Welch Allyn[®] Surveyor™ Central

USER MANUAL ADDENDUM

Manufactured by Welch Allyn, Inc. Skaneateles Falls, NY U.S.A.





CAUTION: Federal law restricts this device to sale by or on the order of a physician.

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For patent information, please visit: www.welchallyn.com/patents

For information about any Welch Allyn product, visit: <u>https://www.welchallyn.com/en/about-us/locations.html</u>

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1.USER SAFETY INFORMATION



NOTE: This manual may contain screen shots and pictures. Any screen shots and pictures are provided for reference only and are not intended to convey actual operating techniques. Consult the actual screen in the host language for specific wording of the corresponding user manual.



Warnings

- This manual gives important information about the use and safety of this system. Deviating from operating procedures, misuse, or ignoring specifications and recommendations could result in increased risk of harm to users, patients and bystanders, or damage to the system.
- Users are expected to be licensed clinical professionals knowledgeable about medical procedures and patient care, and adequately trained in the use of this entire system. Patient monitor captures and presents data reflecting a patient's physiological condition that when reviewed by a trained physician or clinician can be useful in determining a diagnosis; however, the data should not be used as a sole means for determining a patient's diagnosis.
- Before attempting to use this device for clinical applications, the operator must read and understand the contents of the user manual and other accompanying documents. Inadequate knowledge or training could result in increased risk of harm to users, patients and bystanders, or damage to the system. Contact Welch Allyn Technical Service for additional training options.
- Operation of the equipment beyond its specified ranges, or beyond normal physiological conditions of human subjects, may cause inaccurate results.
- Repairs, configurations and modification must be made by authorized and trained technical personnel. Unauthorized modifications and repairs will void the warranty and may pose a danger to patients and users.
- Various alarm conditions require operator to adjust alarm configurations individualized according to patient condition and demographics. Refer to the devices user manuals for details on how to operate or change the alarm settings. Inappropriate alarm configuration settings may render the alarm system useless.
- A patient monitoring system is an addition to monitoring patient status and is not intended to replace clinical assessments and clinical judgments. It is important that a qualified individual regularly supervise the patient.
- In an environment where multiple systems, whether Surveyor and/or other systems, are utilized for monitoring patients, use of different alarm presets on each system may pose a safety risk. Be careful in using different alarm conditions on different systems.
- Always ensure that the Patient Mode (adult, pediatric, neonate) is set appropriately for the patient since different default parameters of the monitor's operation may be used depending on mode.

2. ADDENDUM TO THE USER MANUAL

This addendum is intended to provide information to operators to help them understand how the Welch-Allyn Connex Spot Monitor works (hereinafter CSM) when it is part of a Surveyor Welch Allyn monitoring network. The operator is required to verify that the workflow described in this document corresponds to what they observe and to report any discrepancies.



WARNING: The Welch-Allyn CSM user instructions can be found in the CSM user manual supplied with the device.



WARNING: Similarly, the instructions for use of the Welch Allyn Surveyor Central Station (the monitoring station) are contained in the Surveyor Central user manual.



WARNING: Refer to the above manuals to obtain details and clarifications for operating each individual device.

3. DATA COMMUNICATION

The CSM device will be connected to the data network by Welch Allyn personnel. The connection can be either wired LAN or wireless LAN. Once the connection is made, the operator does not need to perform further operations to connect to the network.

INTERFACED PARAMETERS

The Welch-Allyn CSM device, when introduced into a Surveyor network, allows measurement and subsequent transmission of the following parameters:

- Non-invasive blood pressure
- Temperature (both tympanic and cutaneous)

Any other parameters present on the CSM, such as SpO2, are not part of this interface and are not transmitted to Surveyor Central.

Both non-invasive blood pressure (NiBP) and temperature are spot measurements, *i.e.* they are taken at intervals of time, and are not designed for continuous function.

NOTE ON ALARMS

Both devices (CSM and Surveyor Central) are equipped with an independent alarm generation system. Refer to the respective manuals for information on the functionality and type of alarms available.

The Surveyor monitoring system includes a monitoring station that receives data from different devices, for example CSM and S4, and compares the values of these parameters with the alarm thresholds set by the operator. Therefore, refer only to the Surveyor Central as a device that emits alarms and warnings for the operator. Further details on alarm levels can be found in the Surveyor Central manual.

Similarly, the operator can set the alarm limits on the CSM device as needed. Further details on alarm levels can be found in the CSM manual.

Attention: The alarm thresholds for the CSM and Surveyor Central are independent of each other. Therefore, any changes to the limits made on the CSM will not be extended to Surveyor Central, and vice versa. To have identical configurations the operator will have to manually modify the limits on both devices.

