

Patient SafetyNet™ with Halo ION™



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

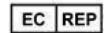
Note: Cleared Use Only: The device and related accessories are cleared by the Food and Drug Administration (FDA) and are CE Marked for noninvasive patient monitoring and may not be used for any processes, procedures, experiments, or any other use for which the device is not intended or cleared by the applicable regulatory authorities, or in any manner inconsistent with the directions for use or labeling.

For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, and precautions.

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Addendum, Patient SafetyNet™ with Halo ION™

This addendum provides updates to the following:

Operator's Manual, Patient SafetyNet™ Supplemental Alarm System Series 5.0.0.0

- 37339/LAB-8419 and equivalent translations

This addendum covers the Halo ION feature of the Patient SafetyNet system. For all other information, refer to the *Operator's Manual, Patient SafetyNet Supplemental Alarm System Series 5.0.0.0*.

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About this Manual

This manual explains how to configure and use the Patient SafetyNet™ with Halo ION™. Important safety information relating to general use of the Patient SafetyNet with Halo ION appears in this manual. Read and follow any warnings, cautions, and notes presented throughout this manual. The following are explanations of warnings, cautions, and notes.

A *warning* is given when actions may result in a serious outcome (for example, injury, serious adverse effect, death) to the patient or user. The following is an example of a warning:

Warning: This is a sample of a warning statement.

A *caution* is given when any special care is to be exercised by the patient or user to avoid injury to the patient, damage to this device, or damage to other property. The following is an example of a caution:

Caution: This is a sample of a caution statement.

A *note* is given when additional general information is applicable. The following is an example of a note:

Note: This is a sample of a note.

Product Description, Features, and Intended Use

The following information is to be used with the information in the **Product Description, Features and Intended Use** section of the **Operator's Manual, Patient SafetyNet Supplemental Alarm System Series 5.0.0.0** manual.

Product Description

Patient SafetyNet is a supplemental remote monitoring and clinician notification system. It provides a secondary display of Masimo SET® pulse oximetry, rainbow SET™ pulse CO-Oximetry and acoustic respiration rate monitors.

Patient SafetyNet may consist of the following components and/or features:

- Halo ION

Technology Overview

The following information is to be used with the information in the *Technology Overview* section of the *Operator's Manual, Patient SafetyNet Supplemental Alarm System Series 5.0.0.0* manual.

Halo ION Overview

Halo ION is a tool intended to be used by clinicians to configure and automate a customizable scoring system that facilitates the assessment of patient status according to hospital protocol. The parameters included in the Halo ION score, the acceptable parameter limits, and the weight of each parameter are configured by the hospital system. Halo ION is not intended to be used as a diagnostic measurement. Monitored parameters, in conjunction with clinical signs and symptoms, should be used as the primary sources for assessing patient status for the purpose of diagnostic decisions.

Note: Halo ION is not intended for the treatment of specific diseases.

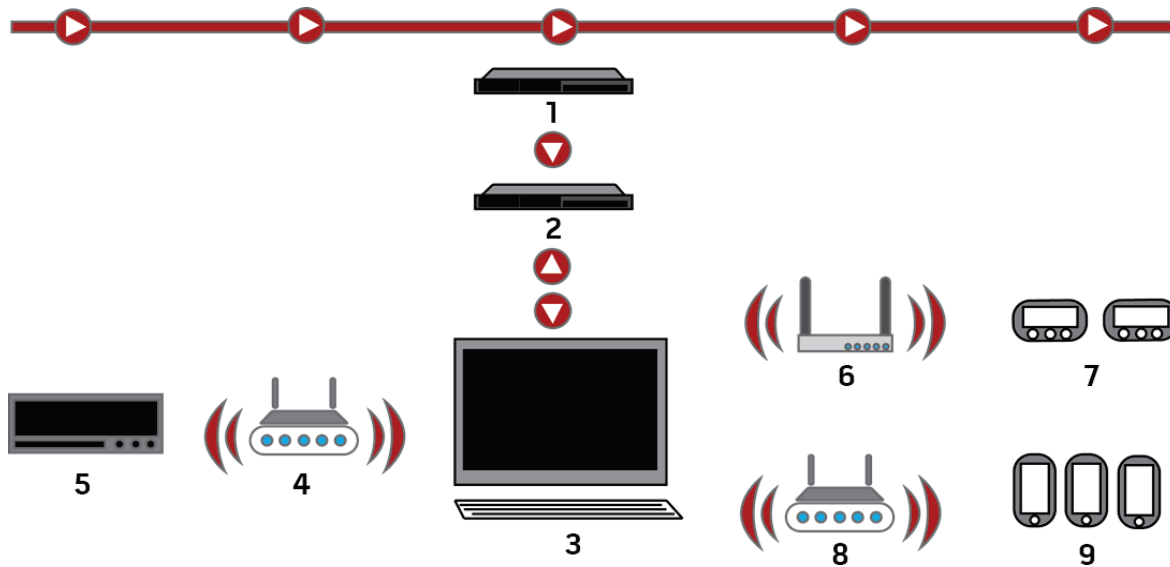
For additional information see *Halo ION* on page 15.



