GE Healthcare

CARESCAPE™ Surveillance Monitoring System
User's Manual

CARESCAPE Surveillance Monitoring System
English
2066502-030 (CD)
2066502-056 (paper)

NOTE
Due to continuing product innovation, specifications in this manual are subject to change without notice.

NOTE
For technical documentation purposes, the abbreviation GE is used for the legal entity name, GE Medical Systems *Information Technologies,* Inc.

Contents

1

About this manual

Manual Information

Purpose

This manual contains the instructions necessary to operate the CARESCAPE Surveillance Monitoring System safely and in accordance with its function and intended use.

Intended audience

This manual is intended for clinical professionals. Clinical professionals are expected to have a working knowledge of medical procedures, practices, and terminology, as required for monitoring of ill patients.

Related documents

The *CARESCAPE Surveillance Monitoring Service Manual* provides information on supplies and accessories approved for use with this system.

For detailed setup instructions and service issues or detailed information on ADT-related issues and networking topics, please see the *CARESCAPE Surveillance Monitoring Service Manual.*

Conventions used

Text styles

This manual uses the following styles to emphasize text or indicate action.

Item	Description
bold	Indicates hardware terms.
bold italic	Indicates software terms.
italic	Indicates terms for emphasis.

Illustrations and names

This manual uses illustrations as examples only. Illustrations in this manual may not necessarily reflect all settings, features, configurations, or displayed data. Names of persons, institutions, places and related information are fictitious; any similarity to actual persons, entities, or places is purely coincidental.

Revision history

The part number and revision letter for this manual are at the bottom of each page. The revision letter changes whenever the manual is revised. The first letter shown in this revision history table is the first customer-released version of this document.

Revision	Description
A	Initial release.

Ordering manuals

A paper copy of this manual will be provided upon request. The part number is shown on the first page of the manual. When ordering additional operator manuals, be sure to include the software version of the product.

Service Calls and Product Support

To open a service call or obtain product support call the number below:
800.558.7044 (US & Canada)

Outside the US, contact your local GE representative or distributor. For other product information please contact one of the offices listed on the back cover of the manual.

Ordering Accessories and Service Parts

Order accessories (leadwires, electrodes, recording papers, etc.) or service parts (manuals, cables, software, etc.) from:

Accessories and Supplies
GE Healthcare
8200 West Tower Avenue
Milwaukee, WI 53223
Telephone: 800.558.5102 (US only)
414.355.5000 (outside US)
Fax: 414.355.3790

Service Parts
GE Healthcare
P.O. Box 9100, 100 Marquette Drive
Jupiter, FL 33468-9100
Telephone: 800.558.7044 (US only)
561.575.5029 (outside US)
Fax: 800.421.6841 (US only)
561.575.5050 (outside US)

Have the following information available before calling:
- part number of the defective part, or
- model and serial number of the equipment,
- part number/name of the assembly where the item is used, and
- item name

Other Questions or Problems

For additional information contact one of the offices listed on the back cover of the manual or visit our website at http://www.gehealthcare.com.

Equipment information

Indications for use

The Intelesens Vital Signs Monitor: Aingeal (VS200) is used to monitor and transmit physiological data to a web based host application for display or analysis by a clinician. The device can be worn by ambulatory or non-ambulatory adult patients in a healthcare environment to support clinical staff when they are carrying out their routine observations or when a patient would otherwise be in an unmonitored or unobserved situation.

This re-usable device is intended to be used on the patient for short term periods only. The device is intended to be used on adult patients for monitoring of ECG, respiration, heart rate, skin temperature and activity levels in a healthcare setting.

The device can be used where information on ECG, respiration, heart rate, skin temperature, and activity levels would be useful.

The device uses on-board ECG arrhythmia detection algorithms to automatically record and send ECG data if the user is suspected to be experiencing an arrhythmia event. The device transmits the data to the host application at user defined intervals or upon the detection of an arrhythmia event

The Bernoulli Management System (MS) Software is a software application intended to be used on a central monitoring station on patients using supported devices in a hospital or hospital-type environment. It is used to provide a secondary display of multi parameter monitor data (ECG, respiratory rate, pulse oximetry, ETCO2, blood pressure, cardiac output, temperature and associated derived outputs), lung ventilator, respiratory gas monitor, IV infusion (including PCA) pump, feeding pump and related ancillary devices, and to provide remote monitoring and alarm surveillance. This application is also intended to provide primary alarm surveillance for devices where no alarm notification capability is enabled or available. The Bernoulli MS is intended to supplement and not replace any part of the current device monitoring procedures.

The Bernoulli Management System (MS) Software is to be used under license by or on the prescription for use by a physician or licensed healthcare professional in the course of his/her professional practice.

NOTE The Bernoulli Management System (MS) Software and the Intelesens Vital Signs Monitor: Aingeal (VS200) are being marketed as the CARESCAPE Surveillance Monitoring System.

Safety statements

Safety message signal words designate the severity of a potential hazard. The signal words danger, warning, caution, and notice are used throughout this manual to point out hazards and to designate a degree or level of seriousness. A hazard is defined as a source of potential injury to a person. Learn their definitions and significance.

DANGER Indicates a hazardous situation that, if not avoided, will result in death or serious injury.

WARNING Indicates a hazardous situation that, if not avoided, could result in death or serious injury.

CAUTION Indicates a hazardous situation that, if not avoided, could result in minor or moderate injury.

NOTICE Indicates a hazardous situation not related to personal injury that, if not avoided, could result in property damage.

NOTE Provides additional information to clarify a particular concept or operation instruction, and appear throughout this manual in each corresponding category.

The order in which safety messages are presented in no way implies the order of importance. The following safety messages apply to the system. Safety messages specific to parts of the system are found in the relevant section of this manual.

Warning safety messages

The following warning safety messages apply to this system:

WARNING Do not use the CARESCAPE Surveillance Monitoring System for real-time patient monitoring as there is a time delay in transmission of data from patient to Surveillance Station.

WARNING Assembly, extensions, readjustments, modifications or repairs to any components of the CARESCAPE Surveillance Monitoring System are only to be carried out by authorized personnel. Failure to comply may impact on the safety, reliability and performance of the system.

WARNING The CARESCAPE Surveillance Monitoring System is not intended to be a substitute for direct clinical supervision. Do not operate unless qualified personnel are in attendance to promptly respond to alarms, inoperative conditions, or sudden malfunctions. Patients on life-support equipment should be visually monitored at all times.

WARNING It is essential that the Surveillance Station be monitored at all times. Do not rely on pagers as the sole source of alarms.

WARNING Do not use medical devices, parts, accessories, or options with the CARESCAPE Surveillance Monitoring System that are not described in this manual.

WARNING Do not use a PG300 device, PG300 battery pack, Surveillance Station or other system component that appears to be damaged.

WARNING The PG300 battery pack or any other system component must be removed from service if they ever become submerged in liquid. Immersion in liquid may cause inaccurate performance or device failure.

WARNING The PG300 device must never be used on patients with a pacemaker or an ICD.

WARNING The PG300 device must be removed along with the PG300 electrode array prior to undergoing an MRI scan, CT scan, x-ray, defibrillation or surgical procedure.

WARNING Do not ignore medical device audible alarms. Alarms indicate conditions that require immediate attention.

WARNING When new alarm settings are created, there is a delay of up to two minutes in transferring these setting changes to the PG300 device. New settings are only transferred during the normal data reporting interval cycle.

WARNING Smart alarm settings and features may create additional (or unwanted) alarms and should be carefully considered before implementing.

WARNING High and Medium priority alarms need to be addressed by a clinician in order of priority. Low priority alarms will clear automatically once the alarm condition is no longer met.

WARNING Acknowledgement of a message may not correct the underlying cause of the alarm. Messaging will continue until the condition which causes the alarm is cleared.

WARNING When audio is silenced or Audio OFF is enabled, alarm audio breakthrough DOES NOT OCCUR.

WARNING No alarms will be displayed until the PG300 device has been connected to the PG300 electrode array patch and the PG300 device has been associated with a patient in the Surveillance Station.

WARNING The Alarm Setup feature is an application to be used by trained administrative users only. Use of the system should be carefully understood, and an institutional procedure should be established that outlines required training and approvals when editing alarm settings.

WARNING Silencing alarms should be done in accordance with hospital procedures.

WARNING Do not apply the PG300 electrode array to a patient with a skin disorder in the electrode array application site. Incorrect PG300 electrode array application may impair the quality of ECG and respiration recordings.

WARNING Place the battery charger in a suitable location, where it will be protected from damage, liquid ingress, moisture or extreme temperature.

WARNING IMPROPER PG300 DEVICE APPLICATION – Applying a PG300 device that is not thoroughly dry to a patient can result in an electrically conductive path being established and a Leads OFF alarm not being provided if the PG300 device detaches from the PG300 electrode array.

WARNING The PG300 device must not be cleaned without a PG300 battery pack correctly fitted.

WARNING SHOCK HAZARD – Disconnect AC-powered devices from the power line before cleaning or disinfecting them. Turn OFF the power to the battery-powered devices before cleaning or disinfecting them.

WARNING Do not expose PG300 battery packs to heat or fire. Avoid storage in direct sunlight.

WARNING Do not short circuit a PG300 battery pack. Do not store batteries haphazardly in a box or drawer where they may short circuit each other or be short circuited by other metal objects.

WARNING In the event of a battery pack leaking do not allow the liquid to come in contact with the skin or eyes. If contact has been made, wash the affected area with copious amounts of water and seek medical advice.

WARNING The PG300 battery pack must not be submerged in water or other liquid.

WARNING Ensure the PG300 device serial number matches the serial number of the PG300 device assigned to the patient on the Surveillance Station.

Caution safety messages

The following caution safety messages apply to this system:

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

CAUTION The Surveillance Station software is intended for use with these medical devices:
- PG300
- Covidien (Nellcor) N-395, N-560, N-595, N-600, N-600X
- Masimo Rad-7, Rad-8, Rad-9

CAUTION Failure on the part of the responsible hospital or institution employing the use of this monitoring equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.

CAUTION The displayed data is limited to that provided by the medical device The care and handling of all software and hardware associated with the Surveillance Station should be in accordance with local hospital guidelines, policies, and procedures.

CAUTION Use only approved accessories and hardware for the Surveillance Station. Use only an approved keyboard that does not have any audio controls.

CAUTION The Surveillance Station software is intended to run on computers that meet the minimum requirements set forth in the Technical Specifications. No applications other than those specified should be installed or executed on the workstation or server.

CAUTION Do not spray, pour, or spill any liquids on any of the Surveillance Station components, its accessories, connectors, switches, or openings in the chassis, since this may damage the system.

