use with the device.



WARNING Liquids can damage electronics inside the vision screener. Prevent liquids from spilling on the vision screener.



WARNING Avoid using the vision screener adjacent to or stacked with other equipment including other vision screening devices or medical electrical systems because it could result in improper operation. If such use is necessary, observe the vision screener and other equipment to verify that they are operating normally.



WARNING Injury risk and equipment damage risk. Ensure device is held securely in use, and in storage to prevent bruising or lacerations of patient or user due to device falling



CAUTION Device contains optical components. Do not use device in dirty, dusty environments, and follow cleaning instructions as needed to maintain device.

Electromagnetic Compatibility



WARNING Use only accessories Welch Allyn recommends for use with the vision screener. Accessories not recommended by Welch Allyn might affect the EMC emissions or immunity.



WARNING Maintain minimum separation distance between the vision screener and portable RF communication equipment. Performance of the vision screener might degrade if you don't maintain sufficient separation distance.



WARNING This device has not been tested for use in clinical environments near high-frequency surgical equipment and magnetic resonance imaging. Do not use this device in environments like these where electromagnetic disturbance is high.



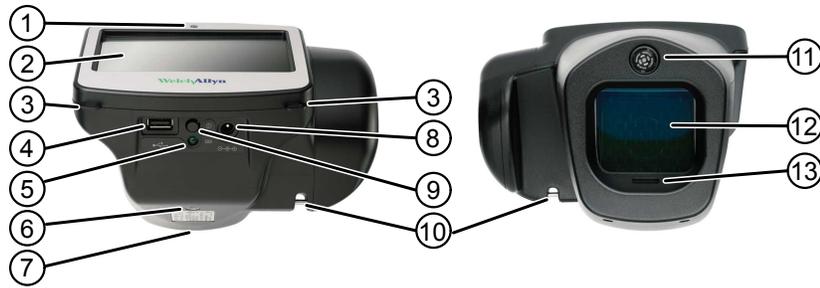
WARNING This equipment/system is intended for use under the supervision of healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the device or shielding the location.

Controls, display window, and connections

Drawings and text are representative of the Spot Vision Screener with all available options.

Features

Front and Rear Views of Vision Screener

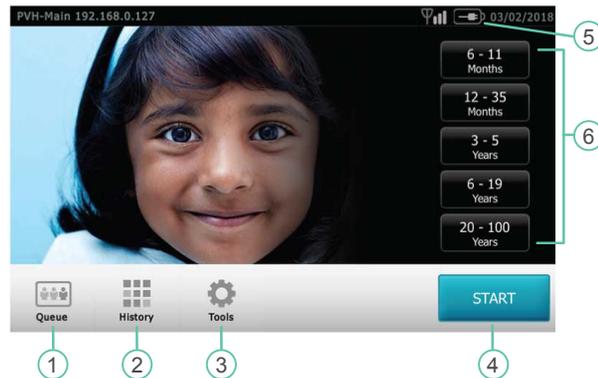


No.	Feature
1	Ambient light sensor
2	LCD screen
3	Neck strap mount
4	USB port
5	Green LED Indicator Battery charging (flashing) or charged (continuous)
6	Tripod mount
7	Serial number label
8	AC power connector
9	Power button
10	Wrist strap mount
11	Ranger finder

No.	Feature
12	Front glass
13	Speaker

Display window

When you turn on the vision screener, the Home screen appears. If the vision screener is connected to a wireless network, the network name and IP address display in the upper left corner of the device status area.



Number	Field	Description
1	Queue	Displays a list of subjects whose information has already been entered. You can search for or select a subject and begin screening. You can also sort subjects by location or clear the queue.
2	History	Displays a list of subjects who have already been screened. You can also sort subjects by location or clear the history.
3	Tools	Provides options to customize the vision screener.
4	Start	Displays the Subject Information screen, so you can enter subject information before the screening.
5	Battery Status	Indicates the status of the battery or whether the vision screener is plugged in.
6	Age Range	Starts a screening without any other subject information. You can add additional subject information after the screening.

Tools

The Tools menu allows you to customize and configure the vision screener with the following options:



About

Displays firmware version, software application version and serial number. Also displayed is a quick reference of important vision screener features, including memory storage levels of the device.



Criteria

View the age-based criteria settings used for exam recommendations that are currently active on the vision screener.



Date/Time

Allows you to set the current date and time for your vision screener.



Import / Export

Enables you to import and export using an inserted USB storage device.



Location

Allows you to set a location for a screening. By default, subjects are associated with this location.



Language

Allows you to select the language that displays on the vision screener.



License

Displays the License Update screen.



Network

Allows you to connect the vision screener to a wireless network. You can enter your network name, select the security type, and enter the password for your network. From this menu you can view and change your TCP/IP settings.



Printer

Allows you to configure a network printer and print a test page. It also lets you view printer status.



Results

Allows you to configure how information is displayed on the Subject Results screen when a screening is complete. This includes data format, cylinder convention, displaying or hiding screening results and recommendations, setting default screening display and screening time-outs.



Helps you set a security PIN for your device. If enabled, a PIN is required whenever you start the device or upon waking it.

Security



Enables the Web server and web services API

Web services

Setting up the vision screener

Contents checklist

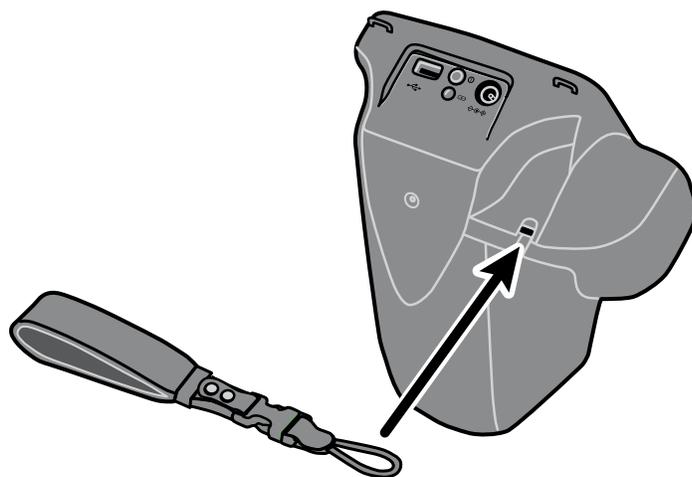
The main shipping box contains the vision screener, user documentation, and the Accessory box.

The Accessory box contains:

- AC Power Cord
- Power Supply/Charger
- Cleaning Cloth
- Cable Straps



CAUTION Do not use the wrist strap as a means to carry the device; it is not designed to carry the weight of the device.



Note

Please do not discard the box and foam. Damages incurred by shipping the device in non-approved packing material voids the limited warranty. (See Warranty for details.)

To turn on the vision screener

To turn the vision screener on, press and release the Power button. After the start-up process completes (in approximately 30 seconds) the Home screen appears.

The first time you turn on the vision screener, the device guides you through selecting the language and setting the date and time.

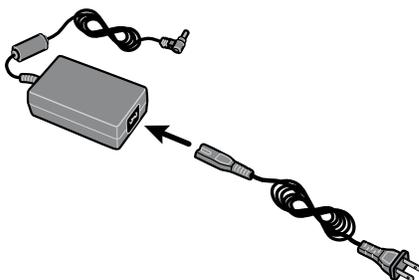
If the power indicator light is...	The vision screener is...
Flashing green	Charging
Steady green	Fully charged
Dark	Not plugged in to a power supply

After one minute without activity, the screen dims. After five minutes without activity, the screen turns black to conserve battery power. To activate the device, tap the screen or press the Power button. If the screen does not light up, plug in the power cord and try again.

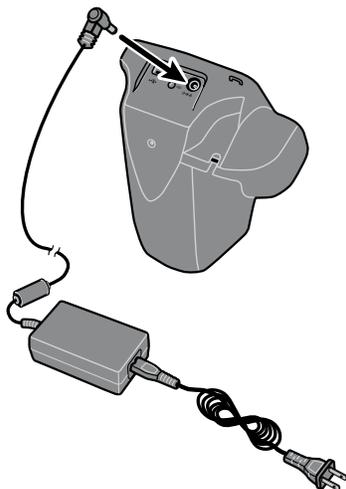
To charge the vision screener

Turn on and charge the vision screener for 4 hours before first use. When the battery reaches a very low level, the screen displays a notice to insert the power cable. If the power cable is not inserted, the device automatically shuts down.