System Components

The following information is to be used with the information in the *System Components* section of the *Operator's Manual, Patient SafetyNet Supplemental Alarm System Series 5.0.0.0* manual.

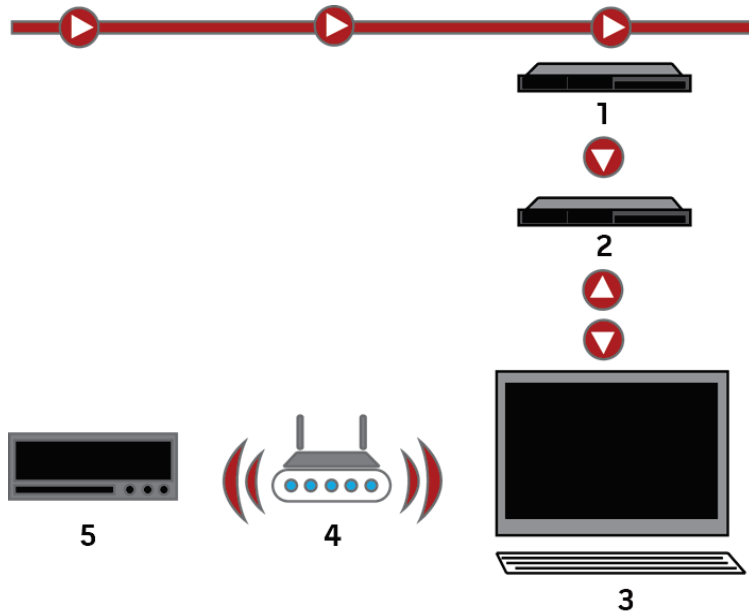
For Clinician Paging/Notification Mode



Item	Description	Item	Description
1	Halo ION Appliance	6	Paging Transmitter
2	Patient SafetyNet Appliance	7	TAP Pagers (Notification Device)
3	Patient SafetyNet View Station	8	Notification Gateway
4	802.11 Wi-Fi Access Point	9	IP Phones or other Notification Devices
5	POC Device	-	--

1. The device is connected to the Point-of-Care (POC) Device via a DB9 serial (male-male) Null Modem Cable. In some cases, devices may have built-in communication technologies.
2. Depending on the network configuration, the POC Device communicates through a wireless access point(s), or is hard wired to a switch.
3. The Wireless Access Point(s) transmit data through a network switch to the Patient SafetyNet Appliance. The Access Point(s) connect to the network switch via standard network cable.
4. The Patient SafetyNet Appliance is capable of communicating with the Wireless Access Points across the network.
5. The Halo ION Appliance is connected to the Patient SafetyNet Appliance through a USB cable.
6. The Patient SafetyNet View Station is capable of communicating with the Patient SafetyNet Appliance across the network. The Patient SafetyNet View Station allows clinicians access to the Patient SafetyNet Appliance for Admission, Discharge, and Notification Device assignments.
7. The Paging Transmitter is capable of communicating with the Patient SafetyNet Appliance across the network.
8. IP phones or other notification devices can communicate through a wireless access point(s) with the Patient SafetyNet Appliance across the network.

For Central Surveillance Mode



Item	Description
1	Halo ION Appliance
2	Patient SafetyNet Appliance
3	Patient SafetyNet View Station
4	802.11 Wi-Fi Access Point
5	POC Device

1. The device is connected to the POC Device via a DB9 serial (male-male) Null Modem Cable. In some cases, devices may have built-in communication technologies.
2. Depending on the network configuration, the POC Device communicates through a wireless access point(s), or is hard wired to a switch.
3. The Wireless Access Point(s) transmit data through a network switch to the Patient SafetyNet Appliance. The Access Point(s) connect to the network switch via standard network cable.
4. The Patient SafetyNet Appliance is capable of communicating with the Wireless Access Points across the network.
5. The Halo ION Appliance is connected to the Patient SafetyNet Appliance through a USB cable.
6. The Patient SafetyNet View Station is capable of communicating with the Patient SafetyNet Appliance across the network. The Patient SafetyNet View Station allows clinicians access to the Patient SafetyNet Appliance for Admission, Discharge, and Notification Device assignments.

Patient SafetyNet User Operation

The following information is to be used with the information in the *SafetyNet User Operation* section of the *Operator's Manual, Patient SafetyNet Supplemental Alarm System Series 5.0.0.0* manual.