CAUTION Do not use the PG300 device on patients who are pregnant or pediatric patients.

CAUTION Monitoring does not begin until a device is assigned to a patient.

CAUTION Do not press the On/Off button unless the intention is to turn ON or OFF the device.

CAUTION Alarm Pause or inactivating an alarm, cannot be undone or terminated. The paused alarm will not reoccur until the pause period has passed regardless of whether or not the alarm condition persists. Reset alarms will reoccur if the alarm condition persists.

CAUTION Data is sent every minute (configurable up to 60 minutes) from the wearable PG300 device to the Surveillance Station. Alarms are sent immediately to the Surveillance Station, and data is sent every minute thereafter, until the alarm condition is cleared. If the Surveillance Station does not receive data in a timely fashion, a system-generated alarm will display “No Current PG300 Data” message and the stale measurement data will be removed shortly thereafter.

CAUTION Care should be taken when removing the PG300 electrode array from the patient to avoid damaging the skin.

CAUTION The PG300 electrode array should only be used by or in consultation with a healthcare provider familiar with its proper placement and use.

CAUTION The Audio Pause button does not apply to bedside SpO_2 monitors. Clicking the Audio Pause button does not silence the SpO_2 monitor.

CAUTION The PG300 device should be connected to the PG300 electrode array as soon as possible, after electrode array application.

CAUTION Data is sent every five minutes from the wearable PG300 device to the Surveillance Station. Alarms are sent immediately to the Surveillance station, and data is sent every five minutes thereafter, until the alarm condition is cleared. If the Surveillance Station does not receive data in a timely fashion, a system-generated alarm will display “No Current PG300 Data” message and the last known measurements will strike-out.

CAUTION Clinicians should understand the nature of each alarm and provide treatment accordingly. If a patient is experiencing more than one alarm condition, care should be given accordingly.

CAUTION Do not pour or spray any liquid directly on cables or leadwires or permit fluid to seep into connections or openings.

CAUTION Never use conductive solutions that contain chlorides, wax, or wax compounds to clean devices.

CAUTION During cleaning of the CARESCAPE Surveillance Monitoring System, never use solutions or products that contain the following:

- Any type of Ammonium Chloride such as, but not limited to:
  - o Dimethyl Benzyl Ammonium Chloride
  - o Quaternary Ammonium Chloride solution
- Abrasive cleaners or solvents of any kind
- Acetone
- Ketone
- Betadine
- Sodium salts

CAUTION DEVICE DAMAGE – Never autoclave or steam clean devices, cables, or leadwires.

CAUTION DISPOSAL – At the end of its service life, the products described in this manual, as well as any accessories must be disposed of in compliance with all regulatory requirements pertinent to the disposal of each product. If you have any questions concerning disposal of a product, please open a service call or obtain product support by calling 800.558.7044 (US & Canada). Outside the US, contact your local GE representative or distributor.

CAUTION The PG300 battery pack is not a serviceable part. Do not attempt to dismantle the battery pack.

CAUTION The PG300 battery pack may only be charged using the 12-bay battery charger. Use with any other battery charger may result in damage to the battery or affect system operation.

Notices

NOTICE Due to the inherent nature of IT networks, connectivity and network delays may occur. This may result in an alert at the Surveillance Station.

Device symbols

The following symbols appear on one or more of the system devices:

Icon	Description
	WLAN connection status LED
	Leads OFF LED
 YYYY-MM	Date of manufacture. This symbol indicates the date of manufacture of this device. The first four digits identify the year and the last two digits identify the month.
	Manufacturer name and address
	Serial Number including Date of Manufacture
	European Union declaration of conformity
	Type CF (IEC 60601-1) protection against electric shock. Isolated (floating) applied part suitable for intentional external and internal application to the patient, including direct cardiac application.
	Non-ionizing
	Underwriters Laboratory (UL) certification covering United States of America, Canada

	This symbol indicates that the waste of electrical and electronic device must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of the device.
	See instructions for use
REF	Catalogue or orderable part number
LOT	Batch code
	Attention
+	Denotes positive charge location
-	Denotes negative charge location
	Do not get wet
	PG300 electrode array placement indication (LEFT)
	PG300 electrode array placement indication (RIGHT)
	Do not reuse
	Use by
LATEX	Latex free
	Upper and lower limits of temperature
FC IPX1	Federal Communications Commission
9900223	ETL SEMKO (formerly Edison Testing Laboratory)

Surveillance Station user interface symbols

Icon	Description
	Low priority alarm indicator
	Medium priority alarm indicator
	High priority alarm indicator
	Audio ON button
	Audio Paused button
	Audio Paused indicator
	Audio OFF button
	Audio OFF indicator
	Alarm Paused indicator
	Alarm Reset indicator
	Unassigned PG300 device, actively transmitting data
	Unassigned PG300 device, not actively transmitting data
	PG300 device icon
	SpO_2 Monitor icon
	Battery fully charged indicator
	Battery Low indicator
 Critical Battery	Critical Battery indicator
	Battery status unknown indicator
C°	Celsius indicator
F°	Fahrenheit indicator
s	Seconds indicator
	Network activity indicator

	Save report
	Print report
	Zoom out report
	Zoom in report
	Barcode icon
	Add Device button
	Remove Device button
	Reporting Patient icon
	Active Patient icon
	Combined ECG and RESP waveform indicator
	ECG waveform indicator
	Resp waveform indicator

PG300 device and battery charger compliance

CE marking compliance information

The PG300 device and battery charger bear CE mark CE-0120 indicating their conformity with the provisions of the Council Directive 93/42/EEC concerning medical devices and they fulfill the essential requirements of this directive. The PG300 device also complies with the R & TTE directive 99/5/EEC. The PG300 device is in radio-interference protection class B in accordance with EN 55011. The PG300 device and PG300 battery charger comply with the requirements of standard EN 60601-1-2 “Electromagnetic Compatibility -Medical Electrical Equipment”.

Device Classification	**Compliance**
Type of protection against electrical shock	PG300 device – Internally powered PG300 battery charger – CE marked, double insulated AC/DC transformer.
Degree of protection against electrical shock	Type CF defibrillation proof applied part
Degree of protection against harmful ingress of water	PG300 device - IPX7 (IEC 60529)
Degree of protection in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.	Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or oxygen or nitrous oxide
Method(s) of sterilization or disinfection recommended by the manufacturer	n/a
Mode of operation	Continuous operation

FCC declaration

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.

No changes shall be made to the equipment without the permission of Intelesens Ltd. as this may void the user's authority to operate the equipment.

RF exposure

This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment.

The PG300 device has been tested and meets the FCC RF exposure guidelines when used against the body under normal usage conditions.

The maximum SAR value reported is 0.933 W/Kg.

This transmitter must be installed in accordance with the operating instructions and must not be co-located or operating in conjunction with any other antenna or transmitter.

Surveillance Station compliance

CE marking information

Products Covered by this Declaration of Conformity	Bernoulli® Enterprise Management System Software
Product Type	Central/Remote Monitoring Software
Device Class	Class IIb
Mode of Operation	Continuous Operation

General Compliance

- IEC 60601-1:2005, EN60601-1:2006, ANSI/AAMI ES60601-1:2005
- ANSI/AAMI/IEC 60601-2-27:2011, IEC 60601-2-27:2011
- IEC 60601-2-49:2011
- ISO 80601-2-56:2009
- IEC 62366:2007
- EN ISO 80601-2-61: 2011
- EN60601-1-8:2007, IEC 60601-1-8:2006
- IEC 62304:2006 Medical Device software - Software Life Cycle Processes
- CAN/CSA-C22.2 No.60601-1:08 – Part 1

2

System overview

Introduction

This chapter provides an overview of the equipment used in the CARESCAPE Surveillance Monitoring System.

WARNING Do not use the CARESCAPE Surveillance Monitoring System for real time patient monitoring as there is a time delay in transmission of data from patient to Surveillance Station.

WARNING The CARESCAPE Surveillance Monitoring System is not intended to be a substitute for direct clinical supervision. Do not operate unless qualified personnel are in attendance to promptly respond to alarms, inoperative conditions, or sudden malfunctions. Patients on life-support equipment should be visually monitored at all times.

WARNING Do not use a PG300 device, PG300 battery pack, Surveillance Station or other system component that appears to be damaged.

WARNING The PG300 device, pager, PG300 battery pack or any other system component must be removed from service if they ever become submerged in liquid. Immersion in liquid may cause inaccurate performance or device failure.

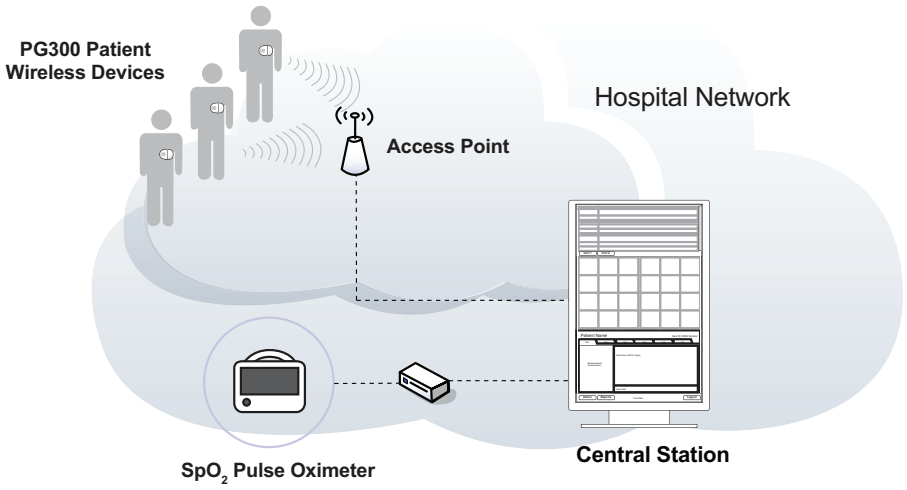
CAUTION US federal law restricts this device to sale by or on the order of a physician.

CAUTION The Surveillance Station software is intended for use only with the medical devices listed.

CAUTION The Surveillance Station software is intended to run on computers that meet the minimum requirements set forth in Appendix E, Technical Specifications. No applications other than those specified should be installed or executed on the workstation or server.

NOTE See the *CARESCAPE Surveillance Monitoring Service Manual* for detailed hardware installation procedures.

CARESCAPE Surveillance Monitoring System



The CARESCAPE Surveillance Monitoring System is a solution that enables clinicians to manage patient data (including alarms) while allowing for patient mobility. Wearable PG300 devices attached to patients communicate via a wireless network to send physiological parameters such as ECG, Heart Rate, Respiration Rate, Skin temperature, as well as lethal and high acuity arrhythmias to the Surveillance Station. The Surveillance Station displays a graphical user interface containing monitored patients, rooms, relevant patient physiological data, and alarms.

