# Welch Allyn<sup>®</sup> Spot<sup>®</sup> Vision Screener Model VS100



# **Directions for use**

Software version 3.0.XX



Advancing Frontline Care™

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# Introduction

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

### **Documentation symbols**



Consult operating instructions/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 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.

## Power symbols

<b>≡</b>	Rated power input, DC
	Battery inside (Not user replaceable)
(+/<	
	Power On/Off
$\bigcirc$	
	USB port
•	
	DC power input port, Center pin positive
♦€♦	

#### **Miscellaneous symbols**

Equipment is not protected against the ingress of liquid

IPXØ

Non-ionizing electromagnetic radiation



This symbol is applicable for EC member countries only. To avoid potential negative consequences for the environment and possibly human health, this instrument should be disposed of (i) for EU member countries - in accordance with WEEE (Directive on Waste Electrical and Electronic Equipment) or (ii) for all other countries, in accordance with local disposal and recycling laws.



The CE mark on this product indicates that it has been tested to and conforms with the provisions noted within the 93/42/ EEC Medical Device Directive.

## User Interface Symbols

	Battery status/level indicator
	Battery charging (Flashing) or charged (Continuous)
	Wireless On/Off button
<b>■</b> ()	
	Connected to the wireless network
ΨIII	
	No wireless network in range
Ψ	
	No IP address assigned by the router
Ψιρ	
	Unknown network
Ψ <b>?</b>	

	Cannot connect to configured network
Ψ!	
	Sound off
×	
	Sound on
	Continue
	Back
	Exit
$\otimes$	
	Print job in progress

## Warnings, cautions and notes



**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** 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 patient leakage currents.

**WARNING** Risk of electric shock. No modification of this equipment is allowed.

**WARNING** Risk of electric shock. 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 void product warranty.

**WARNING** Risk of electric shock. Do not allow the patient 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 patient 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** 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** Lithium ion battery. Risk of fire, explosion, and burns. Do not handle or disassemble the battery pack.

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

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

**WARNING** Patient injury risk. Verify patient identity on the device after manual or barcode entry and before printing or transferring patient 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 may not be used directly for the prescription of corrective eyewear.



**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; this may cause damage to the device, which will not be covered under warranty.

**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.

**Note** A minimum pupil size of 4mm is required for screening to occur and may be difficult to achieve in a room with any light source. If the pupils are too small, the vision screener will notify you on screen to adjust the lighting in the room. For best results, subject's pupils should be 5mm or greater.

## **Contents Checklist**

The main shipping box contains the vision screener, Directions for use, and the Accessory box. The Accessory box contains:

#### AC Power Cord.

Power Supply/Charger.

**Cleaning Cloth.** 

#### Velcro Cable Straps.

**Note** Please do not discard the box and foam. Damages incurred by shipping the device in non-approved packing material will void the limited warranty (see warranty for details).

If you purchased a carrying case, place the foam from the shipping box inside the carrying case for safer transport. Do not store your vision screener in the foam or case while the Power cord is plugged in.

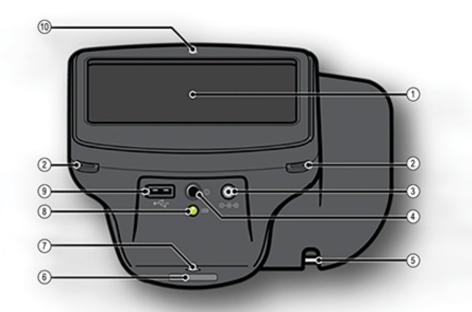
8 Introduction

# 2 Controls, Display Window, and Connections

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

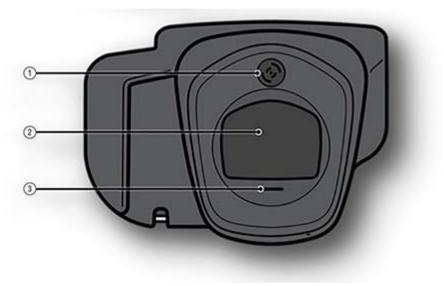
## Features

Rear View of Vision Screener



1	LCD Screen		
2	Neck Strap Mount		
3	AC Power Connector		
4	Power Button		
5	Wrist Strap Mount		
6	Serial Number Label		
7	Tripod Mount		
8	Battery Charge Green LED Indicator		
9	9 USB Port		
10	10 Ambient Light Sensor		

#### Front View of Vision Screener



1	Range Finder Front Glass		
2			
3	Speaker		

# **Display Window**

When the vision screener is powered on, the main menu or **Home** Screen will appear. If the vision screener is connected to a network, the network name and IP address will be visible in the upper left corner in the black bar.



#### 1. Age Range

To begin instant screening, with no personal subject data, select an age range of the subject from the **Home** screen. You will be able to enter subject data after the screening if desired.

#### 2. Start Button

The **Start** button will allow you to:

- Enter subject information such as ID, First and Last Name, Gender and Date of Birth (DOB)/Age (Required)
- Find queued subjects (exact match on the ID screen)
- Begin the screening process (Binocular and Monocular available)
- Review and print screening results

#### 3. Icons on Bottom of Screen

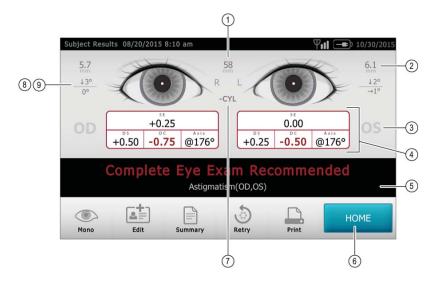
- **Queue** View, select or search for queued subjects from a list to begin the screening process.
- History View already screened subjects (completed records).
- **Tools** A variety of options to customize the vision screener.