1. Connect the power cord to the power supply.



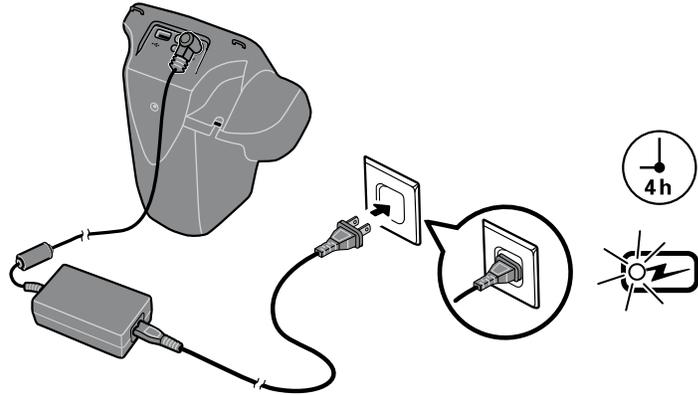
2. Locate the power connector on the vision screener and connect the power supply.





CAUTION Do not force the power connector on the power supply into the vision screener. Using force can damage the device and voids the warranty. The power connector on the power supply easily inserts into the vision screener.

3. Plug the power cord into an available wall outlet and turn on the device to charge the vision screener.



4. Press and release the Power button.

To set the language

1. From the Home screen, touch **Tools**, and then **Language**.
2. Touch the radio button next to the desired language. By default, the selected language is English.
3. To return to the Tools screen, touch the arrow in the upper-right corner.

To set the system clock

The system clock displays in the upper right-hand corner of the Home screen. If the vision screener has been in storage, you might need to reset the system clock.

1. From the Home screen, select **Tools**, and then **Date/Time**.
2. Next to Time or Date, select **Edit**.
3. Delete the current setting, and then update.
4. Touch **OK**.
5. If desired, reset the Date Format.
6. To return to the Tools screen, touch the arrow in the upper-right corner.

Screening subjects

Subject Information screen

You can use the Subject Information screen to enter or verify the subject's data. Date of Birth (or Age) is the only required field. This field displays with a red background if the date of birth (or age) is blank or invalid, or if the subject's age is under 6 months or over 100 years.

Field	Description
Subject ID	Consists of a maximum of 30 characters, letters and numbers.
First name	Consists of a maximum of 20 characters, letters only.
Last Name	Consists of a maximum of 20 characters, letters only.
Date of Birth (Required)	Enter a date of birth in the specified format (MMDDYYYY or DDMMYYYY) or enter the age and touch Months or Years .
Eyewear prescription	Allows you to select None , or Glasses , or Contacts . If this field is left blank, None is selected.
Gender	Allows you to select Male or Female . If this field is left blank, no gender is specified.
OK	Confirms any changes.
Go	Begins the screening.

To screen a subject

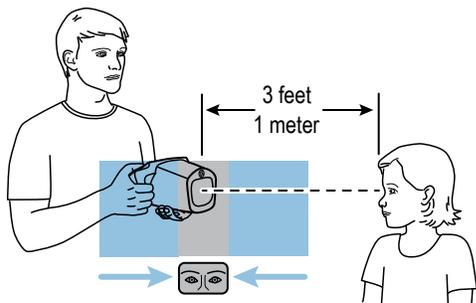
If the vision screener has a location specified, the name of the location is displayed on the top left of the screen in parentheses. If there is no location specified, and you want a location included in the screening information, on the Home screen touch **Tools**, and then touch **Location** to specify the screening location.

Completed exams are saved automatically and a PDF with the exam results is generated.

1. If possible, dim the lights.
2. Turn on the vision screener.

The Home screen appears.

3. Verify the date and time in the upper-right corner of the Home screen.
4. Stand approximately 3 feet (1 meter) from the subject with one foot ahead of the other for stability.
5. Hold the vision screener on an even plane with the subject's eyes.



6. Touch **Start** and enter the subject information. The subject's age or date of birth is required.
7. Touch **Go**.

The screening begins immediately. The vision screener emits the sound of chirping birds. This sound is intended to focus the subject's attention on the device. You can touch the Loudspeaker icon to mute the device.

8. Keep the vision screener steady until the screening wheel appears, indicating the capture process is underway.

The Subject Results screen appears at the end of the screening process.

9. If desired, touch **Edit** to add additional subject information. When finished, touch **OK** twice.
10. To exit the Subject Results screen, touch **Home**.

Results are saved automatically.

11. If you encounter difficulty:
 - If you see a blue screen, the vision screener is either too close or too far from the subject. The vision screener also displays a prompt. Move forward or backward as needed.
 - If the subject's pupils are too small, the vision screener displays a message to adjust the lighting in the room. A darker environment promotes larger pupil size.
 - If the device is taking a long time to start screening, make sure you can see the subject's eyes on the screen and that the vision screener is on a level with the subject's eyes.
 - Avoid pointing the vision screener too high, which encourages the subject to look upward.
12. If you are unable to capture the subject's pupils with a successful screening, the screening cycle stops. You can:
 - Retry the screening.
 - Flag the record.
 - Try using monocular mode.
 - Return to the Home screen

The Troubleshooting section provides additional suggestions to ensure a successful screening. If you still cannot obtain a successful screening, Welch Allyn recommends you refer the subject.

Once finished, you can export the files to a USB drive to easily scan the results on a computer. Individual screening results are saved in the pdf subfolder. A list of all the screening results is saved under the db subfolder.

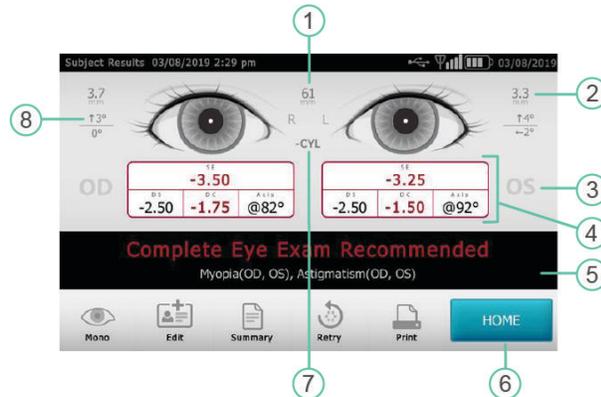
Note Do not allow the device storage to become 100% full. For best results, when the device has accumulated 300 records, delete all records from the vision screener. Verify you have successfully exported all desired records to a USB drive before you select Clear All. For more information, see About importing/exporting.

The Subject Results screen

The Subject Results screen appears at the end of the screening process.

Screening results provide an output that is either in- or out-of-range. A statement displays on the device, such as "Screening Complete" or "Complete Eye Exam Recommended." Results that are out-of-range are indicated in red.

The figure below outlines the Subject Results screen:



No.	Feature
1	Pupillary Distance
2	Pupil Size Indicator
3	Right Eye (OD), Left Eye (OS)
4	Complete refraction SE - Spherical equivalent DS - Sphere DC - Cylinder Axis - Axis
5	Screening Result
6	HOME
7	Cylinder Convention
8	Alignment Indicator Degree Horizontal Vertical

Configuring the Screen Results screen



WARNING Patient Risk - selecting "hide recommendation" causes the device to not show Pass/Refer messages during screening.

1. To select or change viewing options, touch **Tools** and then **Results**.
2. To select an option, touch the radio button next to it.
3. To return to the Tools screen, touch the **X** in the upper-left corner.

To screen in monocular mode

In monocular mode, you can choose which eye to screen. Use this mode when binocular screening does not capture the subject's pupils.

After a binocular screening completes:

1. At the end of the binocular screening process, touch **Mono**.
2. To select the subject's eye to screen, touch the corresponding side of the screen. (OD = subject's right eye; OS = subject's left eye).
3. To repeat the process with the subject's other eye, touch **Mono** from the Subject Results menu.