The system monitors the following parameters on an interval (one sample per interval) of 1 to 60 minutes:

- Heart Rate (8 beat average)
- Respiration Rate (30 second average)
- Skin Temperature

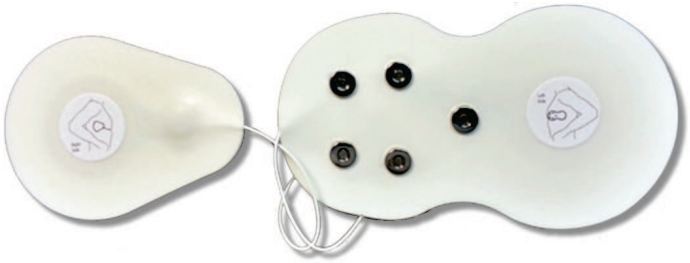
The system consists of the following components:

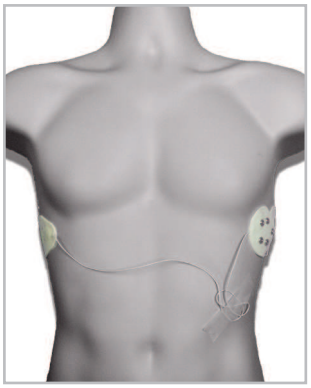
- PG300 electrode array
- PG300 device (wearable transmitter)
- PG300 battery pack
- PG300 battery charger
- AC/DC Transformer and power lead (Country specific)
- Surveillance Station

Optional Components:

- Additional Surveillance Stations
- Bar Code Scanner
- SpO_2 patient monitor
- Paging System
- EMR
- ADT integration

PG300 electrode array





The PG300 electrode array is a disposable, pre-gelled single lead ECG, skin temperature and respiration array that is applied to each side of the patient's body. The PG300 electrode array is to be used only with the PG300 device. The PG300 electrode array may be worn for a continuous period up to 72 hours.

The PG300 electrode array consists of two adhesive patch sensor arrays attached by a wire. The larger patch contains 5 magnetic studs for the attachment to the PG300 device, along with a thermistor used to capture skin temperature. The smaller patch contains a pre-gelled active measurement area. The PG300 electrode array comes in a resealable clear plastic bag. Four of these bagged electrodes are contained within a sealed pouch. To open, tear the pouch seal across the top, starting from the incision on the side.

The pouch contains the PG300 electrode array. The PG300 electrode arrays have the ability to obtain an ECG signal. The wire between the two PG300 electrode arrays is 65 centimeters long, therefore any patient wider than this (one side of rib cage to the other) may not be suitable for monitoring by the PG300 system, as the measurement site will not give accurate results. The patient's chest circumference should be measured prior to opening the PG300 electrode array pouch.

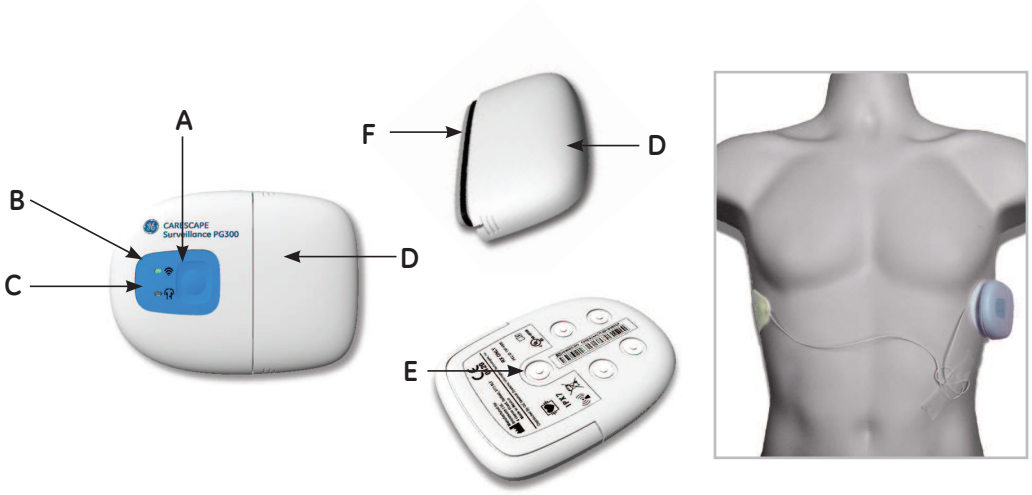
NOTE See Chapter 3, Getting Started, Skin preparation.

PG300 device

The PG300 device monitors physiological parameters and is a wireless, wearable vital signs and respiratory monitor. It is a small, battery-operated system comprised of the PG300 device (a body worn transmitter), and PG300 battery pack. The PG300 device connects to the network using WLAN.

WARNING Do not use medical devices, parts, accessories, or options that are not for use with the CARESCAPE Surveillance Monitoring System as described in this manual. Only recommended computer and network components shall be used.

PG300 device features



A	ON/OFF button
B	Connection LED: Orange or Green LED indicates monitor status
C	Blue LED indicates Leads OFF (fault)
D	PG300 battery pack
E	Connecting studs
F	X-ring

PG300 battery pack

The PG300 battery pack contains a rechargeable 3.7V lithium ion battery required to power the PG300 device. The PG300 battery pack also incorporates a replaceable flexible x ring which creates a waterproof seal when the battery is correctly fitted to the device.

WARNING The PG300 device, pager, PG300 battery pack or any other system component must be removed from service if they ever become submerged in liquid. Immersion in liquid may cause inaccurate performance or device failure.

CAUTION Ensure the x ring is correctly located and is not twisted prior to inserting the PG300 battery pack.

Handling, storage and disposal of PG300 battery packs

WARNING Do not expose PG300 batteries to heat or fire. Avoid storage in direct sunlight.

WARNING Do not short circuit a PG300 battery. Do not store batteries haphazardly in a box or drawer where they may short circuit each other or be short circuited by other metal objects.

WARNING In the event of a battery leaking do not allow the liquid to come in contact with the skin or eyes. If contact has been made, wash the affected area with copious amounts of water and seek medical advice.

WARNING The PG300 battery pack must not be submerged in water or other liquid.

CAUTION The PG300 battery pack is not a serviceable part. Do not attempt to dismantle the battery pack.

CAUTION The PG300 battery may only be charged using the 12-bay battery charger. Use with any other battery charger may result in damage to the battery or affect system operation.

NOTICE Do not subject PG300 batteries to mechanical shock.

NOTICE Do not use any battery which is not designed for use with this equipment.

NOTICE Do not leave a PG300 battery on prolonged charge when not in use.

NOTICE The PG300 battery pack must be disposed of in accordance with relevant waste disposal regulations.

NOTE After extended periods of storage it may be necessary to charge and discharge a PG300 battery pack several times to obtain maximum performance.

NOTE Remove the PG300 battery pack from the PG300 device when not in use.

NOTE Do not remove a PG300 battery pack from its original packaging until required for use.

NOTE Charge the PG300 battery pack in accordance with the instructions in this document.

PG300 battery charger

The 12-bay PG300 battery charger can charge up to 12 rechargeable PG300 battery packs at any one time.

WARNING Do not use medical devices, parts, accessories, or options that are not for use with the CARESCAPE Surveillance Monitoring System as described in this manual. Only recommended computer and network components shall be used.

AC/DC transformer and power lead

An AC/DC transformer and power lead cable (Country specific) is required for connection between the PG300 battery charger and mains supply.

NOTE See Appendix E, Technical Specifications.

Surveillance Station

The Surveillance Station should be placed in an open area that should be clearly visible from a wide viewing angle. The Surveillance Station is configured by the manufacturer according to the system configuration checklist. The display monitor requires a standard cable connection to the Workstation. A standard keyboard and mouse should be securely connected to the Workstation.

The Surveillance Station should be on at all times, and responding to incoming data and user interaction. The workstation is designed to operate in continuous kiosk mode. Access to the operating system, menu bar and desktop are disabled without valid security credentials.

WARNING Assembly, extensions, readjustments, modifications or repairs to any components of the CARESCAPE Surveillance Monitoring System are only to be carried out by authorized personnel. Failure to comply may impact on the safety, reliability and performance of the system

WARNING The CARESCAPE Surveillance Monitoring System is not intended to be a substitute for direct clinical supervision. Do not operate unless qualified personnel are in attendance to promptly respond to alarms, inoperative conditions, or sudden malfunctions. Patients on life-support equipment should be visually monitored at all times.

CAUTION The care and handling of all software and hardware associated with the Surveillance Station should be in accordance with local hospital guidelines, policies, and procedures.

CAUTION Use only approved accessories and hardware for the Surveillance Station. Use only the approved keyboard specified in Technical Specifications that does not have any audio controls.

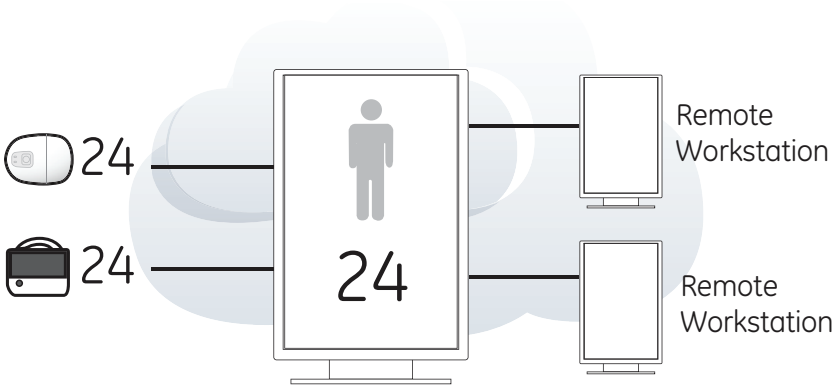
Surveillance Station components

Standard components include:

- 27-inch display
- Application & Database Server with integrated Speakers
- Standard Keyboard
- Standard Mouse