Detail View Screens

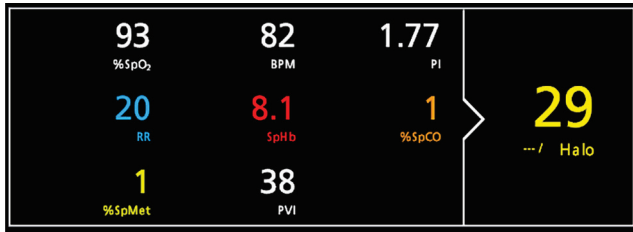
Halo ION



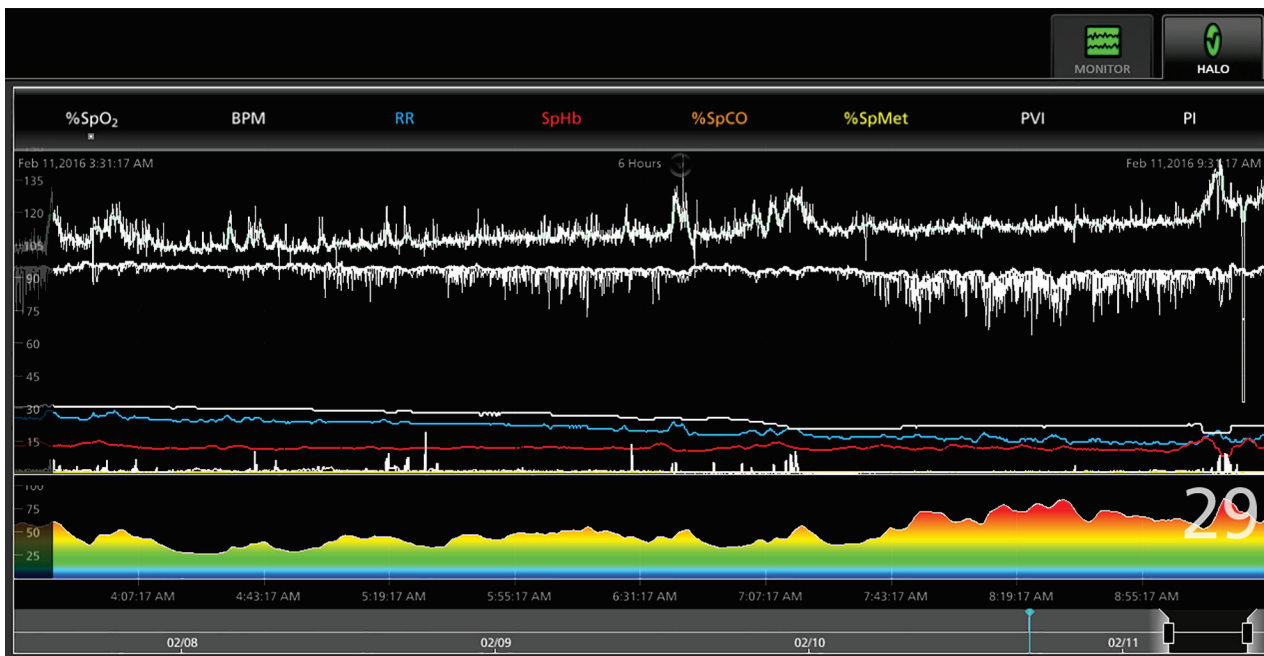
Halo ION is an optional feature of the Patient SafetyNet with Halo ION system. Halo ION is viewed by selecting the *Halo* tab in the *Detail View*. See *Detail View* in the *Operator's Manual, Patient SafetyNet Supplemental Alarm System Series 5.0.0.0* manual for additional information.

Halo ION uses a patient's physiologic parameter measurements from a Masimo device to calculate the Halo ION score. The Halo ION score is a single number with a range from 0 to 100 that combines multiple physiologic parameters to facilitate the cumulative trending assessment of patient status. A high score is indicative of patient risk per hospital protocol.

The parameters, acceptable limits, and the weights with which they contribute to Halo ION scores are unique to the configuration determined by the clinician or hospital system.



All Halo ION parameter trend lines are displayed together in the trend window. Individual parameter trends can be removed from view by selecting the parameter label at the top of the trend window. Below each parameter label, a contribution indicator may be displayed (see SpO₂ as an example in the image below). The larger the indicator, the more that specific parameter is contributing to the Halo ION score.



Monitoring Patients

Admit

When admitting patients to Patient SafetyNet with Halo ION, Date of Birth is a required field.

System Administration

The following information is to be used with the information in the *System Administration* section of the *Operator's Manual, Patient SafetyNet Supplemental Alarm System Series 5.0.0.0* manual.

Configuration

System Settings

Modify System Settings

When modifying Patient SafetyNet with Halo ION System Settings, note the following items:

Note: If the Halo ION appliance is installed, Date of Birth is selected by default and **CANNOT** be de-selected.

CAUTION: Ensure the **CORRECT AGE** of the patient is entered when using Patient SafetyNet with Halo ION. Entering an incorrect age may affect the Halo ION score.

Specifications

The following information is to be used with the information in the **Specifications** section of the **Operator's Manual, Patient SafetyNet Supplemental Alarm System Series 5.0.0.0** manual.

Note: Use only components and accessories approved by Masimo. The use of non-approved parts may produce unreliable system operation.

Halo ION Appliance

Item	Description
Physical Dimensions (H x W x D)	1.74 x 18.36 x 21.65 in (4.43 x 46.64 x 55 cm)
USB	USB cable connection (Patient SafetyNet with Halo ION Appliance connection only)
Operating Temperature	5°C to 40°C (41°F to 104°F)
Storage Temperature	-40° to 70°C (-40°F to 158°F)
Operating Humidity	5% to 95% non-condensing
Storage Humidity	5% to 95% non-condensing



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