# Subject Information Screen

On the subject information screen, confirm all data is correct. You can modify information by touching the field you wish to change. After the change is completed select **OK** and you will come back to the subject information screen. **Date of Birth/Age** is required and will highlight in red if there is no age or if it is not a valid birthdate or age (under 6 months). Select **GO** to begin the screening process.

1792536					
David		Baker			
* DATE OF BIRTH	EYEWEAR P			GENDER	
* Required field	None	Glasses	Contacts	Male	Female

# Understanding the Results



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			
9	Degree, Horizontal, Vertical			

# Tools

The **Tools** menu will allow you to customize and configure the vision screener with the following options:

0	Displays firmware version, software application version and serial number. Also displayed is a quick reference of important the vision screener features, including memory storage levels of the device
≙≓	View the age-based criteria settings used for exam recommendations that are currently active on the vision screener.
	Allows you to set the current date and time for your vision screener.
47	Enables you to import and export using an inserted USB storage device.
9	Location allows you to set a location for a screening and all subjects will be tied to that location.
ΨıII	Allows you to connect the vision screener to a wireless network. You can manually enter your network name (SSID), select the security type, and enter the passphrase for your network. From this page you can view and change your TCP/IP settings.
Γ.	Allows you to configure a network printer and print a test page. It also lets you view printer status.
	Allows you to configure how data is displayed on the 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.
2	Helps you set a security PIN for your device for added security. If enabled a PIN will be required whenever you start the device or upon waking it.
9	Activates the license on the device.
	Allows you to select the language that will display on the vision screener.

# 3

# Setting up the Vision Screener

## Charging

- 1. Connect the provided DC cord set and power supply/charger together.
- 2. Gently lift the back of the vision screener to view the available connections.
- 3. Locate the DC power connector on the vision screener and connect the power supply/charger. The DC power connector on the power supply/charger will easily insert into the DC power connector on the vision screener. <u>Using force to connect the power charger can damage the device and will void the warranty.</u>
- 4. Plug the DC power cord into an available wall outlet to charge the device.

#### Powering the vision screener on and off

- 1. To turn the vision screener on, press and release the power button (start-up process takes approximately 30 seconds). Once powered on, you will see the Main Menu
- 2. To turn the device off, press and hold power button for two seconds. A confirmation screen will appear to confirm shut down.
- 3. A flashing green light means the unit is charging, a steady green light means the unit is fully charged.

#### **Tripod Mount**

The vision screener can be mounted to a standard photographic tripod. A ¼-20 threaded mount located on the bottom of the device is available for attaching a tripod.

#### **Helpful Hints**

- No activity on the vision screener—After 60 seconds the screen will dim; after 5 minutes the screen will automatically turn black to conserve battery power. Tap the screen to 'wake up' the vision screener or press the power button. If the screen does not light up, plug in the power cord and try again.
- **Exporting/Clear All**—Verify you have successfully exported desired data to a USB drive before you select **Clear All**.
- Routinely delete <u>ALL</u> records from the vision screener—Go to the History screen and select Clear All icon. Select Delete All Records. You may also delete all queued records.
- **Avoid powering off during a screening**—Once the screening takes place, exit by selecting the **Exit** button, then power down the device normally.

- **Input Screen**—Holding down the **Back** button on any input (keyboard) screen will delete all data from the field.
- **Low Battery**—When the battery level reaches a very low level, a notice will appear to the User indicating they should insert the power cable or the device will shut down. If no power cable is inserted, the device will automatically shut down due to low voltage

# Wireless Network Configuration

From the **Tools** menu, select the **Network** icon. Current network settings are displayed on the screen. To add or edit any of the fields, see instructions below. If they are correct, select **OK** to be returned to the **Tools** menu.

#### To add/change the network name (SSID):

- 1. Touch the **SSID Name** field; a keyboard will appear.
- 2. Enter the SSID (case sensitive); select **OK** to save your changes and return to the previous screen. The **OK** button will turn dark when changes have been made and are available to be saved.

#### To add/select the security type:

Select the appropriate security type: None, WEP, or WPA.

Note WPA option supports WPA Personal/WPA2 Personal.

#### To add/change the passphrase (password):

- 1. Touch the **Passphrase** button; a keyboard will appear (this is only available when the security field is set to WEP or WPA).
- 2. Enter the passphrase (case sensitive) and select OK.
- 3. On the Network screen, select **OK** to save changes, otherwise changes will not be applied.

#### To enable or disable the wireless capabilities on the vision screener:

Select the **On/Off** button on the network menu.

**Note** Wireless must be on for printing to be enabled.

#### To view advanced network settings:

- 1. Select **TCP/IP**. From here, you can also view your current TCP/IP address as assigned by your network.
- 2. For additional network configurations, select **Static** to manually configure your network address and settings. (Also available is the MAC address of your vision screener).

# **Printer Configuration**

The vision screener is capable of connecting and printing to most network capable Hewlett-Packard (HP) printers. The vision screener also contains some generic PCL drivers that can be used with non-HP printers, as well as a custom driver that supports the Brother QL-720NW label printer.

