

Important Product Update



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Spot™ Vision Screener 100

October 04, 2017

Dear Welch Allyn Customer:

Welch Allyn has identified an issue which could potentially affect all **Spot Vision Screener 100** patient referral recommendations for devices with software versions up to and including 3.0.04.07.

If the device is not used or charged every five months, the coin cell battery that maintains the system clock may become depleted. Once the coin cell battery has depleted, the system clock will reset to a date in the past (date of the last installed software release for example). This may cause the patient age to be calculated incorrectly. Please note, the patient age is used by the Spot Vision Screener 100 to determine referral criteria for certain screening conditions—specifically Anisometropia, Myopia, Astigmatism and Hyperopia. An incorrect patient age could result in an incorrect (either under or over) referral recommendation.

Actions to be taken by distributors:

1. Forward this Important Product Update to your end-user customer and instruct them to take the actions below.
2. If you have any questions, contact Welch Allyn at 1-800-535-6663.

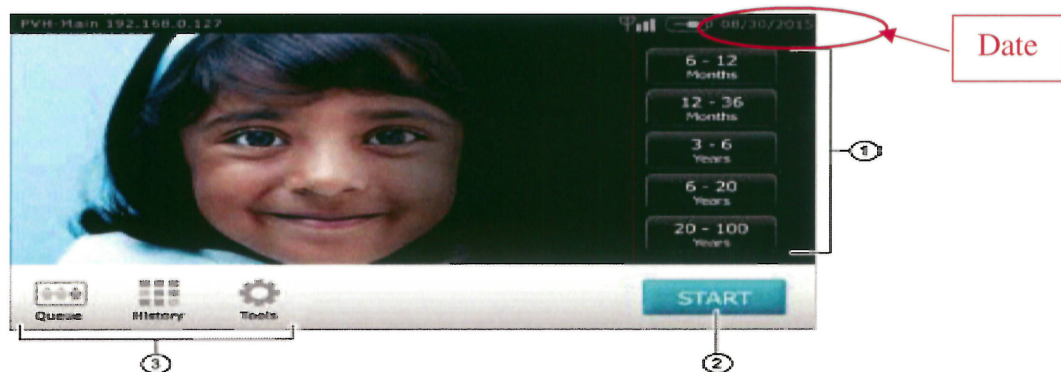
Actions to be taken by end-users:

1. Welch Allyn recommends that you regularly charge and utilize your Spot Vision Screener 100 and check the date associated with the system clock on the device to ensure that it is correct. The date in the top right-hand corner of the display should display today's date. If the date is incorrect, manually set the date using the attached "Setting the System Clock" instructions provided below.
2. Inform all users of the device to check the date associated with the system clock on the device regularly.
3. Add the attached "Setting the System Clock" instructions to the User's Guide as a reminder to check the date associated with the system clock on the device each time the device is used.
4. If you have any questions, contact Welch Allyn at 1-800-535-6663.

As a reminder, the patient referral recommendation is intended to help the healthcare professional assess whether the patient should be referred to an eye care specialist for further evaluation or simply monitored at future screenings. The screening is not intended to replace a full eye examination.

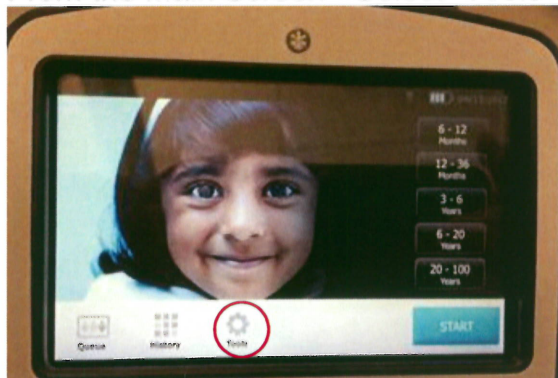
Setting the System Clock

Note: These instructions should be kept with the User's Guide.



Procedure to manually set the date:

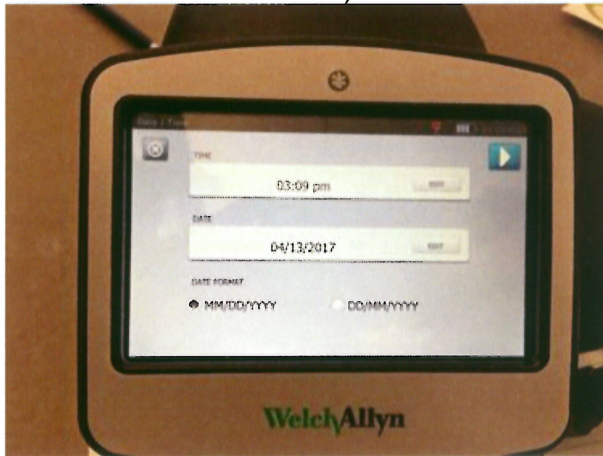
From the Main Screen - Select "Tools"



On the Tools Screen - Select "Date / Time"



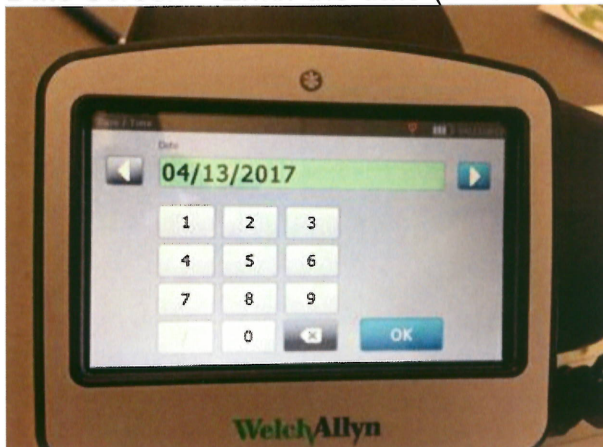
On the Time / Date Screen - Select Time Edit and Date Edit (Note: MM/DD/YYYY is the default Date Format)



Time Screen - Enter the time (HH:MM AM/PM) using the keypad then select OK



Date Screen – Enter the date (MM/DD/YYYY) using the keypad then select OK



When finished press the forward arrow (top right corner) and then close the tools screen (by selecting "X" in the top left corner).