If a measurement is canceled or times out:

1. If a measurement times out after an unsuccessful binocular screening, touch **Mono**.
2. To select the subject's eye to screen, touch the corresponding side of the screen. (OD = subject's right eye; OS = subject's left eye).
3. To repeat the process with the subject's other eye, touch **Mono** from the Measurement Options menu.

Overview: Conducting a mass screening

If you set up a subject list ahead of time, you can screen several individuals quickly without having to stop to add additional information.

Note For best results, when the device has accumulated 300 records, delete all records from the vision screener.



CAUTION Verify you have successfully exported the records to a USB flash drive before you touch Clear All. If you touch Clear All on the Queue screen, all the unscreened subject information is deleted. If you touch Clear All on the History screen, all completed exams on the device are deleted.



WARNING Avoid using the vision screener adjacent to or stacked with other equipment, including other vision screeners, or medical electrical systems because doing so could result in improper operation. If such use is necessary, observe the vision screener and other equipment to verify that they are operating normally.

The following is an overview of the steps involved in screening multiple subjects.

1. Export the .csv files from the vision screener to a USB 2.0 drive. For more information, see Import/Export.

2. Insert the USB drive in a computer and add the subject information to the SpotSubjects.csv file. Save this file at the top level of the USB drive (not in a folder). For more information, see Create a subject list.
3. Import the files back to the vision screener. For more information, see Import.
4. On the vision screener, touch **Queue** to bring up the subject list.
5. Select the subject you want to screen. If needed, modify the subject information. For more information, see To screen a subject.
6. Touch **Go**.
7. When the screening is completed, touch **Home**.
8. Repeat steps 4-7 until you have screened all the subjects.

Once finished, you can export the files to a USB 2.0 drive to easily scan the results on a computer. Individual screening results are saved in the pdf subfolder. A list of all the screening results is saved under the db subfolder.

To delete records



CAUTION Verify you have successfully exported the records to a USB 2.0 drive before you touch Clear All. If you touch Clear All on the Queue screen, all the unscreened subject information is deleted. If you touch Clear All on the History screen, all completed exams on the device are deleted.

1. From the Home screen, touch **Queue** or **History**.
2. Touch **Clear All**.
3. Touch **Delete**.

Advanced settings on the vision screener

Before configuring network security

If the device is configured with wireless network settings, you can view screening results on a computer. If you want to print screening results, you can connect the device to a USB printer or you can add a wireless network printer.

Wireless networks use security to protect your information. Your system administrator can supply you with the security information needed to access the network. Before you can connect the device to a network, you need the network name, password, and security type. By default, the first letter you type in these fields is uppercase. To type the first letter in lowercase, touch the up arrow repeatedly until the arrow displays as a dark arrow with a white outline.

If a network security type is not selected, the connection to the wireless network is not secure and any information sent or received on this network is not necessarily confidential.



CAUTION Product security exploits can cause the device or device data to become unavailable or cause data security breaches. Avoid inserting uncontrolled or unsecured USB drives into the USB port or connecting to a wireless network with incomplete security.

Connecting a device to the network

1. Touch **Tools**, and then touch **Network**.
If the device is already configured with network settings, these display on the bottom of the screen.
2. If the settings are correct, touch the **X** in the upper-left corner to return to the Tools screen.
3. To connect a device to the network, add the network name and security type. For details, see the following sections.

To add/change the network name

1. Touch within the **Network Name** field.
The keyboard appears.
2. Enter the name of the network.
3. Touch **OK** to save your changes and return to the previous screen.

To add/change the security type

1. Use the radio button to select the security type: **WEP**, **WPA/2 PSK**, or **WPA/2 EAP-PEAP**.
2. Touch **Password**.
The keyboard appears.
3. If you selected WPA/2 EAP-PEAP, enter the username and then select **OK**.
4. Enter the password for your organization's network, and then select **OK**.
5. On the Network screen, select **OK** to save the changes.

If you see...	The vision screener is...
	Successfully connected to your wireless network. The vertical bars indicate the strength of the connection.
	Not connected to the network. For tips on connecting to the network, refer to Troubleshooting.

To enable or disable the wireless capability on the vision screener

Note If you disable the wireless capability, you must re-start the vision screener to enable it again.

1. Touch **Wireless On/Off** .
2. Touch **Enable** or **Disable**.

To configure network IP settings

1. Touch **TCP/IP**.
The network address and settings display on the screen.
2. To manually configure the network IP configuration, touch **Static**. When finished, touch **OK**.
3. Touch **OK** to save the changes and return to the previous screen.

Printing

To print screening results, you must connect the vision screener to a printer on a wireless network or connect to a printer using a USB cable. Set the printer you want to print to as the default printer. The vision screener is capable of printing to most wireless network printers. However, it is not guaranteed that every printer works with the vision screener.

The Available Printers screen displays all the printers that have been added to the vision screener. For most printers, all you need to do to print is select the printer from the Add Printers screen, add it to the Available Printers screen, and set it as the default printer. For more information, see To add a printer.

Some printers need you to select a print driver before you can set it as the default printer. Print drivers help the printer to print your content in the correct format. If your printer does not have a print driver associated with it, you need to tell the vision screener which driver to use. The vision screener contains generic PCL drivers that can be used with older printers, as well as a custom driver for label printers. For more information, see [To select a print driver](#).

If you do not see the printer you want on the Add Printers screen, you need to add the printer manually, which requires you to add the printer's location and other details as well as selecting a print driver. For more information, see [To add a printer manually](#).

Note In order to install the QL-820NWB on the vision screener, it must have QL-820 in its name on the network and you must select the driver labeled QL-820NWB from the driver list. Use Brother DK2205 Continuous Length Paper Tape or equivalent.

To add a printer

For most printers, all you need to do is add the printer to the Available Printers screen and set it as the default printer. If a default printer has already been set, it displays first. An icon next to each printer indicates the type of connection.

1. If adding a USB printer, connect the USB cable from the printer to the vision screener's USB port. If adding a network-connected wireless printer, make sure the vision screener has been added to the wireless network.
2. Touch **Tools**, and then touch **Printer**.
The Available Printers screen displays all the printers that have been saved on the vision screener.
3. Touch **Plus**.
The Add Printers screen appears.
4. If you do not see the printer you want to add, touch **Refresh**.
The list of printers may take a moment to update.
5. Select the printer.
If you do not see the printer on the Add Printer screen, see [To add the printer manually](#).
6. Touch **Save**.
The printer is automatically set as the default printer.
7. If the Save icon does not appear, see [To add a print driver manually](#).
8. To verify that the printer is installed correctly, touch **Print test page**.
9. If the test page does not print correctly, refer to the [Troubleshooting](#) section.

To select a print driver

Most printers can be added by selecting them from the Add Printers screen and saving them. If the printer has "No Driver" listed after the name, you need to select a print driver. For best results, select a print driver that matches the series number of the printer. If the printer series is not listed, select a generic print driver that best matches the type of printer you are using.

If you do not see the printer on the Add Printer screen, see To add the printer manually.

1. If adding a USB printer, connect the USB cable from the printer to the vision screener's USB port. If adding a network-connected wireless printer, make sure the vision screener has been added to the wireless network.
2. Touch **Tools**, and then touch **Printer**.
The Printers Available screen displays all the printers that have been saved on the vision screener.
3. Touch **Plus**.
The Add Printer screen appears.
4. Select the printer and touch the right arrow.
The Printer Details screen appears.
5. Touch the Driver field and select the driver. Touch the right arrow.
6. Touch **Save**.
7. To verify that the printer is installed correctly, touch **Print test page**.
8. Touch **X** to return to the previous screen.

Before adding a printer manually

If you need to add a printer manually, consult your local system administrator for the following information about the printer location.

Field	Description	Requirements		
Protocol	IPP or Raw Socket	The default value is IPP.		
Hostname/IP address	Hostname	The maximum length is 40 characters. Allowed characters include a blank space as well as the following:		
		A through Z	a through z	
		0 through 9	-	
		.	~	
		General delimiters		
		:	/	#
		?	[] @
		Subnet delimiters		
		!	\$	&
		'	()
*	+	, ;		
	IP Address	An IP address consists of numbers between 0 and 9 in the format xxx.xxx.xxx.xxx. For example, 1.92.123.100.001.		
Port	Port numbers range from 0 to 65535.			
	IPP	The default port is 631.		
	Raw Socket	The default port is 9100.		
Resource Path	Available when IPP is the selected protocol.	The maximum length is 40 characters. For allowed characters, see Hostname. The default value is ipp/print.		