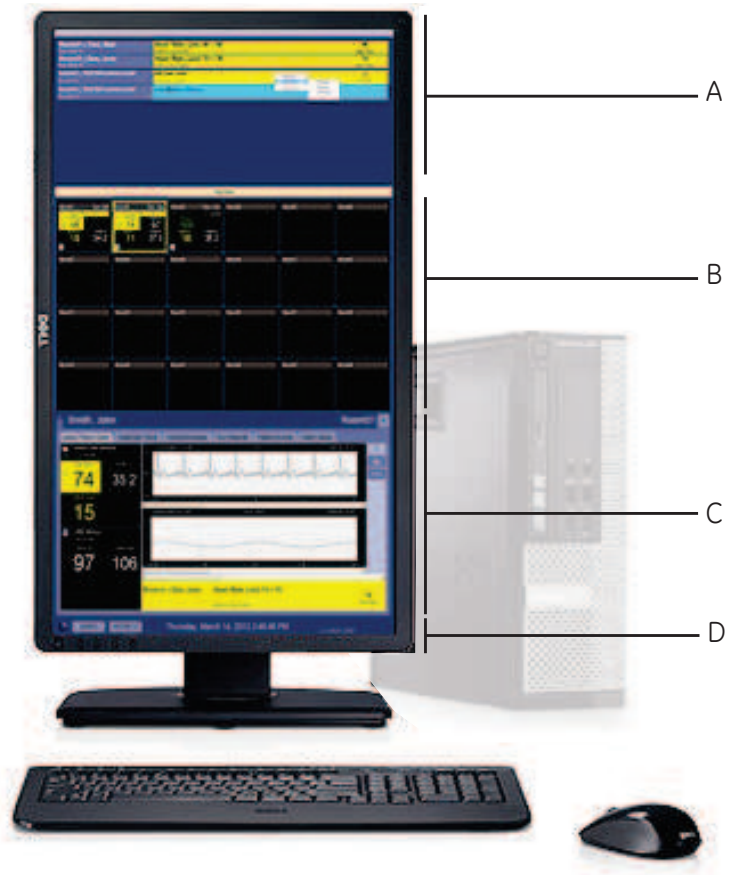
Single-ward configuration

The Surveillance Station (single-ward configuration) is a system designed to support individual care units in a hospital, that allows for a maximum of 24 beds (rooms) and up to 48 devices (24 PG300 devices and 24 SpO_2 patient monitors). A total of 24 patients can be monitored with 2 devices; one PG300 device and one SpO_2 monitor. The single-ward configuration may incorporate up to two additional workstations (different locations for viewing) that provide a remote view of the same 24 beds.



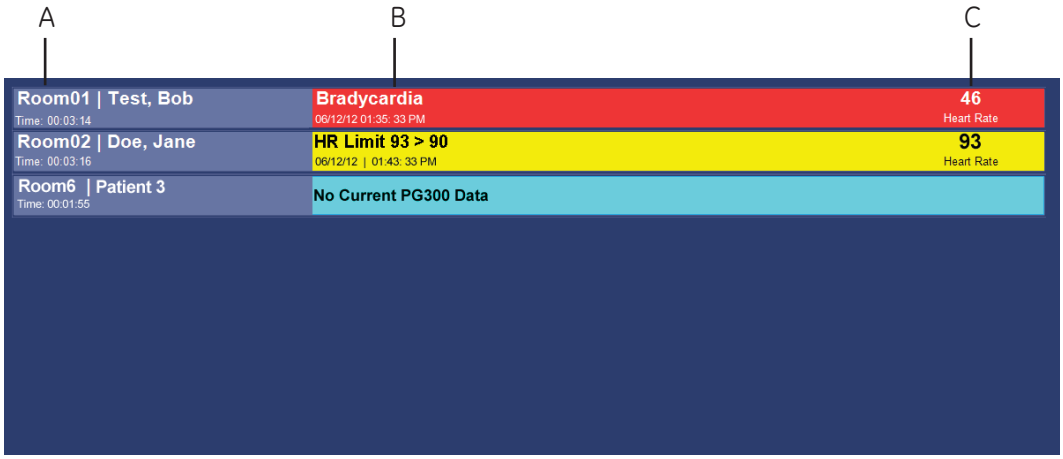
Surveillance Station function areas

The Surveillance Station screen incorporates three distinct viewing areas that perform different functions. These viewing areas are described below in either a single or dual display configuration.



Display area	Description
A	Alarm Summary Scrolling window
B	Tile View with Unit Buttons
C	Single Patient View with Tabs
D	System Date/Time Status Messages

Alarm Summary



A	Room/Bed & Patient Name, Elapsed Time since event
B	Alarm Descriptions & Time of Event
C	Patient's current measurement for parameter in alarm

The Alarm Summary provides a listing of active patient alarms. When a patient alarm occurs, an Alarm Bar will display. This bar contains data related to the alarm including Room/Bed ID, Patient Name, alarm description, elapsed time of the alarm, and measurement of the parameter in alarm.

Left-clicking an Alarm Bar with the mouse will cause the Single Patient View to activate. Right-clicking each Alarm Bar offers additional options for managing alarms.

NOTE The Alarm Summary is used to alert caregivers of specific alarm conditions related to an PG300 device or SpO_2 monitor. If a device alarms that is not associated with the system, it will not display.

NOTE Alarms are displayed in reverse chronological order. High priority alarms will always be displayed first (top). Alarms that have not been addressed (elapsed time) will be displayed first. Up to 350 alarms can be displayed.

NOTE Technical alarms will be removed if a condition is no longer present. An **Alarm Bar** from a device alarm will display until a user resets or pauses the alarm.

NOTE When an alarm is paused at the device (SpO_2), audio will be paused but the **Alarm Bar** will remain. When audio is restarted at the device (SpO_2), audio will resume if the alarm condition still exists.

Tile View

24 Tiles

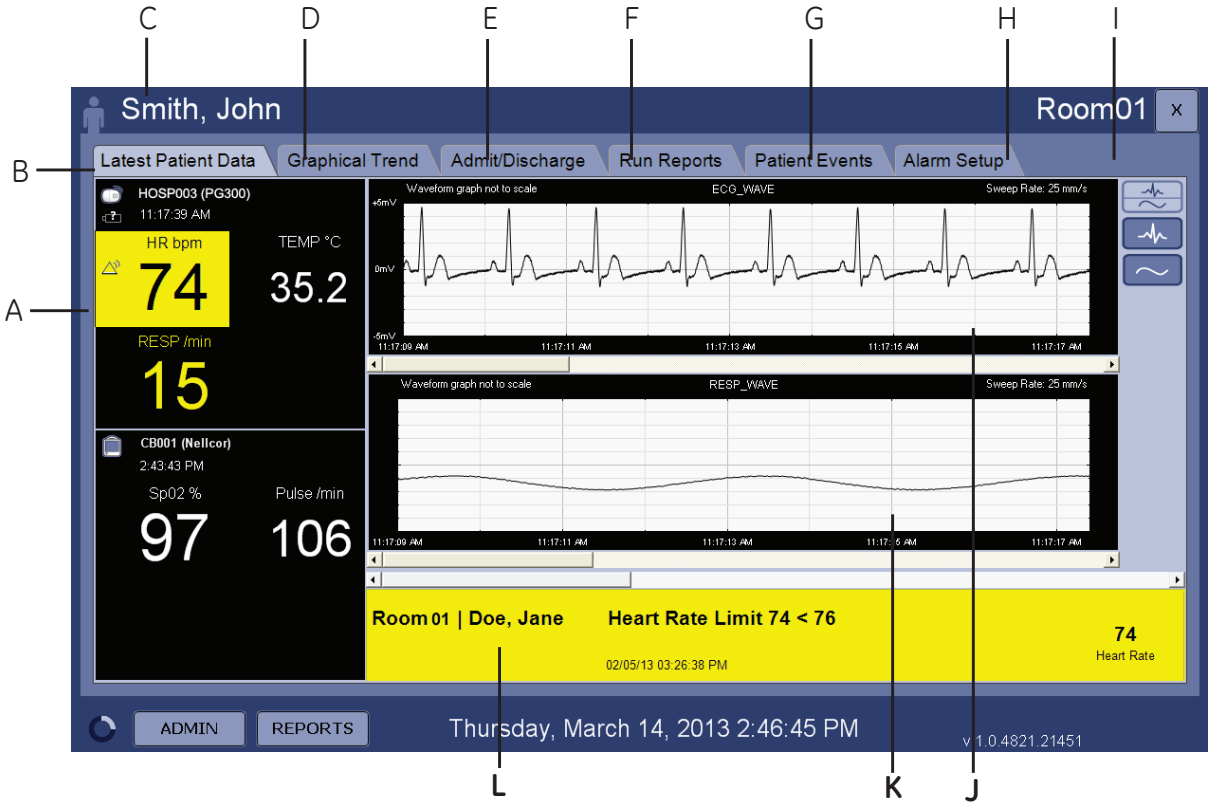
A	Unit Buttons
B	Active Patient Tiles
C	Inactive Patient Tile

The Tile View provides a grid of up to 24 Patient Tiles that display a patient's clinical measurements, along with alarms and alarm messages. When an alarm is triggered, the Patient Tile border changes color, an audible tone sounds, the parameter in alarm is highlighted, and an appropriate text description of the alarm is displayed.

Left-clicking or selecting a Patient Tile on the Tile View with the mouse will cause the Single Patient View to activate.

NOTE Devices are associated to patients by users, and patients are associated with a Room/Bed. Rooms/Beds are grouped by Units.

Single Patient View



A	Device data area
B	Default Tab view, Latest Patient Data
C	Patient Name
D	Graphic Trend Tab view
E	Admit/Discharge Tab view
F	Run Reports Tab view
G	Log of Events Tab view
H	Alarm Setup Tab view
I	Room/Bed or MRN
J	ECG waveform area
K	RESP waveform area
L	Alarm Bar

The Single Patient View provides a detailed assessment of a patient's condition, displaying the latest patient data, waveform images and alarm conditions. The Single Patient View uses a Tab concept with the default view showing the latest measurements and data provided by the PG300 device or SpO_2 patient monitor. Additional Tab views enable users to perform clinical tasks such as viewing Graphic Trends, Running Reports, and Changing Alarm Limit settings. Users can also perform administrative tasks by selecting Admit/Discharge to change patient information, transfer or discharge patients.

NOTE Reports and Alarm Setup Tabs may require security authentication.

System bar

On the top of the screen, a bar provides system identification and displays license-related messages such as:

- Licenses expiring

Navigation bar, date/time, and status

At the bottom of the display screen is a navigation bar containing 2 buttons along with the system date and time. The buttons provide management features including patient administration and running patient reports.

Admin

Patient administration is done using this feature. When the **ADMIN** button is clicked a security pop-up is displayed requiring a valid user name, password and domain. Upon successful login, the patient administration window is displayed.

Reports

To run patient reports, click the **REPORTS** button on the bottom navigation bar. When the **REPORTS** button is clicked, a security pop-up is displayed requiring a valid user name, password and domain. Upon successful login, the patient reports window is displayed.