OPERATING MODE

There are two modes of operation:

Without deletion of patient information

This mode requires that the operator choose a patient from among those available in the patient list (see below for updating this list). From this moment, all the measurements taken will be assigned to the chosen patient, until the operator selects a different patient. The operator can choose to perform manual or timed measurements. In the case of timed measurements, these will be automatically sent to Surveyor Central without the need for confirmation by the operator. For manual measurements, the device requires the operator to save a measurement before sending.

With cancellation of patient information

In this mode, the operator needs to select a patient from the patient list each time a measurement is taken.

The device requires the operator to save the measurement before sending it to Surveyor Central.

After the measurement has been sent to Surveyor Central, the patient data is deleted. It will therefore be necessary to select a new patient before proceeding to a new measurement.

Naturally, the type of mode depends on the context of use and the needs of the medical personnel. In any case, the operating mode to be used is defined during the device installation.

NOTE: To change from one mode to another, the CSM must be reprogrammed. Contact Welch Allyn personnel if a mode change is necessary.

PATIENT LIST AND DEVICE ASSOCIATION WITH PATIENT ANAGRAPHY

When the CSM is in a Surveyor monitoring network, the patient list is provided by the Surveyor Central. The implemented interface does not include the insertion of patients outside the Surveyor Central list. Therefore, any personal data entered manually on the CSM cannot be sent to Surveyor Central. From the CSM it is always possible to select a patient from the list sent by Surveyor Central. As we will see below, there are other restrictions on the type of patient with which the parameters measured on the CSM device can be associated.

The choice of a new patient typically occurs when a patient has been discharged, especially in timed mode.

Note: In order to always have current patient data available, it is advisable to update the patient list before making the patient association on the CSM. Refer to the instructions below.

MODE WITHOUT CANCELLATION OF PATIENT INFORMATION

To obtain the patient list follow the procedure below (consult the CSM manual for details).

1. Turn on the CSM



2. Click on the arrow as shown



3. The patient list last downloaded will appear. Click on the "Rec.list" button



4. If the communication between the CSM and Surveyor Central has been successful, the patient list will update. Note the patient list shown on the CSM includes only the patients monitored by Surveyor Central through Surveyor S4. In case the patient list update cannot be completed, a visual and acoustic notification message will display. The visual message will be at the top of the screen.

5. Select a patient, for example, JOHN DOE:



The patient selected will become the new active patient, and all measurements taken will be assigned to this patient.

6. Press OK to continue.

	09:51	n 🖬 🖇 🖬
Nome paziente		Posizione del paziente
Cognome	ID paziente	Stanza
DOE,JOHN	121212	
Nome		Letto
SC000000015	Adulto	
Iniziali	Data di nascita	
		Elenco

As you can see in the picture, Patient JOHN DOE, ID no. 121212, is the one currently selected.

-	09:51		D (199)
D PAZIENTE 121212	TIPO Adult D O N	NOME PAZIENTE DOE, JOHN, SCO	
	SIS 220	EPOLS	
SIS/DIA mmHg (PAM)		©/MIN	2
Sp02 +	100	TEMPERATURA	
	90	°C (°F)	34.5
Alt. Ps IJ	MC D RR BPM	Cancella Sal	Na
Home	Allierrei	Riesamina	to dia

4. MODE WITH CANCELLATION OF PATIENT INFORMATION

To obtain the patient list, follow the procedure below (consult the CSM manual for details).

1. Turn on the CSM



2. Click on the arrow as shown



3. The patient list last downloaded will appear. Click on the "Rec.list" button



4. If the communication between the CSM and Surveyor Central has been successful, the patient list will update. Note the patient list shown on the CSM includes only the patients monitored by

Surveyor Central through Surveyor S4. In case the patient list update cannot be completed, a visual and acoustic notification message will display. The visual message will be at the top of the screen.

5. Select a patient, for example, JOHN DOE:



6. The patient selected will become the new active patient for a single measurement. As soon as the measurement is sent to the Surveyor Central, the patient is dissociated from CSM. The operator must associate a new patient by following the instructions above.

5. PATIENT DATA ASSOCIATION BETWEEN CSM AND SURVEYOR CENTRAL

The Surveyor Central provides the following personal data, associated with the fields displayed on the CSM as shown in the table below:

CSM field name	Field content with data from the monitoring station
Surname	Surname + first name
First name	HIS identifier
ID	Patient ID
Date of birth	Date of birth

Important: if the CSM device is completely switched off, the association with the selected patient will be lost. Perform the association again, as described above.

Loss of an association will be highlighted when you try to send a measurement. The device will emit a sound and an error message.