- **Note** In order to install the QL-720NW on the vision screener, it must have QL-720 in its name on the network and you must select the driver labeled QL-720NW from the driver list. Use Brother DK2205 Continuous Length Paper Tape or equivalent.
- 1. From the **Tools** menu, select the printer icon.
- 2. The next screen will list the available printers on the vision screener. This is a list of all printers already added to the vision screener.

#### To select or change a default printer:

From the printer list, find and select the desired printer (it will auto-highlight in blue.) If more than one printer is listed, touch **Set as Default** button for the highlighted printer.

#### To configure a printer

Select a printer then press the **Edit** button to view printer status or print a test page.

#### To delete a printer

- 1. Select the printer from the available printer list; touch the **minus** button to delete.
- 2. A pop-up will appear asking you to confirm deletion of the printer.

#### To reset the printer system

This will delete all printers:

- 1. Touch the **Trashcan** icon.
- 2. A pop-up will appear; select **Delete**. This will remove all current printer configurations.

#### Adding a network printer

- 1. From the **Printers Available** screen, select the plus sign to add a printer.
- 2. If any printers are found on the network, they will appear in the list. If your printer is not shown, select **+ Add New Printer** at the top of the screen or you can select the printer you wish to add then press the continue icon.
- **Note** Make sure you are connected to a wireless network with available printers for the vision screener to show printers available.
- 3. Review the printer details (Name, Driver and Location). To change or add settings touch the field you wish to change. If you need to add a driver, you can use the search feature by typing part of the driver name in the **Search** field.

- **Note** PCL drivers are available for non-HP printers. It is not guaranteed that every printer will work with the vision screener.
- 4. Once changes have been made, select **Save**.
- 5. Once saved, the **Print Test Page** will appear dark.
- 6. A printer icon will appear in the menu bar indicating the job is processing. The number of jobs in the print queue will show up in the **Jobs** box at the top of the **Printer Details** screen, along with the current printer status.
- **Note** If you are having a problem with your printer or a print job is stuck in the queue, select the reset button to clear the print job and reset the printer.
- 7. Return to the Printers Available screen and be sure to highlight the desired installed printer and set is as the default by selecting the **Set as Default** button.

#### Adding a Direct Connect (USB) Printer

- 1. Connect the Vision Screener to a wireless network.
- 2. Connect the USB cable from the printer to the VS100's USB port.
- 3. Note the IP address of the VS100 from the main menu.
- 4. Visit the following URL on a computer on the same network: http://<ip\_address\_of\_VS100>:631/
- 5. Click on the Administration tab; under **Printers**, click on the **Find New Printer** button.
- 6. Click **Add This Printer** on the one listed with USB in the title, for example: HP ENVY 5530 series (HP ENVY 5530 series USB CN3C91S1N205XT HPLIP).
- **Note** Give the printer a simpler name for ease of typing on the VS100, for example: use ENVY5530 instead of HP\_ENVY\_5530\_series\_USB\_CN3C91S1N205XT\_HPLIP.
- 7. Click Continue.
- 8. Choose Make and click Continue, for example: HP.
- 9. Choose **Model** and click **Add Printer**, for example: HP Envy 5530 Series hpijs, 3.13.9 (en, en).
- 10. Click Set Default Options.
- 11. On the VS100, press Tools, then choose Printer.
- 12. Press the + arrow to add a new printer, then press the right arrow to choose **Add New Printer.**
- 13. Give the printer a name, for example: HP Envy 5530.
- 14. Press Edit under Driver, choose the proper driver for the printer.
- 15. Press **Edit** under **Location**, type in ipp://127.0.0.1/printers/<printer\_name>, for example: ipp://127.0.0.1/printers/ENVY5530.
- 16. Press the **Save** button.
- 17. You may now press the **Print Test Page** button to confirm everything works.

# Importing/Exporting Files

- 1. From the **Tools** menu, select **Import/Export** and you will be directed to the Import/ Export screen.
- 2. Insert a USB storage device into the USB port on the vision screener (Recommended USB size is 8GB or larger).
- 3. Once the USB device is detected, the **Import** and **Export** buttons will be available for selection and you will see the USB symbol in the upper right black bar next to the date.
- 4. The **Import** button will only become available if the vision screener recognizes a valid import file. Number of import files found will be shown on the screen.
- **Note** If the buttons do not highlight within five seconds of inserting the USB drive, remove the USB, insert it into your PC and remove all files from the drive before attempting to retry.

#### Export

- Select the Export button. If you wish to export one file containing no subject specific data select Exclude Personal Data, If you do not choose this option, then all data will be exported. Select Export button again to begin the export process.
- 2. Wait until the message "Export Finished successfully" displays, select **OK** then you may safely remove the USB drive from the vision screener.
- The exported folder name on the USB will be "Spot\_SerialNumber\_YYYYMMDD\_HHMMSS" (the folder labeled "Spot\_SerialNumber" will only contain screening data if inserted while screening subjects). It will contain:
  - Spot Criteria file (located in the "import" folder).
  - Spot Subjects Template file (located in the "db" folder).
  - Spot Results file (located in the "db" folder).
  - Spot Banner file (located in the "import" folder, will only be visible if custom banner was added).
  - Subject PDF files (located in the "pdf" folder).
- **Note** If the USB drive is removed prior to export completion, data transfer may be incomplete or become corrupted as a result.