To add a printer manually

If the vision screener cannot discover a printer, you must add it manually. The printer does not need to be connected to the wireless network when you add it to the vision screener. The vision screener will print to the printer when it is connected.

1. Touch **Tools**, and then touch **Printer**.

The Printers Available screen appears.

2. Touch **Plus**.
The Add Printer screen appears.
3. Select Add New Printer, and then touch the right arrow.
The Printer Details screen appears.
4. Touch and edit the Name, Location, and Driver fields.
 - a. **Name:** The name can consist of any printable character except for Tab, a blank space, the question mark (?) or hash tag (#) characters.
 - b. **Location:** Enter the printer location. For more information, see Before adding a printer manually. If you do not know the printer location, consult your system administrator.
 - c. **Driver:** Select the driver from the list.
5. Touch **Save**.
6. To verify that the printer is installed correctly, touch **Print test page**.
If the test page does not print correctly, refer to the Troubleshooting section.
7. Touch **X** in the upper-left corner of the screen to return to the previous screen.

To change printer settings

1. On the Printers Available screen, select a printer.
2. Perform one of the following:
 - To view the number of print jobs, touch **Edit**.
 - If you need to change a particular setting, touch the field.
 - To delete a printer, touch **Minus**.
 - To set the printer as default, touch **Set as default**.
3. Touch **X** in the upper-left corner of the screen to return to the previous screen.

To reset the printer system

Resetting the printer system deletes all currently saved printers.

1. On the Printers Available screen, touch the Trash icon.
2. A pop-up appears; touch **Delete**.

All current printer configurations are removed.

Before you can print, you need to add a printer and set it as the default printer.

About importing and exporting

You can import a subject list and a customized banner file to the device as well as a customized criteria file. The banner file must be in the graphic .png format and the other files must be in the .csv format.

A .csv file is a text file that has information separated by commas. For example: "First Name, Last Name, Age". Files in a .csv format can be opened in a spreadsheet program, which makes it easier to view the information. You can create a .csv file in a spreadsheet or text program. The file must have a .csv suffix.

The vision screener comes with a template and sample .csv files. You can export these files to your computer to add information about the subjects to be screened and then import the files into the vision screener before beginning the screening.

When you first export files from the device, two folders appear on the USB drive. Open the folder with the format "Spot_SerialNumber_YYYYMMDD_HHMMSS". For example, Spot_19719_20180920_152020.

The exported folder contains the following .csv files:

.csv File	Location	Description
SpotResults	db subfolder	This file contains the basic screening results. When you first export this file to a computer, it contains only the header row. When you screen subjects and export to a computer, this file is filled with the test results.
SpotResultsExtended	db subfolder	This file contains the basic screen results as well as more in-depth results. When you first export this file to a computer, it contains only the header row. When you screen subjects and export to a computer, this file is filled with the test results.
SpotSubjects	db subfolder	This is a template that you can use to create a subject list. For more information, see Create a subject list.
SpotCriteria	import subfolder	This file contains the Vision Screener criteria. Before modifying the criteria, see Vision screener criteria. Note: this folder also contains a SpotCriteria.default file. This file is not modifiable.

Importing/exporting files

Importing or exporting files requires a USB 2.0 storage device. The recommended device size is 16 GB or larger.



CAUTION If the USB drive is removed before the export is finished, the information might not be completely transferred or it might become corrupted.

Export

When you export a file, it is saved on the USB 2.0 drive in a folder named with the device serial number and timestamp. Each time you export, a new folder is created with this format: Device-Name_Serial-Number_YYYYMMD_HHMMSS.

For example, the first time you export to the USB drive, the exported files could be in a folder named Spot_19719_20180911_110449. The next time you export to the USB drive, the most recently exported files are in a folder with a later timestamp, such as Spot_19719_20180920_152020

The Exclude Personal Data option lets you export content without subject-specific data. If you do not choose this option, then all data is exported. If you choose this option, no individual PDF results are exported.

The first time you export files, the files only contain subject headings, with no personal data. If you have screening results on the vision screener before you create a subject list, the subject information is exported to the USB drive when you export.

If you want to create a subject list, do not select Exclude Personal Data.

1. Select **Tools** and then **Import/Export**.
2. Touch **Export**.
 - If you want to create a subject list, do not select Exclude Personal Data.
 - To export files without subject-specific data, touch **Exclude Personal Data**.
3. Touch **Export** again to begin the export process.
4. When the device displays a successful export notification, touch **OK**.

You can now safely remove the USB drive from the vision screener.

Create a subject list

A subject list allows you to screen subjects quickly, without having to enter their information before each screening. You can expedite the process of conducting a mass screening if you have prepared a subject list before the screening.

You must export the SpotSubjects.csv file to a USB 2.0 drive before you can update it on your computer. After you import the updated list into the vision screener, the subject information displays in the queue. When you select a subject and complete the screening, the subject's information disappears from the queue and is added to the list of completed screenings in the SpotResults.csv file. Individual results appear in the pdf subfolder.

1. After exporting the .csv files to the USB drive, insert the drive in your computer.
2. Go to the folder with the latest timestamp.
3. Select the db subfolder.
4. Open the SpotSubjects.csv file in a spreadsheet or notepad program.
5. Add the subject information. Do not modify the column names.

Note If you are not sure how to fill out the subject information, refer to the Subject Information Screen. You must enter a date of birth or age in a valid format. For example: 5/24/1963, 8 months, or 5 years. If you do not enter the subject's date of birth or age in a valid format, the vision screener cannot import the file. If you do not fill out the other fields in the correct format, the vision screener leaves those fields empty when it imports the file.

6. Save the file as a .csv file. Give the file one of the following names:

Name	Description
<i>MyLocation.csv</i>	Use the name of the location where the screenings will take place. For example, if you are conducting screenings in Beaverton, name the file <i>Beaverton.csv</i> . The vision

Name	Description
SpotSubjects.csv	screener automatically fills in the location in the subject information in the SpotResults.csv file. If the vision screener has a location specified that is different from the .csv file, the location specified in the .csv file is included in the results. Use this name if if the location is already specified on the vision screener. If no location is specified on the device, the location is not included in the results.

7. Move the file to the top level of the folder structure. For example, if your USB drive shows upon your computer as the D:/ drive, save the .csv file as D:/spotsubject.csv or D:/mylocation.csv.

You can now import the file to the vision screener.

Import

Before you import a file, make sure it is on the top-level of the USB 2.0 drive. You cannot import files that are in folders.

1. Insert the USB device into the USB port of the vision screener.
2. Select **Tools** and then **Import/Export**.

Once the USB device is detected, Import and Export become available for selection and the USB symbol displays in the upper right black bar next to the wireless connectivity symbol. The number of import files found appears on the screen.

Note Import is only available if the vision screener recognizes a valid import file. If there are no files in the top-level of the USB drive, Import is not available.

3. Touch **Import**.
4. To return to the previous screen, touch the **X** in the upper-left corner.

The Troubleshooting section provides additional suggestions to ensure a successful import.

Custom banner

Welch Allyn offers the ability to add a custom banner to the bottom of the printable reports. Create your banner using the specifics below:

- Banner files must be named `banner.png`
- No larger than 1MB
- Image must be 1376 x 240 pixels

To add a custom banner

1. Place the banner.png file on the root/top-level directory of the USB.
2. Insert the USB in the vision screener. Touch **Tools**, and then touch **Import/Export**.
3. Once import file option highlights, touch **Import**.

4. To verify that the file was imported successfully, screen a new subject, or select a completed screening and print the report. Your new banner prints on the bottom of the report.

Web access

When connected to a wireless network, the vision screener gives you the ability to view files from a web browser (for example, Internet Explorer, Firefox, Safari) on a computer on the same network.

To access the webserver on the vision screener

Make sure your computer and the vision screener are on the same network.