Attention: Check that the device is associated with the correct patient before sending a spot measurement or before starting a series of measurements in timed mode.

6. MEASUREMENTS IN SPOT MODE

To take a measurement of NIBP (non-invasive blood pressure) or temperature (both tympanic and cutaneous) as recommended by the manufacturer, refer to the operating manual of the CSM device.

The following images show the main stages of taking a measurement.

For temperature measurement, (the examples refer to a tympanic temperature measurement):

1. Take the measurement



2. Place the meter in the device



3. The screen will show the data acquired



4. Press the "Save" button. At the top left of the screen, one of the following two messages will appear:



If the transmission is successful, after about two seconds, the measured values in the associated patient window will appear on the control panel screen:



As can be seen, the non-invasive blood pressure and external temperature values are displayed within the associated patient window.

Note: The non-invasive blood pressure value (NiBP) is displayed on Surveyor Central patient slot together with the acquisition time.

Note: The temperature figure will be deleted from the screen 30 minutes after reception of the parameter on the control panel. Therefore, in the absence of subsequent temperature measurements, the temperature field on the control unit for the associated patient will be empty.

Note: Similarly, if you request a printout when the temperature value has been removed because older than half an hour, the printout will exhibit a question mark where the temperature value is expected.

Note: If a transmission fails, wait a few seconds, verify the association with the patient and repeat the transmission. If the error persists, contact Welch Allyn technical assistance.

7. MEASUREMENTS IN TIMED MODE

Timed mode is only available for NiBP measurements. Refer to the CSM manual for using timed mode.

Once timed mode has started, the sending of NiBP measurements will be automatic (it is not necessary to press **Save** at the end of each measurement).

However, temperature measurements require the presence of the operator to determine the patient's temperature. To send a measurement taken, press **Save.**

8.ALARMS

The Surveyor Central allows setting of all the alarms related to all the parameters of the connected devices.

For telemetry patients associated to a CSM, the following alarm thresholds can be set:

- High systolic (SYS) non-invasive pressure
- Low systolic (SYS) non-invasive pressure
- Mean high non-invasive pressure
- Mean low non-invasive pressure
- High diastolic (DIA) non-invasive pressure
- Low diastolic (DIA) non-invasive pressure
- High external temperature
- Low external temperature

For each alarm threshold, it is possible to set additional parameters that depend on the type of alarm. Refer to the Surveyor Central operator's manual for full details.

NOTE: In the event of a delay in receiving the parameters, if the measured values violate the threshold, the alarm time displayed on Surveyor Central will be different from the acquisition time and will be equal to the received time in Surveyor Central; this can occur in the case of network connection problems that prevent the parameters from being sent immediately.

NOTE: Surveyor Central generates a new alarm for each measurement sent by the CSM that breaches the set alarm thresholds. For example, if the systolic non-invasive pressure alarm threshold is 140 mmHg and the CSM transmits a value of 150, Surveyor Central will sound an alarm. If the next measurement is 160, Surveyor Central will sound a new alarm.

NOTE: Any local alarms set on the CSM are not sent to Surveyor Central.

NOTE: Surveyor Central does not manage the technical alarms relating to the non-invasive pressure and temperature parameters received from the CSM.

9. PATIENT DISCHARGE

It is important that the operator rigorously follow the workflow to associate a patient with the CSM to avoid incorrect patient-device associations.

Therefore, at the time of admitting a new patient it is essential that the operator perform the association operation both on the monitoring station and on the CSM. After the application of an ECG cable and SpO2 sensor on the S4 it is required that the operator select the new patient on the CSM. In this way, all subsequent NiBP and temperature measurements will be assigned to the new patient.

Likewise, if a patient is discharged from the monitoring station, *i.e.* if monitoring on the monitoring station is stopped, the operator must disassociate the patient by making a new association on the CSM, because disassociation is not automatic.

10. COMMON PROBLEMS

- Measurements not transmitted by the CSM to the monitoring station. Check that there is an LAN cable or Wi-Fi signal. Check that the CSM is able to update the patient list. Check that the CSM is associated with the right patient. Check that the associated patient is currently being monitored. Check that the transmission services (NCE - Gateway) are active. Contact Welch Allyn technical personnel for further details.
- 2. Measurements transmitted to the wrong patient.

Check that the CSM is associated with the correct patient. See the following example:

There is a limited risk of assigning measurements to an incorrect patient in this specific case:

- Patient Rossi is in Bed 5 (for example)
- Patient Rossi is transferred to Bed 9 (for example)
- Patient Verdi is admitted to Bed 5
- The CSM of Bed 5 is not re-programmed for the new patient
- All measurements taken by the CSM for Bed 5 (Patient Verdi) will be assigned to Patient Rossi