#### Import

With the import function, you can import:

- Updated criteria files (SpotCriteria.csv)
- Future, queued, screening files (SpotSubjects.csv or Location.csv By using a Location in the name of the file, this will default all subjects in the file to a location via the name of the file, ex LakeMary.csv would default to "LakeMary" as the location for all subjects in this file)
- Custom banner for the screening reports (banner.png) The file must follow the correct naming convention for a successful import (i.e., banner.png, SpotCriteria.csv, SpotSubjects.csv. Remember SpotSubjects can have a location as the name of the file).
- Updated criteria files (SpotCriteria.csv)

#### **Custom Banner**

Welch Allyn offers the ability to add a custom banner to the bottom of the printable reports. Please note that Welch Allyn does not supply custom banners. You will need to 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. Go to **Tools**, then select **Import/Export**.
- 3. The import file option will highlight; select Import.
- 4. To verify that the file was imported successfully, screen a new subject or select a completed record and print the report. Your new banner will be printed 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 (Internet Explorer, Firefox, Safari, etc.) on a PC on the same network.

To access the webserver on the vision screener:

- 1. From your computer, open a web browser; enter the devices IP address in the address bar (this is located on the top black bar on the Home Screen).
- 2. You will be prompted to enter the username and password.

Username: *spot* Password: *0000* 

- **Note** If you have enabled security on your device, the password will be your four-digit pin code.
- 3. Default will go to the Report folder. This contains the pdf folder where you can find subject PDF files.
- 4. To view the SpotResults.csv file change to the "db" directory.

#### Licensing

In order 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 instruction document, your license is already installed and active. If you have updated the software on your device, the licensing will need to be updated as follows:

- 1. Connect an empty USB device to the vision screener USB port.
- 2. Go to **Tools**, then press the **License** button.
- 3. After a moment, a dialog box will appear indicating that the registration file has been exported to the USB drive.
- 4. Send the file titled spot-[serial number].reg to Welch Allyn Support at customerservice@welchallyn.com.

Welch Allyn Support will review your registration file and email you a valid license key. Once you receive the key, perform the following:

- 1. Save the file to the top level (root directory) of a USB Drive.
- 2. Insert the USB drive into the USB port on the vision screener.
- 3. From the **Tools** menu, select **License**. After a moment, a dialog box will appear indicating that the license file has been imported onto the device.

# 4

# Vision Screener Operation

## **Screening Environment**

For optimal screening results, screen in an environment with lower level subdued lighting. Be sure to eliminate or block any sources of sunlight and/or incandescent light from reflecting on the subject's eyes. Florescent light is acceptable but note that the subject's pupil size can be affected and can decrease your chances of a successful screening.

**Note** A minimum pupil size of 4mm is required for screening to occur and may be difficult to achieve in a room with any light source. If the pupils are too small, the vision screener will notify you on screen to adjust the lighting in the room. For best results, subject's pupils should be 5mm or greater.

#### Screening a Subject

- 1. Position yourself approximately 1 meter from the subject. If using a tripod, place the tripod approximately 1 meter from subject.
- Start screening and slowly rotate the device upward to meet both of the subject's eyes. Adjust your distance from the subject until both eyes are clear on the screen. With a tripod, adjust the tripods position up or down and side to side until the subjects eyes are in focus on the screen.

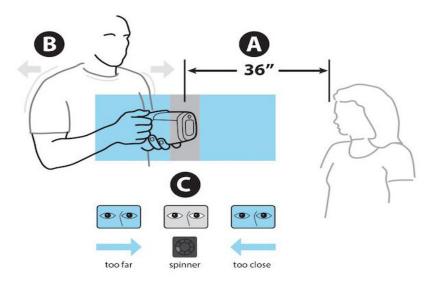
A blue screen indicates you are too close or too far from the subject.

**Note** Keeping the vision screener even (on axis) with the subject's eyes will promote quicker results and help ensure you are not capturing other objects.

Position yourself with one foot in front of the other, slowly rock forward and back until the screen turns grey, indicating you are in the capture range. When using a tripod, move the tripod as needed to ensure focus on the subject's pupils until the screen turns grey.

- 3. Keep the vision screener device steady until the screening wheel appears, indicating the capture process is underway.
- 4. If you were unable to capture the subject's pupils with a successful screening, the screening cycle will be stopped. You can retry the screening, flag the record, try monocular mode, or return to the **Home** screen.
- 5. If the pupils are too small, the device will notify you on screen to adjust the lighting in the room to promote larger pupil size.

## How to Focus the vision screener



- A Position vision screener approximately 36 inches (1 meter) away from subject.
- B Hold vision screener close to body and lean forward and backward until the screen becomes gray.
- C Make small movements until the spinner appears on the gray screen.
- **Note** Eyes should be wide open and kept on the center of the frame for best results.

#### Monocular Mode

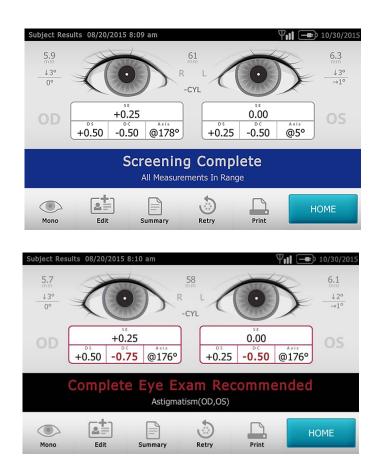
In monocular mode, you will be given the option to choose which eye to screen. This should be attempted when binocular screening does not capture the subjects' pupils.