1. From your computer, open a web browser.
2. Enter the vision screener IP address in the address bar, for example 123.45.67.89. The IP address is located on the top black bar on the Home screen.
3. If the web browser displays a security warning, proceed.
4. Enter the username and password.

Username: **spot**

Password: **0000**

Note If you have enabled security on your device, the password is your four-digit pin code.

5. To view the exam results of each individual screening, select the pdf folder.

Vision screener criteria

Spot Vision Screener's criteria was developed in accord with the American Academy of Pediatric Ophthalmology and Strabismus (AAPOS) and American Academy of Pediatrics (AAP) recommendations for instrument based vision screening. The criteria is age specific to assist with early detection of amblyopic risk factors in children.



WARNING Risk of false positive and false negative results. Modification of referral criteria should be performed only by a vision specialist.

Note Any deviation from this criteria may lead to over referrals or under referrals. If you enter criteria that is not within accepted limits, the vision screener automatically restores the system default criteria.

Note Verify the system clock settings after modifying criteria.

- The subject age in months shall have no overlapping ages between the age ranges.
- No subject age range can span 240 months (20 years).
- Anisometropia Threshold Value(age): Range 0.25D to 14.00D in increments of 0.25 diopters.
- Myopia Threshold Value(age): Range 0.00 to +7.00 diopters in increments of 0.25 diopters.

Note Myopia criteria ranges from -7.00 to 0 diopters. Because the vision screener cannot accept a .csv file with negative numbers, enter the criteria in positive values. Myopia criteria values are automatically interpreted as a negative number.

- Hyperopia Threshold Value(age): Range 0.00 to +7.00 diopters in increments of 0.25 diopters.
- Astigmatism Threshold Value(age): Range 0.25D to +3.00D in increments of 0.25 diopters.
- Anisocoria Threshold Value(age): Range 0.00 to +5.00 mm in increments of 0.10 mm.
- Strabismus Threshold Value(age): Range 0 to +20 degrees in increments of 1 degree.

To modify current screening criteria



WARNING Risk of false positive and false negative results. Modification of referral criteria should be performed only by a vision specialist.

Note Verify the system clock settings after modifying criteria.

1. Perform an export and insert the USB 2.0 drive into your computer.
2. Go to the USB drive folder and open the Spot folder with the most recent timestamp. Select the import subfolder.
3. Copy the SpotCriteria.csv file to the top level on the USB drive. The file cannot be within a folder. Once copied, open the file.
4. Make any desired changes using a spreadsheet or notepad program.
5. Save file as a Comma Separated Value (.csv) file. Do not change the file name. Eject the USB drive from your computer and insert into the vision screener.
6. Touch **Tools**, and then touch **Import/Export**.
7. Touch **Import** to import the updated criteria file.
8. To verify the file was imported successfully, touch **Tools**, and then touch **Criteria**. Review the new settings.
9. To revert to the default criteria that was shipped with the device, touch **Restore** twice.

The custom criteria is deleted from the vision screener and the default criteria is restored.

About licensing

To use the screening functionality of the vision screener, the device needs to be licensed. If your device came new from the factory with this Directions for use, your license is already installed and active. If you encounter an issue with the license, contact Welch Allyn Support at customerservice@welchallyn.com.

To enable/disable security on the vision screener

If you want to prevent unauthorized access, you can enable security on the vision screener by adding a four-digit security PIN code



CAUTION If you create a security PIN, you cannot disable security on the device without the PIN. If you lose or forget the PIN, contact customer service. The device must be restored to factory settings. Any data on the device will be lost.

1. Touch **Tools**, then touch **Security**.
2. Check Use security PIN code.
3. Enter and then re-enter the security PIN code.
4. To disable security, touch **Tools**, then touch **Security**.
Uncheck Use security Pin code.
5. Enter the security PIN code.
6. To return to the previous menu, touch the **X** in the upper-left corner of the screen.

To lock/unlock the vision screener

1. To lock the vision screener, hold down the **Power** button.
2. Touch **Lock**.
A Lock symbol appears on the screen.
3. To unlock the vision screener, touch .
4. Enter the security PIN code.

To check the storage capacity

If the storage capacity is 100% full, the vision screener stops working until you delete records from the device.

1. From the Home screen, touch **Tools**, and then **About**.
The storage displays in the upper-right corner.
2. To return to the Tools screen, touch the **X** in the upper-left corner.

Maintenance and cleaning

Cleaning the vision screener



WARNING Electric shock hazard. Before cleaning the vision screener, disconnect the DC power cord from the power outlet and the vision screener.



WARNING Liquids can damage electronics inside the vision screener. Prevent liquids from spilling on the vision screener.

If liquids are spilled on the vision screener:

1. Turn off the vision screener.
2. Disconnect the power plug.
3. Dry off excess liquid from the vision screener.

If liquids possibly entered the vision screener, remove the vision screener from use until it has been properly dried, inspected, and tested by qualified service personnel.

Clean on a routine basis according to your facility's protocols and standards or local regulations.

The following agents are compatible with the vision screener:

- 70 percent isopropyl alcohol
- 10 percent chlorine bleach solution

Note Disinfect according to your facility's protocols and standards or local regulations.

Cleaning with 70 percent isopropyl alcohol

Wipe the vision screener with a clean cloth slightly dampened with 70 percent isopropyl alcohol.

Cleaning with 10 percent chlorine bleach solution

1. Wipe the vision screener with a clean cloth slightly dampened with a 10 percent bleach and water solution. Follow the cleaning agent manufacturer's guidelines.
2. Rinse with a clean cloth slightly dampened with water that meets EP and USP quality standards.

3. Allow the vision screener surface to dry for a minimum of 10 minutes before using the vision screener.

Storing the equipment

When storing the device, cords, and accessories, observe the environmental storage conditions that are identified in the product specifications.

If the vision screener has not been used or charged in 5 months or longer, the battery clock might become depleted. Turn on and charge the vision screener. Check the system clock and if necessary reset the date and time. If the device has not been used or charged in 18 months, charge the device overnight, while the device is turned on, before using. For best results, use and charge the vision screener regularly.

Disposing of electronic equipment



■ This product and its components must be disposed of according to local laws and regulations. Do not dispose of this product as unsorted municipal waste.

For more specific disposal or compliance information, see www.welchallyn.com/weee, or contact Welch Allyn Customer Service.

This device contains Lithium ion cells and other electronic materials. Please contact your local government authorities for proper electronic waste recycling or disposal methods at end of life.

Troubleshooting

System restart

1. To restart the vision screener, press and hold the **Power** button until a confirmation screen appears. Touch **Confirm** to turn off the vision screener.
2. When the screen turns black, wait 30 seconds and then press the **Power** button to turn the vision screener back on. Ensure the device has power by plugging in the power cord.

System freeze

If the vision screener locks up and is unresponsive to touch, you need to perform a hard system reset.



CAUTION This may cause some data loss (such as printer configuration and subject data).

1. Press the **Power** button.
2. Once the Power Off window appears, touch **Confirm** to turn off the device.
3. If the Power Off window does not appear, press and hold the **Power** button until the screen goes black, then release the button.
4. Wait about one minute, and then perform the normal start-up process.

Printer issues

Check that your printer is turned on and has sufficient ink or toner.

1. Verify the printer is set as the default printer.
2. Print a test print page directly from the printer.
3. After you confirm your printer is in proper working order, verify the printer is on a local network by printing to the printer from a computer on the same local network.
4. Verify the vision screener and the printer are on the same local network.
5. If all of the above are in working order, restart the vision screener.
6. If you are having a problem with your printer or a print job is stuck in the queue, touch **Tools**, and then **Printer**. Select the printer and touch **Pencil**, then touch **Reset**. This clears any print jobs in the queue and resets the printer.
7. If you are using a network that doesn't support or enable multicast DNS, you need to configure the printer information. For more information, see To add a printer manually.
8. If you have a USB printer, you can connect the device with a USB cable and print to that printer.