Status messages

The navigation bar will indicate when there are any network or connectivity issues occurring in the system. Status messages may include:

- **Communication Lost to the Local Authority**
- **Communication Lost to the Central Authority**
- **Communication Lost to the Configuration Service**

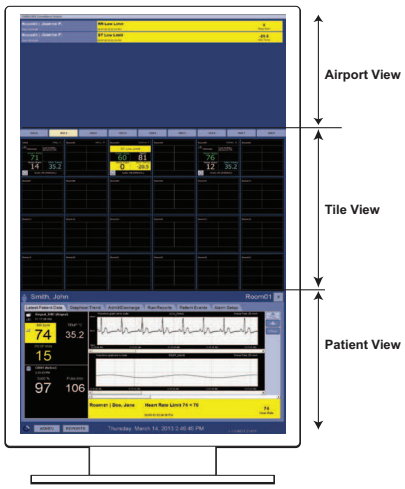
NOTE See Appendix D, Troubleshooting.

Display configurations

Surveillance Station displays are ideally designed for a minimum screen resolution of 1200 x 1920.

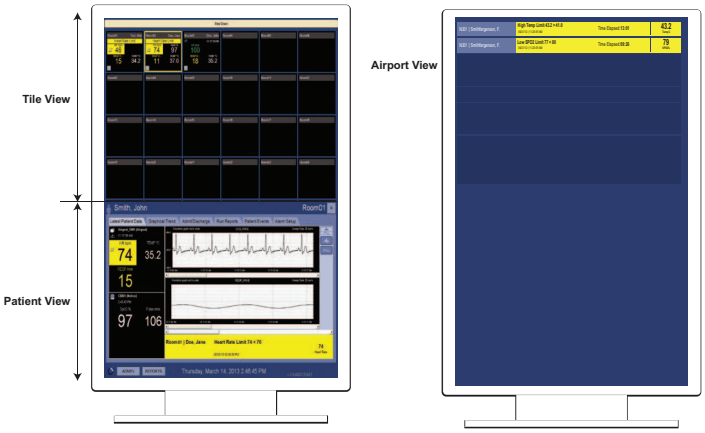
Single display configuration

In a single display configuration as shown, the Alarm Summary is displayed on the top third of the screen, the Tile View is displayed on the middle third of the screen, and the Single Patient View is displayed on the bottom third of the screen.



Dual display configuration

In a dual display configuration as shown, the Tile View is displayed on half of the screen, and the Single Patient View is displayed on the other half of the screen. The Alarm Summary View is displayed on its own screen.



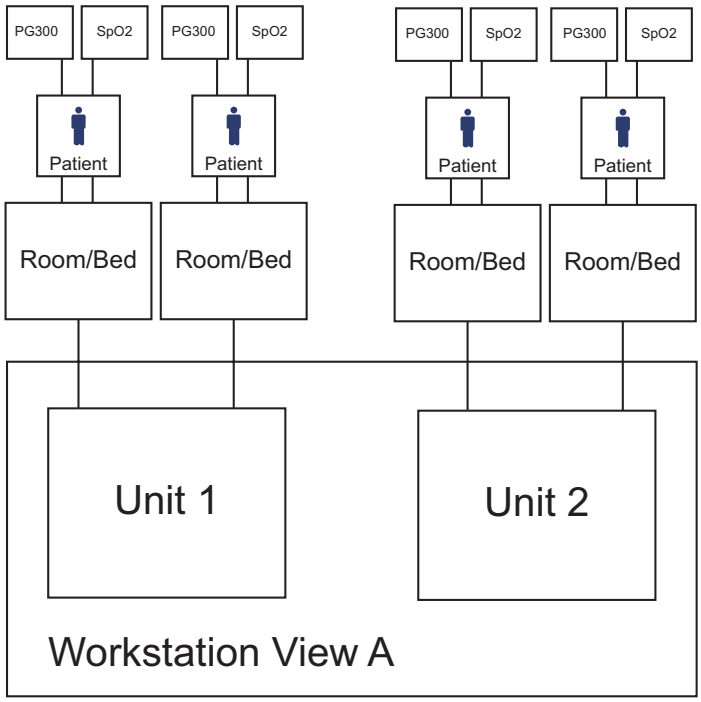
System settings

The Surveillance Station can be customized to your facility. Authorization is required to make changes to the system, and all system changes should only be done in coordination with qualified service personnel. For detailed information on these features, see the *CARESCAPE Surveillance Monitoring Service Manual*.

Feature	Description
Rooms/Beds	Unique identifiers for Rooms or Beds
Units/Care Areas	Rooms/Beds are grouped by Unit
Workstation Views	Groups of Units/Care Areas for custom views
Devices	PG300 devices are assigned to a specific Unit
PG300 System Defaults	Unit level parameter limits and reporting intervals
Alarm Management	Customizable alarm behavior

The following diagram explains the relationships between devices, rooms, patients and Units. Devices are assigned to patients, and patients are assigned to Rooms/Beds. Clinicians may choose to use a wireless PG300 device or an SpO_2 monitor, or both for monitoring. Rooms/Beds are assigned to Units, and Units are grouped into Workstation Views.

NOTE System customization is typically done during installation.



Device names

All devices used throughout the system are given default, system-generated names on the Surveillance Station. These default names can be changed during installation if required.

- Manufacturer (Device model) Serial number
- Example 1: PG300-001 (PG300)
- Example 2: CB003 (N-395)
- Example 3: Masimo-001 (Rad-9)

NOTE SpO_2 monitors are connected to a wired or Wireless Client Bridge, and are identified by the CB (Client Bridge) number of the device transmitting the data. The Client Bridge is labeled with a number that corresponds to the device name.

Rooms/Beds

Patient Tile header	**Room Number/Name, Patient Name**
Alarm Bar identification	**Room Number/Name, Patient Name, Time elapsed**
Patient Detail header	**Patient Name, Room Number/Name**

Room and Bed descriptive names are displayed throughout the system in multiple locations, and can be customized using the Control Panel, along with display order.

Units

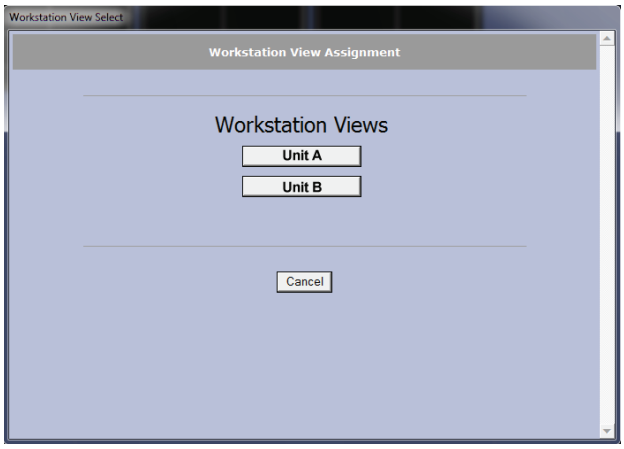
Units (or Care Areas) and Unit names are displayed throughout the system, and can be added, customized or deleted via the Control Panel. Unit Buttons are displayed on top of the Tile View, with each Unit containing rooms. The yellow highlighted button indicates which Unit you are currently viewing.

Assigning a Workstation View

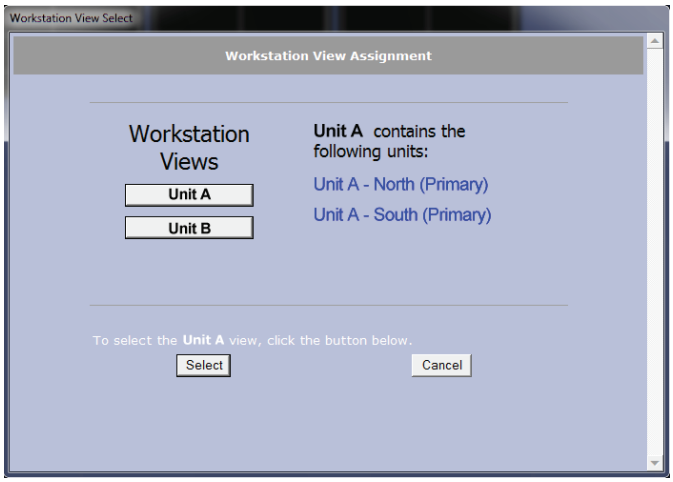
A Workstation View is a grouping of Units. Workstation Views can be added, customized or deleted via the control panel. Workstation Views enable users to view additional Units if required.

To display the Units assigned to this workstation, complete the following procedure:

1. Select the ***F7*** function key.
The Units assigned to this workstation will display.



2. Under Workstation Views, select the appropriate Unit and choose Select. The Units and Beds associated with this Unit will display.



To select a Workstation View, select the Workstation View, verify the associated Units, and **select *Select.*** Close the window and the Units and corresponding rooms associated with this Workstation View will be displayed.

Optional components

The CARESCAPE Surveillance Monitoring System may incorporate additional licensed components that hospitals may wish to integrate in the future. See the *CARESCAPE Surveillance Monitoring Service Manual* for detailed specifications and information.

These licensed components may include:

Bar Code Scanner

Barcode scanners may be used for certain functions in the system. The following barcode scanners are supported:

- Honeywell 4600g Barcode Scanner

SpO_2 patient monitor

The Surveillance Station monitoring system that is compatible with multiple bedside devices from different manufacturers. The following SpO_2 patient monitors are supported:

- Masimo Rad-7, Rad-8, Rad-9
- Covidien (Nellcor) N-395, N-560, N-595, N-600, N-600x

Paging System

The Surveillance Station supports multi-vendor paging systems like Ascom and TAP-compatible systems. The Surveillance Station can be interfaced to existing alphanumeric hospital paging systems, SMTP capable paging systems, TAP-compatible paging systems, or a compatible phone system.

EMR

The Surveillance Station provides connectivity to Medical Facility's EMR systems via HL7 data exchange.

ADT integration

Hospitals may use the Surveillance Station for ADT, but other facilities may want to incorporate an existing ADT system. The Surveillance Station is flexible enough to work as a standalone system for managing patients, or incorporate a hospital's ADT system which automates the workflow.

3

Getting started

Quick start guide

The various getting started steps described in this section can be carried out in multiple ways. For detailed information, please see each step in the chapter below.

Main Workflow	Optional Workflow
Assign patient and device to Surveillance Station	Apply PG300 electrode array
Apply PG300 electrode array	Apply PG300 device
Apply PG300 device	Verify device status
Verify device status	Assign patient and device to Surveillance Station

Step 1: Assign patient and device to Surveillance Station

CAUTION Do not use the PG300 device on patients who are pregnant or pediatric patients.

NOTE Make note of the serial number located on the back of the PG300 device. This will be required later during device assignment at the Surveillance Station.