- 1. Touch the side of the screen that corresponds with the eye you would like to screen. (OD = subjects right eye; OS = subjects left eye).
- 2. When complete, you can repeat the process with the other eye by choosing **Mono** from the **Results Options** Menu.

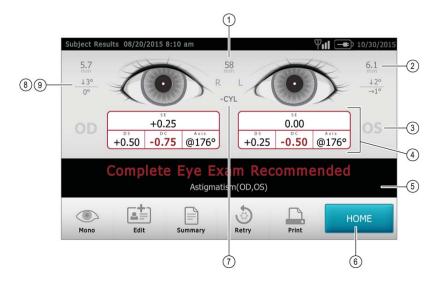
#### Viewing the Results

The results screen will appear at the end of the screening process.

All results viewing options are in the Tools menu under Results including: defaulting to a summary screen or the detailed results screen, hiding recommendations or screening results, cylinder convention options and raw or rounded data.



#### Understanding the Results



The figure below outlines the results screen and what it shows you:

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		
9	Degree, Horizontal, Vertical		

Results that are out-of-range are indicated in red.

**Note** 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.

#### Vision Screener Criteria

To modify current screening criteria:

- 1. Perform an export and insert the USB drive into your PC.
- 2. Go to the USB drive folder and open the Spot folder that you just exported; select the import folder.
- 3. Copy the file "SpotCriteria.csv" to the top folder on the USB drive (the file cannot be within a folder). Once copied, open the file.
- 4. Make any desired changes using Microsoft Excel or compatible program.
- Save file as a Comma Separated Value (.csv) file. You must make sure the file is called "SpotCriteria.csv". Eject the USB drive from your PC and insert into the vision screener.
- 6. Go to the **Tools** menu and select **Import/Export**. Select the **Import** button to import the updated criteria file.
- 7. To verify the file was imported successfully, go to the **Tools** menu and select **Criteria**; review new settings.
- **Note** When custom criteria has been imported and is in use, there will also be a **Restore** button at the bottom of the screen. This button will prompt the user to confirm they want to revert to the default criteria that was shipped with the device. By confirming, the custom criteria will be deleted from the vision screener and replaced with the default criteria.

#### **Subjects**

The vision screener gives you the ability to populate a subject list for queued subjects.

- 1. Perform an export, once complete, remove the USB drive from the vision screener and insert it into your PC.
- 2. Select the Spot folder that was just created.
- 3. Select the "db" folder, then select the "SpotSubjects.csv" file.
- 4. The SpotSubjects.csv file contains six columns; do not change any of the column headings. Simply add information to the columns as shown below:
- **Note** You may add a column before the Patient ID column and call it Location if you need to create specific locations for each subject.
  - **Patient ID**—You can use any combination of alpha, numeric characters and symbols. This field is used for quick subject look-ups.
  - First Name—Enter the first name. Use any combination of alpha characters.
  - Last Name—Enter the last name. Use any combination of alpha characters.
  - **Date of Birth**—Enter the date of birth in the format MM/DD/YYYY. You can enter the age of subject in years, months or a combination of both. This field is **required** for the import to work.

For example: If a subject were 2 years and 10 months old, you would enter 2Y10M. Use numeric and alpha characters.

- **Gender**—Select Male or enter M; select Female or enter F. Alpha characters only; leaving the field blank will default to no gender identified.
- **Eyewear prescription**—Select <u>None</u>, <u>Glasses</u>, or <u>Contacts</u>. By leaving the field blank, 'None' will be set as the default.

After updating the import file:

- 1. Confirm the file is saved as a Comma Separated Values (.csv) file.
- 2. Verify file name is 'SpotSubjects.csv' or 'DesiredLocation.csv'.
- **Note** If labeling your subject file(s) with a location, the vision screener will import all files found on the USB drive at the same time
- 3. Follow the import procedures to load the file onto the vision screener. To verify the file was imported successfully: Return to the **Home** screen and go to the **Queue** icon to view the new records.



# Troubleshooting

#### System Restart

- 1. To power cycle the vision screener press and hold the **On/Off** button until a confirmation screen appears. Select **Confirm** to power off.
- 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

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

- 1. Press the **On/Off** button.
- 2. If the **Power Off** window appears, select **Confirm** to shutdown the device.
- 3. If not, **press and hold** the **On/Off** button until the screen goes black, then release the **On/Off** button.
- 4. Wait about one minute then perform the normal start-up process.
- Note This may cause some data loss (ex. printer configuration and subject data).

#### **Printer Issues**

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

- 1. Print a test print page directly from the printer.
- 2. 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 PC on the same local network.
- 3. If all of the above are in working order perform a System Restart (see above).

#### Wireless Issues

If you encounter problems connecting to a wireless network:

- 1. Check for the **Wireless** icon in the upper right corner. If the icon is red, try power cycling the vision screener first.
- 2. Verify all network settings are entered correctly.
- 3. If the settings are correct, try turning the vision screener off, then back on.

- 4. Check on the **Home** screen to see if your network name and IP address is identified in the upper left corner in the black bar.
- **Note** Restarting helps to reinstate the connection to the network.
- 5. If the connection does not automatically reconnect, go to **Tools**, **Network**, select **Security Type**, reselect the correct type (None, WEP, WPA) then select the highlighted **OK**. This should re-instate the network connection.