Wireless issues

If you encounter problems connecting to a wireless network:

1. Verify all network settings are entered correctly.
2. Check the Home screen to see if your network name and IP address are identified in the upper left corner of the black bar.
3. If the settings are correct, check the Wireless icon in the upper right corner. If the icon is red, try restarting the vision screener.
4. If the connection does not automatically reconnect, touch **Tools**, and then **Network**.
5. Select the correct security type (None, WEP, WPA/2 PSK, and WPA/2 EAP-PEAP), re-enter the username (if required) and password or passphrase. Select **OK**.

Battery Issues

Issue	Recommendation	For more information, see
Tapping the screen does not light up the display.	Plug it into an available wall outlet and restart the vision screener.	System restart
Message: Battery is almost depleted, please plug into power source.	Plug the vision screener into an available wall outlet to charge the device. For best results, turn on and charge the vision screener for four hours.	To charge the vision screener

Restoring and restarting system messages

Message Text	Meaning
Are you sure you want to delete the custom loaded criteria and restore system default criteria? To save your custom criteria, use the Export option in Import/Export tool.	You have requested a restore to the factory default settings for the age based criteria settings. If you select Restore, current criteria settings are removed. All subject information on the device is deleted.
The database has been reset and recovery files have been built. (selecting export from the tools menu will transfer the recovery files).	There was an internal error while restoring the subject history file. A backup recovery file has been generated and copied to the recovery area for export. You can select Delete to delete the recovered files or Cancel to retain the files. If the recovered files remain on the device, this message displays each time you restart the device until you export the files.
Sorry for the inconvenience. We need to reboot the device.	Screening mode has encountered a problem and the device needs to be restarted. You can restart the device or, if you select Cancel, continue in Read Only mode. Read Only mode lets you review

Message Text	Meaning
	existing screening results. You cannot perform new screenings until you restart the device.
Problem encountered. The device needs to reboot.	The system was not able to start and has attempted to correct the issue. Restart the device.
Un-calibrated device	The system cannot read the device configuration file. Restart the device. If the issue is not resolved, contact Welch Allyn Technical Support.

For more information on troubleshooting or error messages, contact Welch Allyn Technical Support: www.welchallyn.com.

Screening tips

If the pupils are too small, the vision screener displays a notification to adjust the lighting in the room. Follow these steps to encourage the subject's pupils to dilate.

1. Dim the lights, if possible.
2. Close blinds or curtains, if possible.
3. The subject's back should be positioned to the interfering light source.
4. Avoid direct light into the subject's eyes from:
 - ambient light sources
 - exterior light
 - incandescent and halogen lights (florescent light is the best testing environment, if options are limited)

Screening Issues

Screening system messages

Issue	Recommendation	For more information, see
Message: The screening system is not initialized.	The exam system did not initialize or is unresponsive. Restart the device.	System restart
Message: Unable to save PDF report for current subject	The file system may not have enough space. Export data and clear the device history to free up additional storage space.	To delete records

Import/Export Issues

Issue	Recommendation	For more information, see
Cannot see the .csv file trying to import	Make sure that the file is at the root level of the USB folder structure, not in a subfolder. Make sure the file is in the .csv format. You cannot import a file that ends in .xls or .txt or .doc.	About Importing/Exporting
Cannot see the banner .png file trying to import	Make sure the banner file is: <ul style="list-style-type: none"> • Named "Banner.png" • At the top level of the USB folder structure • No larger than 1 MB • Has the image size 1376 x 240 pixels 	Custom banner
Cannot see the pdf subfolder or individual PDF screening result files	Make sure the Exclude Personal Data option is not selected when you export.	Export
Message: Imported 0 file. Failed to import 1 file.	Check that the subject information in the SpotSubject.csv file is formatted correctly. Enter the date of birth in the specified format or enter the age in months or years. For example, <i>12/19/1963, 8 months, or 10 years.</i>	Subject Information Screen
After exporting to a computer, get an error message: The file or directory is corrupted and unreadable.	Delete or move all the files and folders from the USB 2.0 drive and retry the export.	Importing/Exporting files
Message: Export failed due to an internal error.	Data export failed. Retry the export.	Importing/Exporting files
Message: Unable to exclude personal data from recovered files, would you like to proceed?	If you select Continue, the device exports the recovered data with the personal information included.	Export
Message: Would you like to delete the recovered files from this device?	If an export contains recovered data files, you can delete the recovered files or keep them on the device. A warning display during startup until the files are deleted.	Export
The Import and Export icons do not highlight after inserting the USB drive.	Verify the USB drive is 2.0 and that files are on the top level of the folder structure. Insert the USB drive into your computer. Remove the files from the drive, and copy them back again.	Import

Specifications

The vision screener has the following characteristics:

- This vision screener DFU document is valid for software versions 3.1.xx.yy.
- The vision screener has been calibrated as part of the manufacturing process and does not require calibration henceforth.
- The external power supply/charger supplied is an IEC Class II equipment and the vision screener is also an IEC Class II equipment when connected to the external power supply/ charger.
- The vision screener is internally powered by equipment (battery) when not connected to the external power supply/charger.
- Protection against electric shock, no applied part.
- The vision screener is rated IPX0 and thus not protected from the ingress of water.
- The vision screener is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- The vision screener is suitable for continuous operation.
- The vision screener screens for vision issues across all age groups from 6 months to 100 years.
- Welch Allyn suggests a battery replacement, at an appointed Welch Allyn repair facility, every 2.5 years at the owner's expense. The vision screener regular maintenance consists of wiping dust or dirt off the front glass surface and the LCD display as needed.

Power supply specifications

Item	Specification
Mfg:	SL Power Electronics
Model:	MENB1040A1503N01 or MENB1040A1541N01
Japanese Model:	MENB1040A1503N02
Input Voltage:	90 – 264VAC (100 – 240VAC Nominal)
Input Frequency:	47 – 63 Hz
Input Current:	100VAC: 1.1A

Item	Specification
Avg. Efficiency:	81-87% @ 0-50 W, ≥ 87% @ >51 to 250
Infrared radiation (light)	850 nm, <2mw/cm ²

Vision Screener specifications

Item	Specification
Dimensions (cm/in):	21.6 cm x 17.1 cm x 12.1 cm (8 ½ in. x 6 ¾ in. x 4 ¾ in.)
Weight (lbs.):	~2.55
Wireless Network:	802.11 a/b/g/n
Operating Temperatures (°C):	+10 to +40
Operating Humidity:	30% to 95% Relative Humidity (non-condensing)
Operating Atmospheric Pressure:	800 hPA to 1060 hPA
Storage/Shipping Temperatures (°C):	-10 to +55
Storage/Shipping Humidity:	10% to 95% Relative Humidity (non-condensing)
Storage/Shipping Atmospheric Pressure:	700 hPA to 1060 hPA
Expected Battery Life:	2.5 Years (Under Normal Usage)

Screening capacity

Screening results provide an output that is either in- or out-of-range, accompanied by the appropriate statement in the device output display (“Screening Complete” or “Complete Eye Exam Recommended”). The displayed message is intended to prompt the caregiver to assess whether the subject should be referred to an eye care specialist for further evaluation or simply be monitored at future screenings.

Refraction

Spherical equivalent:

- Range: -7.50D to +7.50D in 0.25D increments
- Accuracy:
 - 3.50D to 3.50D, ± 0.50D
 - 7.50D to < -3.50D, ± 1.00D
 - > 3.50D to 7.50D, ± 1.00D

Cylindrical:

- Range: -3.00D to +3.00D in 0.25D increments

- Accuracy: -1.50D to 1.50D, $\pm 0.50D$
-3.00D to < -1.50D, $\pm 1.00D$
>1.50D to 3.00D, $\pm 1.00D$

Cylindrical axis:

- Range: 1 to 180 degrees in 1-degree increments
- Accuracy: ± 10 degrees (for cylinder values > 0.5D)

Pupil size:

- Range: Years 0.5 - 19: 4.0 mm to 9.0 mm in 0.1 mm increments
Years 20 - 100: 3.0 mm to 9.0 mm in 0.1 mm increments
- Accuracy: ± 0.4 mm

Pupil distance:

- Range: 35mm to 80 mm in 1 mm increments
- Accuracy: ± 1.5 mm

Screening principle: Eccentric photorefractive (photoretinoscopy) is used to estimate the magnitude of ametropia based on characteristics of the light reflex in the pupil.