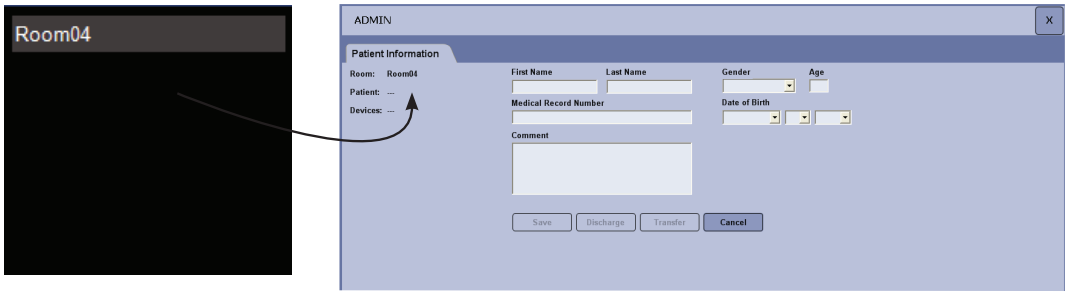
NOTE If security is enabled, certain features require authorization at the Surveillance Station , for example select the ***ADMIN*** button on the bottom navigation bar will require a username and password.

NOTE All activity is logged, and therefore may require authorization. If you do not have a username and password, see your IT department.

To begin, there are two (2) ways to admit a patient. Users can start by selecting an empty patient room from the Tile View, or use the ***Admin*** section as described below.

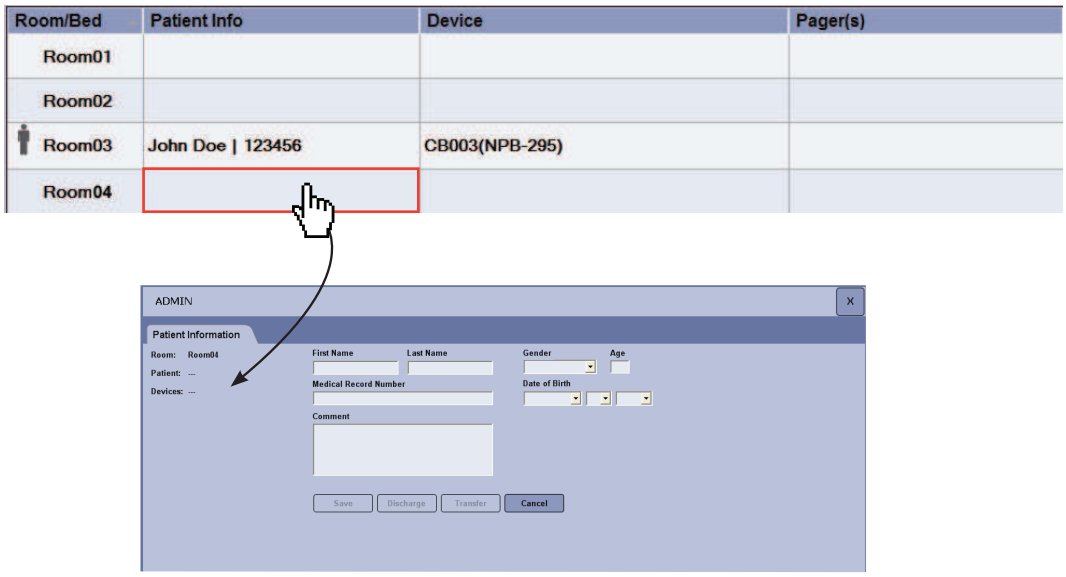
Start with an empty room

When an empty Patient/Room Tile is selected, the Patient Information screen is displayed, allowing a new patient to be added.



Start from the Admin screen

Patient information can also be added (and edited) from the ***Admin*** summary view. Select a ***Patient cell*** beside the room number you wish to admit the patient into. Users may only admit a new patient to an unassigned room.

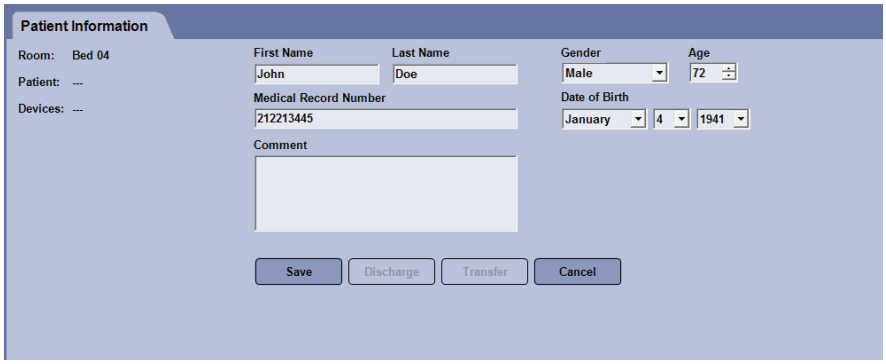


NOTE Since this is a new patient, the Transfer and Discharge buttons are inactive.

The Patient Information screen displays the current patient and/or device assigned, along with fields for adding/editing data, including:

- Name
- Room/Bed
- Medical Record Number
- Comments
- Patient Age (Date of Birth)
- Gender

Enter patient information

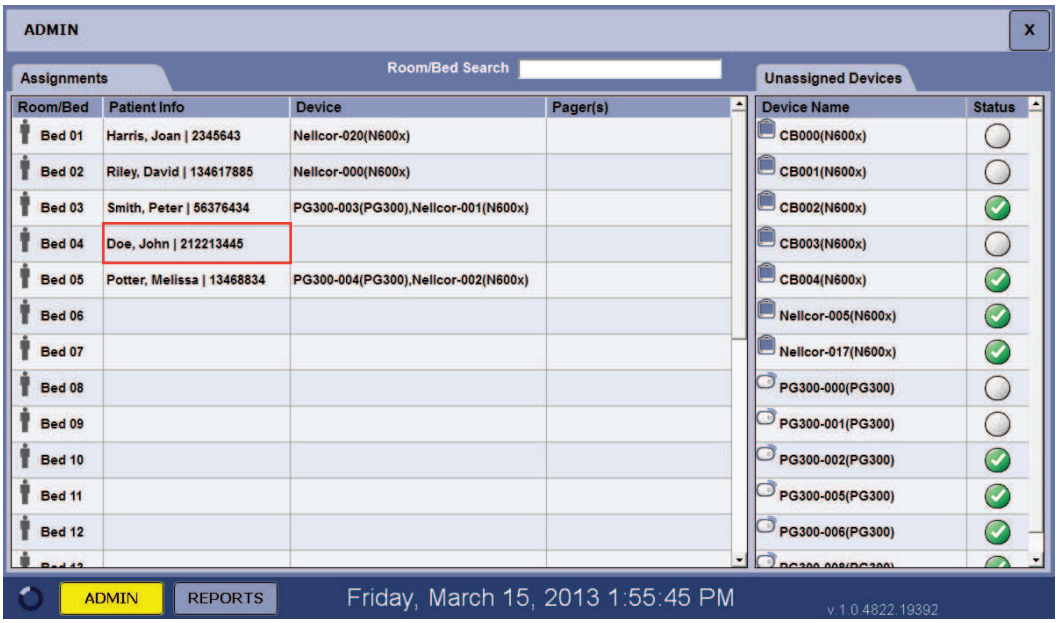


Enter patient information, including patient name, Medical Record Number, comment, gender and date of birth. The Date of Birth field allows the user to input a specific date. If the user inputs a valid date, the Age field automatically calculates the patient's age and displays it in the text box.

Select ***Save.*** A confirmation box will is displayed asking the user to save changes. Select ***OK,*** and the patient is admitted to the system immediately, or ***Cancel*** to abort the admit process.

NOTE ADT systems will retrieve this information from an HL7-ADT source. The Surveillance Station will display read-only versions of the patient's information. Transfer and discharge functions occur in the ADT system.

The new patient will be displayed in the Admin summary view.



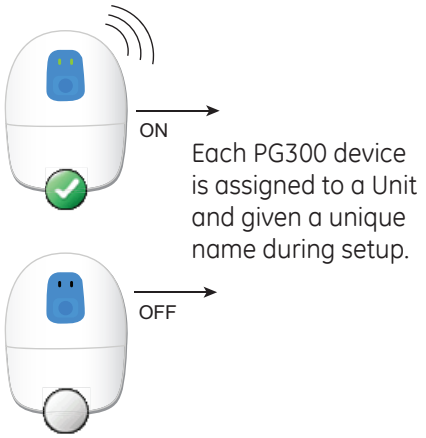
Assign a device

On the right side of the ***Admin*** screen, is a Tab labeled ***Unassigned Devices***. All available devices in the system (including SpO_2 monitors) will be displayed in this list. The serial number of the PG300 device will be displayed as the last four digits in the Device Name.

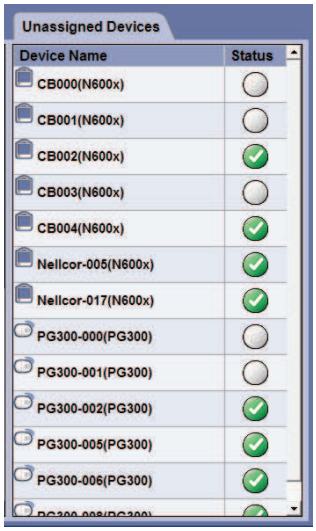
NOTE Devices with a green check arrow in the status column indicate they are turned on and transmitting data. Devices with a gray circle indicate they are most likely turned OFF and not transmitting data. Either status is eligible for assignment to a patient.

NOTE Devices that are already assigned to a patient or room will not be displayed in the Unassigned Devices column.

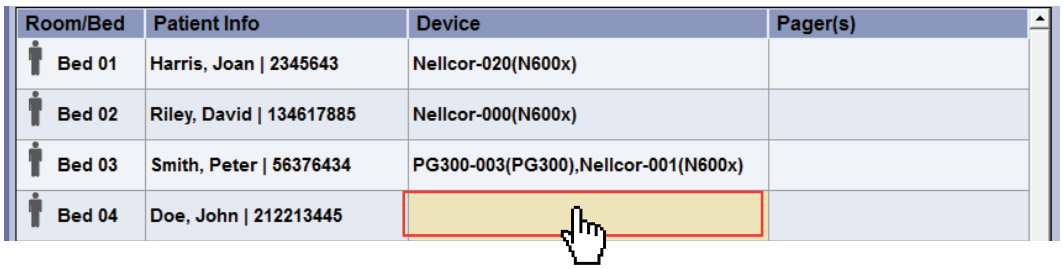
NOTE A scroll bar is displayed, if the number of Unassigned Devices exceeds the display area.