#### System Messages

Specific system messages may appear while operating the vision screener. If so, the information below will assist you in identifying what the messages indicate:

Message Text	Message Actions	Meaning	Action
Sorry for the inconvenience. We need to reboot the device.	OK or Cancel	Screening mode has encountered a problem and the device needs to be restarted.	Select Continue to reboot the device or Cancel to continue using the device in Read Only mode. If the problem persists, contact Welch Allyn Support.
Problem encountered. The device needs to reboot.	Reboot	The system was not able to start and has attempted to correct the issue.	Select Reboot and try again. If problem persists, contact Welch Allyn Support.
The screening system is not available.	None	The Exam system did not initialize, or is unresponsive.	Power cycle the device and try again. If problem persists, contact Welch Allyn Support.
The screening system is not initialized.	None	The Exam system did not initialize, or is unresponsive.	Power cycle the device and try again. If problem persists, contact Welch Allyn Support.
Device has not finished saving the previous screening.	None	The system has detected that it is still saving files to disk from a previous exam.	Power cycle the device and try again. If problem persists, contact Welch Allyn Support.
Un-calibrated device	None	The system has not been able to read the device configuration file.	Power cycle the device. If problem persists, contact Welch Allyn Support.

For more information on troubleshooting or error messages, contact Welch Allyn's support team (refer to the inside cover of this manual for additional contact information).

# 6

# **Cleaning the Vision Screener**

#### **Clean the Vision Screener**



**WARNING** Electric shock hazard. Before cleaning the monitor, 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. Power down 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. If the vision screener is on, lock the display and disconnect the DC power cord.

The following agents are compatible with the vision screener:

- 70 percent isopropyl alcohol
- 10 percent chlorine bleach solution

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

#### 70 percent isopropyl alcohol

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

#### 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 monitor.

# 7

# Specifications

The power supply/charger's supplied with the vision screener have the following characteristics:

- This vision screener DFU document is valid for software versions 3.0.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 a Class II equipment and the vision screener is also a 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 quickly and easily detects vision issues across all age groups starting at 6 months.
- 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.
- The USB port shall only be used for software download/upload via a USB flash drive and shall not be cable connected to any other device.

#### **Specifications**

Mfg: SL Power Electronics Model: MENB1040A1503N01 or MEMB1040A1541N01 Input Voltage: 90 – 264VAC (100 – 240VAC Nominal) Input Frequency: 47 – 63 Hz Input Current: 100VAC: 1.1A Avg. Efficiency: 81-87% @ 0-50 W, ≥87% @ >51 to 250 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 b/g/n Operating Temperatures (°C): +10 to +40 Operating Humidity: 30% to 75% Relative Humidity (non-condensing) Storage/Shipping Temperatures (°C): 0 to +50 Storage/Shipping Humidity: 0% to 95% Relative Humidity (non-condensing) Storage/Shipping Atmospheric Pressure: 800 hPA to 1060 hPA Expected Battery Life: 2.5 Years (Under Normal Usage)

#### Screening capacity

**Note** 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</li>
   > 3.50D to 7.50D, ± 1.00D

Cylindrical:

- Range: -3.00D to +3.00D in 0.25D increments
- Accuracy : -1.50D to 1.50D,±0.50D
   -3.00D to < -1.50D, ±1.00D</li>
   >1.50D to 3.00D, ±1.00D

Cylindrical Axis:

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

Pupil size:

- Range: 4.0 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 photorefraction (photoretinoscopy) is used to estimate the magnitude of ametropia based on characteristics of the light reflex in the pupil.

## **Environmental Protection**

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.

# 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 EN 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.

This product 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 this product in the presence of high-frequency surgical equipment.
- However, it is good practice to avoid using this product in extremely close proximity to other equipment.



**WARNING** Avoid using the vision screener adjacent to or stacked with other equipment 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** Use only accessories recommended by Welch Allyn for use with the vision screener. Accessories not recommend by Welch Allyn might affect the EMC emissions or immunity.

**WARNING** Maintain minimum separation distance between the vision screener and portable RF communication equipment. Vision screener performance might degrade if you do not maintain a proper distance between equipment.

**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.

Emission 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 cause any interference in nearby electronic equipment.	
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments other the domestic establishments and those directly connected to a public low-voltage power supply network that supplies buildings used for domestic purposes, provided the follow	
Harmonic emissions IEC 61000-3-2	Class A	warning is heeded: WARNING This equipment/system is intended	
Voltage fluctuation/ flicker emission IEC 61000-3-3	Complies	for use by healthcare professionals only. This equipment/ system may cause radio interfere or may disrupt the operation of nearby equipment <sup>a</sup> . It may be necessary to take mitigation measures, such as re-orienting or relocating the device or shielding the location	