Gaze

Corneal Light Reflex (Gaze):

- Range: 0.0 to 20.0 degrees in increments of 1 degree Nasal(N) or Temporal(T)
0.0 to 20.0 degrees in increments of 1 degree Inferior(I) or Superior(S)
- Accuracy: ± 1.5 degrees

Guidance and manufacturer's declaration

EMC compliance

Special precautions concerning electromagnetic compatibility (EMC) must be taken for all medical electrical equipment. This device complies with IEC 60601-1-2:2014.

- All medical electrical equipment must be installed and put into service in accordance with the EMC information provided in this *Directions for use*.
- Portable and mobile RF communications equipment can affect the behavior of medical electrical equipment.

The device complies with all applicable and required standards for electromagnetic interference.

- It does not normally affect nearby equipment and devices.
- It is not normally affected by nearby equipment and devices.
- It is not safe to operate the monitor in the presence of high-frequency surgical equipment.
- It is good practice to avoid using the device in extremely close proximity to other equipment.

Note The VS100 has no essential performance (patient safety) requirements associated with vision screening.



WARNING Avoid using the vision screener adjacent to or stacked with other equipment or medical electrical systems because doing so could result in improper operation. If such use is necessary, observe the vision screener and other equipment to verify that they are operating normally.



WARNING Use only accessories Welch Allyn recommends for use with the vision screener. Accessories not recommended by Welch Allyn might affect the EMC emissions or immunity.



WARNING Maintain minimum separation distance between the vision screener and portable RF communication equipment. Performance of the vision screener might degrade if you don't maintain sufficient separation distance.



WARNING This device has not been tested for use in clinical environments near high-frequency surgical equipment and magnetic resonance imaging. Do not use this device in environments like these where electromagnetic disturbance is high.

Emissions and immunity information

Electromagnetic emissions

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

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The device 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.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Electromagnetic emissions



WARNING This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment ^a. It may be necessary to take mitigation measures, such as re-orienting or relocating the device or shielding the location.

^a The device contains a 5-GHz orthogonal frequency-division multiplexing transmitter or a 2.4-GHz frequency hopping spread-spectrum transmitter for the purpose of wireless communication. The radio is operated according to the requirements of various agencies, including FCC 47 CFR 15.247 and Radio Equipment Directive 2015/53/EU. The transmitter is excluded from the EMC requirements of 60601-1-2, but should be considered when addressing possible interference issues between this and other devices.

Electromagnetic emissions

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV ±15 kV	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 ±1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	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 (>100 % dip in UT) for 1 cycle 70 % UT (30 % dip in UT) for 25/30 cycles <0 % UT (>100 % drop in UT) for 0.5 cycles@ 0°, 45°, 90°, 135°, 180°, 225°, 270°, & 315° for 250/300 cycles	<0 % UT (>100 % dip in UT) for 1 cycle 70 % UT (30 % dip in UT) for 25/30 cycles <0 % UT (>100 % drop in UT) for 0.5 cycles@0°, 45°, 90°, 135°, 180°, 225°, 270°, & 315° for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device 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: U_T is the a.c. mains voltage prior to application of the test level.

Electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d=(1.17)\sqrt{P}$ 150 kHz to 80 MHz
Radiated RF IEC 61000-4-3	3 V/M, 80 MHz to 1 GHz	6 V/M	$d=(1.17)\sqrt{P}$ 80 MHz to 800 GHz
Surge EN 61000-4-5	Differential mode: ±1 kV Common mode: ±2kV	10 V/M	$d=(2.33) \times \sqrt{P}$ 800 MHz to 2.7 GHz

where P is the maximum output power rating of the transmitter in watts (W) and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a, should be less than the compliance level in each frequency range^b. Interference may occur in the vicinity of equipment marked with the following symbol:



Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

^aField strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

^bOver the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the device

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the device can help prevent electromagnetic interference by maintaining a minimum distance

Recommended separation distances between portable and mobile RF communications equipment and the device

between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Separation distance according to frequency of transmitter (m)			
Rated max. output power of transmitter (W)	150 kHz to 80 MHz $d=(1.17)\sqrt{P}$	80 MHz to 800 MHz $d=(1.17)\sqrt{P}$	800 MHz to 2.7 GHz $d=(2.33)\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.38	0.73
1	1.17	1.20	2.30
10	3.69	3.79	7.27
100	11.67	12.00	23.00

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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)
385	380 - 390	TETRA 400	Pulse modulation ^b 1.8 18 Hz	1.8	0.3	27
450	430 - 470	GMRS 460, FRS 460	FM ^c ±5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704 - 787	LTE band 13, 17	Pulse modulation ^b 217 Hz	0.2	0.3	9
810 870 930	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation ^b 18 Hz	2	0.3	28

Test specifications for enclosure port immunity to RF wireless communications equipment

1720	1700 - 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation ^b 2 217 Hz	0.3	28
1845					
1970					
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ^b 2 217 Hz	0.3	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation ^b 0.2 217 Hz	0.3	9
5500					
5785					

NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the monitor 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 percent duty cycle square wave signal.

^c As an alternative to FM modulation, 50 percent pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

FCC compliance statement

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

Note This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in any environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.



WARNING Changes or modifications not expressly approved by Welch Allyn could void the user's authority to operate the equipment.

Vision Screener radio

The vision screener radio operates on 802.11 networks.

Wireless network interface	IEEE 802.11 a/b/g/n
Frequency	2.412 GHz to 2.484 GHz 4.910 GHz to 5.825 GHz
Wireless data rates	802.11a (OFDM): 6, 9, 12, 18, 24, 36, 48, 54 Mbps 802.11b (DSSS, CCK): 1, 2, 5.5, 11 Mbps 802.11g (OFDM): 6, 9, 12, 18, 24, 36, 48, 54 Mbps 802.11n (OFDM, HT20, MCS 0-7): <ul style="list-style-type: none"> 6.5, 13, 19.5, 26, 39, 52, 58.5, 72.2 Mbps 7.2, 14.4, 21.7, 28.9, 43.3, 57.8, 65 Mbps
Output power	2.412GHz-2.484GHz 802.11 b/g 17.5 avg. 4.920GHz - 5.825GHz 802.11a 19.5 avg.
Modulation	OFDM, DSSS, CCK
Channels	2.412-2.484 (1-14) 4.910-5.825 (24 non-overlapping)
Security/encryption/authentication	WEP (64/128/256), AES, TKIP, WPA, and WPA2
Antenna	Pulse W1039B030 with 76 mm I-PEX cable, Max Gain: 2.0dBi
Agency approvals	<p>US:</p> <ul style="list-style-type: none"> FCC 15.247 DTS – 802.11b/g (Wi-Fi): 2.4 GHz & 5.8 GHz FCC 15.407 UNII – 802.11a (Wi-Fi): 2.4 GHz & 5.4 GHz FCC 15.247 DSS – BT 2.1 FCC Part 15 Class B <p>Canada:</p> <ul style="list-style-type: none"> RSS-210 – 802.11a/b/g/n (Wi-Fi) – 2.4 GHz, 5.8 GHz, 5.2 GHz, and 5.4 GHz ICES-003, Class B CSA C22.2, No. 60950 RSS-210 – BT 2.1 <p>Europe: Annex 3.2 2014/53/EU Radio Equipment Directive https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32014L0053</p>

General radio compliance

The wireless features of this device must be used in strict accordance with the manufacturer's instructions as described in the user documentation that comes with the product. This device complies with Part 15 of the FCC rules and with the rules of the Canadian ICES-003 and the essential requirements of the 2014/53/EU Radio Equipment Directive as described below.

This device complies with EN62479, RSS-102 and 47 CFR 2.1093 for RF exposure.

Industry Canada (IC) emissions

This device complies with RSS 210 of Industry Canada.

Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of this device.

L'utilisation de ce dispositif est autorisée seulement aux conditions suivantes: (1) il ne doit pas produire de brouillage et (2) l'utilisateur du dispositif doit être prêt à accepter tout brouillage radioélectrique reçu, même si ce brouillage est susceptible de compromettre le fonctionnement du dispositif.

This Class B digital apparatus complies with Canadian ICES-003.