Each PG300 device is assigned to a Unit and given a unique name during setup.



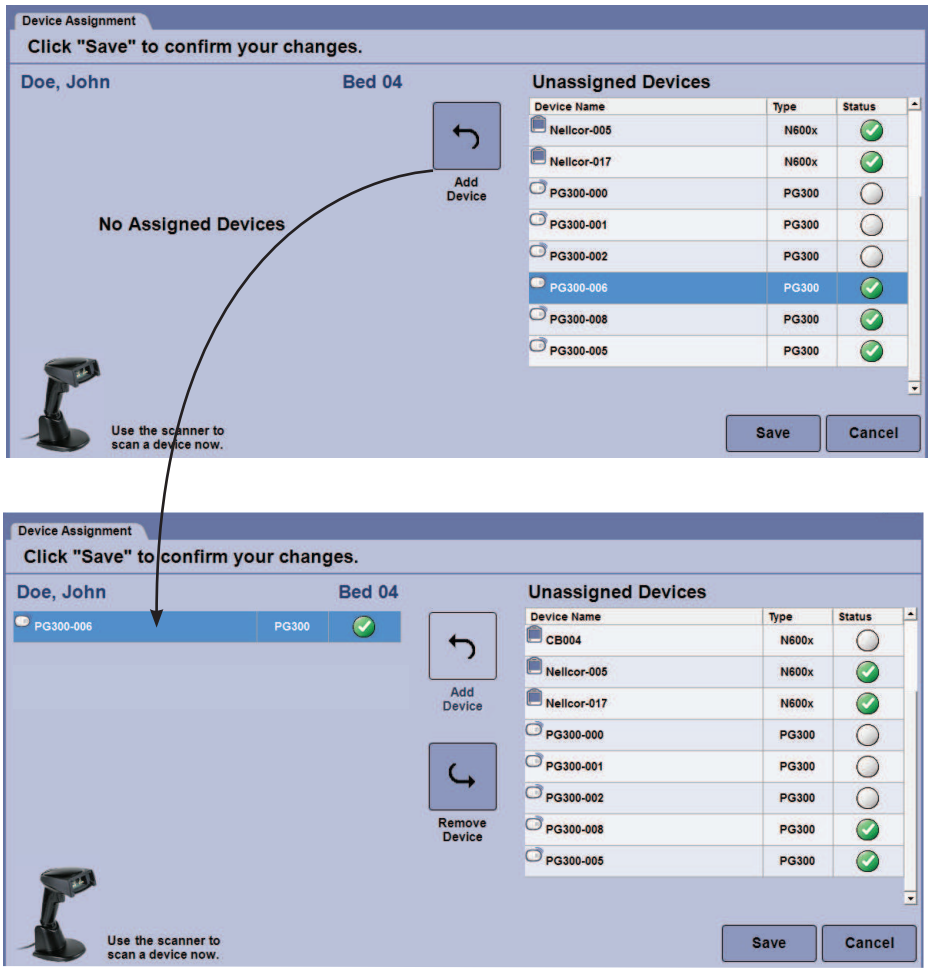
From the ***Admin*** summary view, select the ***Device cell*** next to Patient Name.



To add a device, select a ***Device name*** in the Unassigned list. If using a barcode scanner, scan the ***barcode label*** on the back of the PG300 device. Once a valid device is found, it is highlighted in the list. Select the large ***Add Device*** button to assign it to the selected patient/room. The device name will be removed from the Unassigned list and moved to the current patient/room.

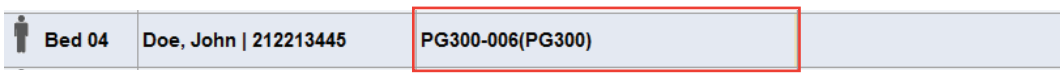
NOTE Only one device type is allowed to be assigned to a patient.

NOTE If a device is not assigned to any other patient or room, then the device is displayed here, as it is still communicating with the system and available for assignment.



Once any changes have been made, the Save button will activate. Make sure you select the ***Save*** button to successfully assign devices. To swap a similar device type, select the device name from the Unassigned Devices list and select the **Add Device** button, overriding the current device assignment. The Save button confirms your assignments. To remove a device assignment, select the Device name under the Patient/Room on the left side of the screen, and select the **Remove Device** button.

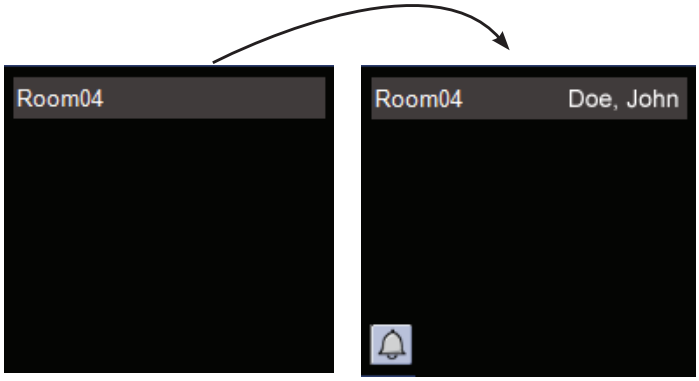
Once a patient is associated with a device, it will immediately be displayed on the ***Admin*** Summary view, and on the Tile View for monitoring.



Confirm the assignment

On the Tile View, the patient's name will be displayed in the selected Room/Bed.

At this point, the PG300 device has to be properly applied to the patient. Once data is received, it will be displayed on the corresponding Patient Tile.



Before device assignment

After device assignment

A ***No Current PG300 Data*** alarm may be displayed (dependent on reporting interval) if the PG300 device is not applied to the patient. Users can suspend the alarm by right-clicking Alarm Summary Alarm Bar and resetting, or selecting the alarm message on the Tile View. Measurements will be displayed with a strike-through. After a period of time, these measurements will be removed. When data is subsequently received, monitoring will begin.

NOTE There are multiple ways to assign patients to devices/rooms by selecting a specific Room/Bed, patient, or device field in the Assignments window. For more detailed instructions, see Chapter 6, Managing patients.

NOTE It may take up to five minutes before patient data is displayed at the Surveillance Station.

Step 2: Apply PG300 electrode array

WARNING Do not apply the PG300 electrode array to a patient with a skin disorder, open wound, lesions, infected or inflamed skin in the area of the electrode array application site. Incorrect electrode array application may impair the quality of ECG and respiration recordings.

CAUTION The PG300 electrode array should only be used by or in consultation with a healthcare provider familiar with its proper placement and use.

Skin preparation

Assess the condition of the patient's skin at the PG300 electrode array application site to ensure it is suitable. Measure the patient's chest circumference to ensure it is within the range of 67.4 to 129.1 cm (26.5 to 50.8 in). Prepare the skin if required to ensure the surface is clean, dry and excess hair is removed. Skin preparation may include the trimming of excess body hair in the area of PG300 electrode array application.

NOTE During skin preparation, do not abrade the skin or use any alcohol solutions. This may cause skin irritation during electrode wear.

NOTE Failure to perform adequate skin preparation may affect the signal quality of the ECG.

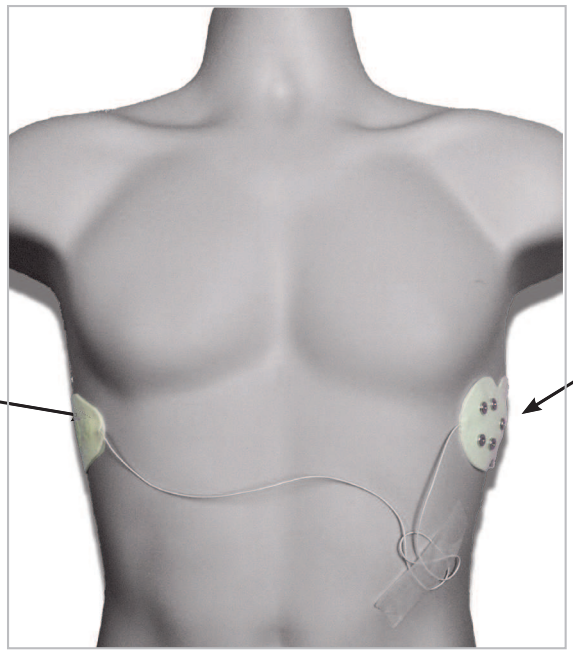
Apply the PG300 electrode array

NOTE When applying the PG300 electrode array to patients of larger size, ensure that the PG300 electrode array patches are not creased or folded.

NOTE Minimize the contact of undergarments with the PG300 electrode array.

Tear the PG300 electrode array pouch seal across the top to open the pouch and remove the electrode array. Remove the PG300 electrode array from the clear bag.

When ready to apply, remove the clear plastic covers from the PG300 electrode array. After exposing the adhesive foam, the patient should take and hold a deep breath before and during the PG300 electrode array application in order to maximize comfort during wear.



The PG300 electrode array should be placed between the fifth and seventh rib parallel to the Xiphoid (bottom of the sternum) to the patient's body around the side of the rib cage as shown below, for optimum recording quality. The studded portion of the PG300 electrode array is placed on the patient's left side. The smaller electrode array portion is placed on the patient's right side.

The wires should be coming out the electrode at the front of body. Variation from this PG300 electrode array position may affect the quality of the signal being recorded.

Smooth each adhesive area firmly to the skin ensuring that there are no creases. Dispose of the packaging as stated on the label. Coil any excess length of wire and tape to the patient's skin using suitable medical grade tape.

NOTE Avoid touching or rubbing the PG300 electrode array once it has been applied.

Right Electrode

Left Electrode

Step 3: Apply PG300 device

WARNING Ensure the PG300 device serial number matches the serial number of the PG300 device assigned to the patient on the central station.

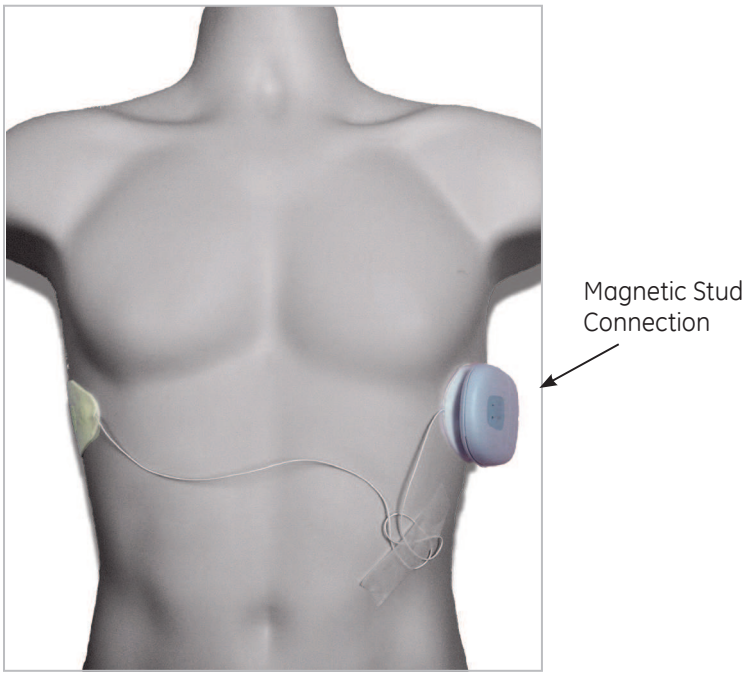
CAUTION Ensure the x ring is correctly located and is not twisted prior to inserting the PG300 battery pack.