<sup>a</sup> 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 RED 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) EN 61000-4-2	±8 kV contact ± 15 kV air	±8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±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 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	$\begin{array}{c} <0 \ \% \ U_T \ (>100 \ \% \ dip \ in \ U_T) \\ for 1 \ cycle \ 70 \ \% \ U_T \ (30 \ \% \ dip \ in \ U_T) \\ dip \ in \ U_T) \ for \ 25/30 \ cycles \\ <0 \ \% \ U_T \ (>100 \ \% \ drop \ in \ U_T) \\ for \ 0.5 \ cycles @ \\ 0^\circ, \ 45^\circ, \ 90^\circ, \ 135^\circ, \ 180^\circ, \\ 225^\circ, \ 270^\circ, \ \& \ 315^\circ \ for \ 250/ \\ 300 \ cycles \end{array}$	<0 % $U_T$ (>100 % dip in $U_T$ ) for 1 cycle 70 % $U_T$ (30 % dip in $U_T$ ) for 25/30 cycles <0 % $U_T$ (>100 % drop in $U_T$ ) 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 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<sub>T</sub> is the AC 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), /P 150 kHz to 80 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 1 GHz	3 V/m	d= (1.17) <b>/P</b> 80 MHz to 800 MHz
Surge EN 61000-4-5	Differential mode: ±1 kV Common mode: ±2kV	Differential mode: ±1 kV Common mode: ±2kV	d= (2.33) x $\sqrt{P}$ 800 MHz to 2,5 GHz where <i>P</i> 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 <sup>a</sup> , should be less than the compliance level in each frequency range <sup>b</sup> . Interference may occur in the vicinity of equipment marked with the following symbol: (((:)))

Note1: 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.

<sup>a</sup>Field 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.

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

#### Recommended separation distances between portable and mobile RF communications equipment and the 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 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 at the transmitter Output maximum frequency (m)

Rated max. output power of transmitter (W)	<b>150 kHz to 80 MHz</b> d= (1.17) √ <b>P</b>	<b>80 MHz to 800 MHz</b> d= (1.17) √ <b>P</b>	<b>800 MHz to 2,5 GHz</b> d= (2.33) √ <i>P</i>
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distanced 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 frequency (MHz)	Band <sup>a</sup> MHz	Service <sup>a</sup>	Modulation <sup>b</sup>	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380 - 390	TETRA 400	Pulse modulation <sup>b</sup> 18 Hz	1.8	0.3	27
450	430 - 470	GMRS 460, FRS 460	FM <sup>c</sup> ±5 kHz deviation 1 kHz sine	2	0.3	28
710	704 - 787	LTE band 13, 17	Pulse modulation <sup>b</sup> 217 Hz	0.2	0.3	9
745						
780						
810	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation <sup>b</sup> 18 Hz	2	0.3	28
870						
930						
1720	1700 - 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation <sup>b</sup> 217 Hz	2	0.3	28
1845						
1970						
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation <sup>b</sup> 217 Hz	2	0.3	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation <sup>b</sup> 217 Hz	0.2	0.3	9
5500	_					
5785	_					

#### Test specifications for enclosure port immunity to RF wireless communications equipment

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.

<sup>a</sup> For some services, only the uplink frequencies are included.

<sup>b</sup> The carrier shall be modulated using a 50 percent duty cycle square wave signal.

<sup>c</sup> 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: (1) this device may not cause harmful interference and (2) 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 the 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 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 802.11b/g/n	
Frequency	802.11b/g: 2.402 GHz to 2.480 GHz, 802.11n	
Wireless data rates	WLAN11n(OFDM)7.2/14.4/15/21.7/28.9/30/43.3/45/57.8/60/ 65/72.2/90/120/135/150 Mbps	
	WLAN11g (OFDM) 54/48/36/24//18/12/9/6 Mbps,	
	WLAN11b (CCK) 11/5.5/2/1 Mbps	
Output power	43.5 mW typical, country dependent	
Modulation	OFDM, CKK	
Channels	1 to 13	
Security/encryption/ authentication	WEP (64/128), AES, TKIP, WPA, WPA2 and WAPI	
Antenna	Pulse W1049B050 with I-PEX cable, Max Gain: 2.0dBi	
Agency approvals	US: FCC 15.247:2014, KDB 558074 V3	
	Canada: (IC) RSS-210:2010 specification RSS-Gen:2010, RSS-102, IC:4168A-VS100 based on FCC testing	
	Europe: Annex 3.2 R&TTED in 2.4 GHz bands, EN 300 328 V1.8.1:2012, EN 301 489-17 V2.2.1:2012, EN 301 489-01 V1.9.2:2011, EN62479	

# International radio compliance

Argentina	Autoridad Federal de las Tecnologias de la Informacion y las Comunicaciones (AFTIC)	Contiene Modulo CNC I.D. C-15169
Brazil	Agência Nacional de Telecomunicações (ANATEL) 4569-15-8547	"Este equipamento opera em caráter secundário, isto é, não tem direito a proteção contra interferência prejudicial mesmo de estações do mesmo tipo, e não pode causar interferência a sistemas operando em caráter primário."
	ANATEL	
Mexico	Instituto Federal de Telecomunicaciones (Federal Telecommunications Institute—IFETEL)	This product contains an approved module, Model No. WATY, IFETEL No. RCPWEWA15-1278
Singapore	Infocomm Development Authority of Singapore (iDA) ( 新加坡资讯通信发 展管理局 )	Singapore: Complies with IDS standard
South Africa	1 C A S A	TA-2015/443