Cet appareil numérique de la classe B est conforme à la norme NMB-003 du Canada.

European Union

This device complies with the essential requirements of the 2014/53/EU Radio Equipment Directive. The following test methods have been applied in order to prove presumption of conformity with the essential requirements of the 2014/53/EU Radio Equipment Directive:

This device is a 5.8 GHz wideband transmission system (transceiver), intended for use in all EU member states and EFTA countries, except in France and Italy where restrictive use applies.

In Italy the end-user should apply for a license at the national spectrum authorities in order to obtain authorization to use the device for setting up outdoor radio links and/or for supplying public access to telecommunications and/or network services.

This device may not be used for setting up outdoor radio links in France and in some areas the RF output power may be limited to 10 mW EIRP in the frequency range of 2454 – 2483.5 MHz. For detailed information the end-user should contact the national spectrum authority in France.

Norway - Does not apply for the geographical area within a radius of 20 km from the center of Ny-Ålesund.

Czech	Welch Allyn tímto prohlašuje, že tento RLAN device je ve shodě se základními požadavky a dalšími příslušnými ustanoveními směrnice 2014/53/ES.
Danish	Undertegnede Welch Allyn erklærer herved, at følgende udstyr RLAN device overholder de væsentlige krav og øvrige relevante krav i direktiv 2014/53/EF
Dutch	Bij deze verklaart Welch Allyn dat deze RLAN device voldoet aan de essentiële eisen en aan de overige relevante bepalingen van Richtlijn 2014/53/EC.
English	Hereby, Welch Allyn, declares that this RLAN device is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EC.
Estonian	Käesolevaga kinnitab Welch Allyn seadme RLAN device vastavust direktiivi 2014/53/EÜ põhinõuetele ja nimetatud direktiivist tulenevatele teistele asjakohastele sätetele.
Finnish	Welch Allyn vakuuttaa täten että RLAN device tyyppinen laite on direktiivin 2014/53/EY oleellisten vaatimusten ja sitä koskevien direktiivin muiden ehtojen mukainen.
French	Par la présente, Welch Allyn déclare que ce RLAN device est conforme aux exigences essentielles et aux autres dispositions de la directive 2014/53/CE qui lui sont applicables
German	Hiermit erklärt Welch Allyn die Übereinstimmung des Gerätes RLAN device mit den grundlegenden Anforderungen und den anderen relevanten Festlegungen der Richtlinie 2014/53/EG. (Wien)

Greek	ΜΕ ΤΗΝ ΠΑΡΟΥΣΑ Welch Allyn ΔΗΛΩΝΕΙ ΟΤΙ RLAN device ΣΥΜΜΟΡΦΩΝΕΤΑΙ ΠΡΟΣ ΤΙΣ ΟΥΣΙΩΔΕΙΣ ΑΠΑΙΤΗΣΕΙΣ ΚΑΙ ΤΙΣ ΛΟΙΠΕΣ ΣΧΕΤΙΚΕΣ ΔΙΑΤΑΞΕΙΣ ΤΗΣ ΟΔΗΓΙΑΣ 2014/53/EK
Hungarian	Alulírott, Welch Allyn nyilatkozom, hogy a RLAN device megfelel a vonatkozó alapvető követelményeknek és az 2014/53/EC irányelv egyéb előírásainak.
Italian	Con la presente Welch Allyn dichiara che questo RLAN device è conforme ai requisiti essenziali ed alle altre disposizioni pertinenti stabilite dalla direttiva 2014/53/CE.
Latvian	Ar šo Welch Allyn deklarē, ka RLAN device atbilst Direktīvas 2014/53/EK būtiskajām prasībām un citiem ar to saistītajiem noteikumiem.
Lithuanian	Šiuo Welch Allyn deklaruoją, kad šis RLAN device atitinka esminius reikalavimus ir kitas 2014/53/EB Direktyvos nuostatas.
Malti	Hawnhekk, Welch Allyn, jiddikjara li dan RLAN device jikkonforma mal-htigijiet essenzjali u ma provvedimenti oħrajn relevanti li hemm fid-Dirrettiva 2014/53/EC
Portuguese	Welch Allyn declara que este RLAN device está conforme com os requisitos essenciais e outras disposições da Directiva 2014/53/CE.
Slovak	Welch Allyn týmto vyhlasuje, že RLAN device spĺňa základné požiadavky a všetky príslušné ustanovenia Smernice 2014/53/ES.
Slovene	Šiuo Welch Allyn deklaruoją, kad šis RLAN device atitinka esminius reikalavimus ir kitas 2014/53/EB Direktyvos nuostatas.
Spanish	Por medio de la presente Welch Allyn declara que el RLAN device cumple con los requisitos esenciales y cualesquiera otras disposiciones aplicables o exigibles de la Directiva 2014/53/CE
Swedish	Härmed intygar Welch Allyn att denna RLAN device står i överensstämmelse med de väsentliga egenskapskrav och övriga relevanta bestämmelser som framgår av direktiv 2014/53/EG.

Warranty

Vision Screener

Your Welch Allyn product, when new, is warranted to be free from original defects in material and workmanship and to perform in accordance with manufacturer's specifications under normal use and service. The warranty period* begins from the date of purchase from Welch Allyn, Inc. or its authorized distributors. Welch Allyn's obligation is limited to the repair or replacement of components determined by Welch Allyn to be defective within the warranty period. These warranties extend to the original purchaser and cannot be assigned or transferred to any third party. This warranty shall not apply to any damage or product failure determined by Welch Allyn to have been caused by misuse, accident (including shipping damage), neglect, improper maintenance, modification, or repair by someone other than Welch Allyn or one of its authorized service representatives.

* 1 (one) Year Limited Warranty

These express warranties are in lieu of any and all other warranties, express or implied, including the warranties of merchantability and fitness for a particular purpose, and no other person has been authorized to assume for Welch Allyn any other liability in connection with the sale of the Welch Allyn product. Welch Allyn shall not be liable for any loss or damages, whether direct, incidental or consequential, resulting from the breach of any express warranty, except as set forth herein.

Service policy

All repairs on products under warranty must be performed by Welch Allyn or by a service provider authorized by Welch Allyn. Unauthorized repairs voids the warranty. In addition, whether or not covered under warranty, any product repair should be performed exclusively by Welch Allyn or by a service provider that has been authorized by Welch Allyn. For information about the Partners in Care Comprehensive Support Program, refer to www.welchallyn.com.

If the product fails to function properly—or if you need assistance, service, or spare parts—contact the nearest Welch Allyn Technical Support Center.

Before contacting Welch Allyn, try to duplicate the problem, and check all accessories to ensure that they are not causing the problem. When calling, please be prepared to provide:

- Product name, model number, software version and serial number of your product.
- Complete description of the problem.
- Complete name, address and phone number of your facility.
- For out-of-warranty repairs or spare parts orders, a purchase order (or credit card) number.
- For parts orders, the required spare or replacement part numbers.

If your product requires warranty, extended warranty, or non-warranty repair service, please call the nearest Welch Allyn Technical Support Center first. A representative will assist you troubleshooting the problem and will make every effort to solve it over the phone, avoiding potential unnecessary return of your product.

In case a return cannot be avoided, the representative will record all necessary information and will provide a Return Material Authorization (RMA) number, as well as the appropriate return address. An RMA number must be obtained prior to any return.

If you have to return your product for service, follow these recommended packing instructions:

- Remove all cables, power cords, and other accessories (as appropriate) before packing, unless you suspect they are associated with the problem.
- Wherever possible use the original shipping carton and packing materials.
- Include a packing list and the Welch Allyn Return Material Authorization (RMA) number.

It is recommended that all returned goods be insured. Claims for loss or damage to the product must be initiated by the sender.

Configuration options for the VS100 vision screener

Model	Description
VS100S-XXX*	Welch Allyn VS100 Spot Vision Screener with Carrying Case and 8' (2.5m) power cord.
VS100-XXX*	Welch Allyn VS100 Spot Vision Screener with wrist strap and 8' (2.5m) power cord. (Carrying Case not Included)

*Indicates the appropriate country-specific power cord.

WelchAllyn®

Advancing Frontline Care™

Material No.

728900



(91)728900