Install a PG300 battery pack

Select a fully charged PG300 battery pack from the PG300 battery charger.

Holding the PG300 device, slide a fully charged PG300 battery pack onto the device until it secures in place.

Connect PG300 device



Line the studs on the PG300 device up with the studs on the PG300 electrode array, making sure the device is correctly oriented as shown above. Allow the magnetic studs to connect the device to the PG300 electrode array.

Make sure each stud is properly connected to the PG300 electrode array.

Activate the PG300 device

Turn the PG300 device on by holding down the ON/OFF button for two seconds until the LED indicator lights turn on.

CAUTION Do not press the ON/OFF button unless the intention is to turn ON or OFF the device.

NOTE The PG300 device requires a charged PG300 battery pack to be fitted at all times to ensure continuous monitoring.

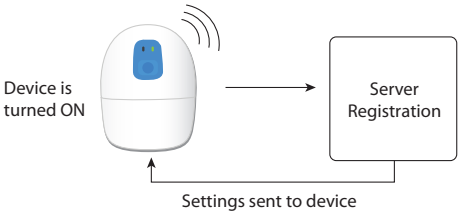
Step 4: Verify device status

Approximately 15 seconds after the ON/OFF button is pressed, three beeps will be heard and the WLAN LED (right LED) will change from orange to green indicating successful connection to the WLAN (Wireless Local Area Network).

The LEADS LED (left LED) will be blue if the device is not connected to the patient and will be OFF when connected to the patient. Verify that the left LED is OFF and the right LED is green before continuing. Refer to the table below for status indicators.

Device status	Leads LED status	Connection LED status	Visual indication	Sound indication	Status
Searching for WLAN	OFF	Solid orange		n/a	PG300 device is searching for WLAN. **NOTE** If the PG300 device is unable to connect to WLAN, then LED will remain orange.
Connected to WLAN	OFF	Solid green		Three beeps	Successful connection has been established and device has obtained configuration. **NOTE** The device will not transmit data until connection LED turns solid green.

Once successfully connected to WLAN, the PG300 device will connect to the server to retrieve configuration settings, such as Unit-specific parameter limits and reporting interval.



Step 5: Assign a Pager to patient

The Pager(s) column displays pager(s) associated to a room. Primary and secondary pager(s) are identified with the label (P) or (S) after the pager name.

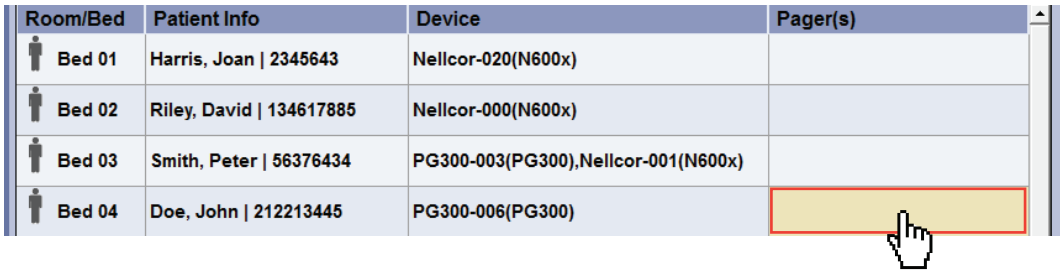
Selecting on a ***Pagers*** column cell opens the Pager Assignment screen.

NOTE If a device is not assigned, the Pager Assignment screen is displayed, followed by the Device Assignment screen.

NOTE If a patient is not assigned, the Pager Assignment screen is displayed followed by the Device Assignment screen, and then the Patient Information screen.

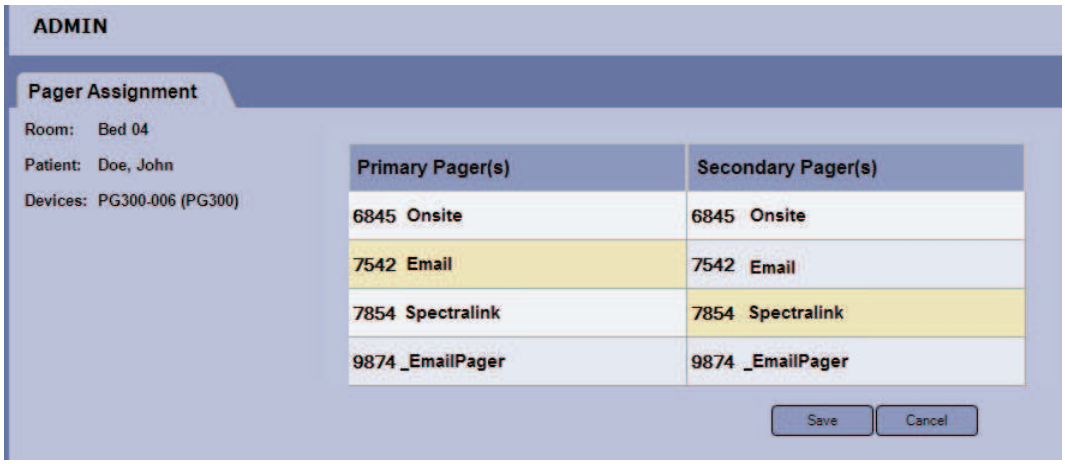
Assign a pager

From the Admin Summary View, Select the Pager Assignments cell corresponding to the patient/device.



Room/Bed	Patient Info	Device	Pager(s)
Bed 01	Harris, Joan | 2345643	Nellcor-020(N600x)	
Bed 02	Riley, David | 134617885	Nellcor-000(N600x)	
Bed 03	Smith, Peter | 56376434	PG300-003(PG300),Nellcor-001(N600x)	
Bed 04	Doe, John | 212213445	PG300-006(PG300)	

The Pager Assignment screen allows the user to associate primary and secondary pager(s) to a medical device/patient. Select a ***Primary Pager*** option. If necessary, select a ***Secondary Pager*** option.



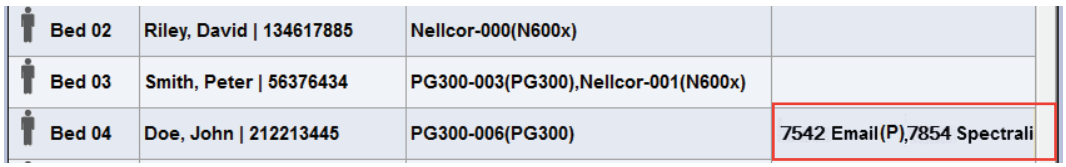
NOTE The primary pager option is automatically selected as the secondary option, however any number of primary or secondary pager combinations can be assigned.

NOTE At least one primary pager must be assigned if any secondary pagers are selected.

NOTE Scroll buttons are displayed and can be used to view pagers outside the display area.

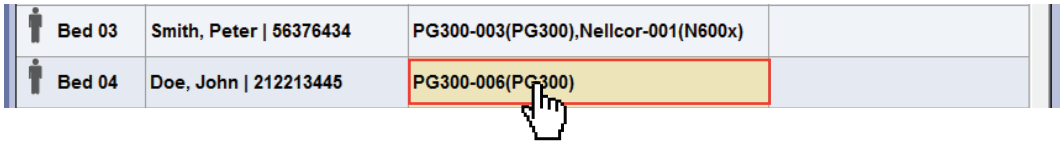
Save and confirm the assignment

To save assignments, ***select the Save button***. ***Cancel*** exits the Pager Assignment screen without saving. Verify that the correct pager(s) is displayed for the appropriate room in the Admin screen.



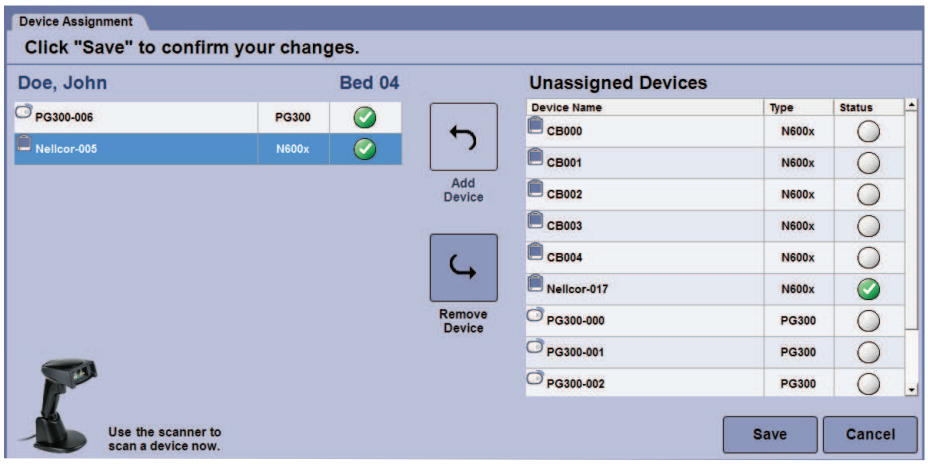
Step 6: Assign SpO_2 device to patient

All SpO_2 devices are registered with the Surveillance Station during setup. Select the Device
cell corresponding to the Room/Patient.



On the right side of the screen, is a column labeled ***Unassigned Devices***. All available devices (including SpO_2 monitors) will be displayed in this list. The Client Bridge number located of the back of the serial device or wireless transmitter will be displayed as the last four digits in the Device Name.

Select the SpO_2 device you intend to use, and click the ***Add Device*** button. Click ***Save.***



NOTE Devices with a green check arrow in the status column indicate they are turned on and transmitting data. Devices with a gray circle indicate they are most likely turned OFF and not transmitting data. Either status is eligible for assignment to a patient.

NOTE Devices that are already assigned to a patient or room will not be displayed in the Unassigned Devices column.

NOTE If the incorrect device is added to the Assigned Devices column select Remove Devices to undo the assignment.

NOTE If a SpO2 device is added to a patient already with an assigned SpO2 device, the devices are swapped.