South Korea Communications This equipment is Industrial (Class A) Korea Commission ((대한민 electromagnetic wave suitability equipment and 국 방송통 신위원 seller or user should take notice of it, and this 회 - KCC equipment is to be used in the places except for home. Certification number: MISP-CRI-db3-WATY 이 기기는 업무용 (A 급 ) 전자파적합기기로서 K 판 매자 또는 사용자는 이 점을 주의하시기 바라 며, 가정외의 지역에서 사용하는 것을 목적으로 합니다. **Class A Equipment** (Industrial Broadcasting & Communication Equipment) A 급 기기 (업무 용 방 송통신기자재) National Communications低功率電波輻射性電機管理辦法 Taiwan Commission(國家通 第十二條 經型式認證合格之低功率射頻電 訊傳播委員會) NCC 機, 非經許可, 公司、 商號或使用者均不得擅自變更頻率、加大功 率或變更原設計 之特性及功能。 第十四條 低功率射頻電機之使用不得影響飛 航安全及干擾合法

> Contains NCC I.D. CCAB1CLP1C20T8

This product can be used with the following restriction(s):

France — Outdoor use is limited to 10 mW EIRP within the band 2454 to 2483.5 MHz.

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

Note Effective Isotropic Radiated Power (EIRP).

### 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, rules of the Canadian ICES-003 and the essential requirements of the R&TTE Directive 1999/5/EC 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 étre prêt à accepter tout brouillage radioélectrique reçu, même si ce brouillage est susceptible de compromettre le fonctionnement du dispositif.

To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (EIRP) is not more than that required for successful communication.

This device has been designed to operate with an antenna having a maximum gain of 2.0 dBi. Antenna having a higher gain is strictly prohibited per regulations of Industry Canada. The required antenna impedance is 50 ohms.

Pour réduire le risque d'interférence avec d'autres utilisateurs, le type d'antenne et son gain doivent être choisis afin que la puissance isotrope rayonnée équivalente (PIRE) ne dépasse pas ce qui est nécessaire pour une communication réussie"

Ce dispositif a été conçu pour fonctionner avec une antenne ayant un gain maximal de 2.0 dBi. Antenne ayant un gain supérieur sont strictement interdites par la réglementation d'Industrie Canada. L'impédance d'antenne requise est de 50 ohms.

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

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

### **European Union**

This device complies with the essential requirements of the R&TTE Directive 1999/5/EC. The following test methods have been applied in order to prove presumption of conformity with the essential requirements of the R&TTE Directive 1999/5/EC:

This device is a 2.4 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.

Czech	Welch Allyn tímto prohlašuje, ze tento <i>RLAN device</i> je ve shodě se základními po_adavky a dalšími příslušnými ustanoveními směrnice 1999/5/ES.		
Danish	Undertegnede Welch Allyn erklærer herved, at følgende udstyr RLAN device overholder de væsentlige krav og øvrige relevante krav i direktiv 1999/5/EF.		
Dutch	Bij deze verklaart Welch Allyn dat deze RLAN device voldoet aan de essentiële eisen en aan de overige relevante bepalingen van Richtlijn 1999/5/EC.		
English	Hereby, Welch Allyn, declares that this RLAN device is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC.		
Estonian	Käesolevaga kinnitab Welch Allyn seadme RLAN device vastavust direktiivi 1999/5/EÜ põhinõuetele ja nimetatud direktiivist tulenevatele teistele asjakohastele sätetele.		
Finnish	Welch Allyn vakuuttaa täten että RLAN device tyyppinen laite on direktiivin 1999/5/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 1999/5/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 1999/ 5/EG. (Wien)		
Greek	ΜΕ ΤΗΝ ΠΑΡΟΥΣΑ Welch Allyn ΔΗΛΩΝΕΙ ΟΤΙ RLAN device ΣΥΜΜΟΡΦΩΝΕΤΑΙ ΠΡΟΣ ΤΙΣ ΟΥΣΙΩΔΕΙΣ ΑΠΑΙΤΗΣΕΙΣ ΚΑΙ ΤΙΣ ΛΟΙΠΕΣ ΣΧΕΤΙΚΕΣ ΔΙΑΤΑΞΕΙΣ ΤΗΣ ΟΔΗΓΙΑΣ 1999/5/ΕΚ.		
Hungarian	Alulírott, Welch Allyn nyilatkozom, hogy a RLAN device megfelel a vonatkozó alapvető követelményeknek és az 1999/5/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 1999/5/CE.		
Latvian	Ar šo Welch Allyn deklarē, ka <i>RLAN device</i> atbilst Direktīvas 1999/5/EK būtiskajām prasībām un citiem ar to saistītajiem noteikumiem.		
Lithuanian	Šiuo Welch Allyn deklaruoja, kad šis RLAN device atitinka esminius reikalavimus ir kitas 1999/5/EB Direktyvos nuostatas.		
Malti	Hawnhekk, Welch Allyn, jiddikjara li dan RLAN device jikkonforma mal-htigijiet essenzjali u ma provvedimenti ohrajn relevanti li hemm fid-Dirrettiva 1999/5/EC.		
Portuguese	Welch Allyn declara que este RLAN device está conforme com os requisitos essenciais e outras disposições da Directiva 1999/5/CE.		
Slovak	Welch Allyn týmto vyhlasuje, ze RLAN device spĺňa základné po_iadavky a všetky príslušné ustanovenia Śmernice 1999/5/ES.		
Slovene	Šiuo Welch Allyn deklaruoja, kad šis RLAN device atitinka esminius reikalavimus ir kitas 1999/5/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 1999/5/ 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 1999/ 5/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.

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Advancing Frontline Care™

Material Number 728994