

Replica™



These operating instructions provide the necessary information for proper operation of all models of the Replica. There may be information provided in this manual that is not relevant for your system. General knowledge of pulse oximetry and an understanding of the features and functions of Replica are prerequisites for its proper use. Do not operate Replica without completely reading and understanding these instructions.

Notice: Purchase or possession of this device does not carry any express or implied license to use with replacement parts which would, alone or in combination with this device, fall within the scope of one of the relating patents.

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

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

Masimo Corporation
52 Discovery
Irvine, CA 92618, USA 
Tel.: 949-297-7000
Fax.: 949-297-7001
www.masimo.com

EU authorized representative for Masimo Corporation:



MDSS GmbH
Schiffgraben 41
D-30175 Hannover, Germany

Patents: www.masimo.com/patents.htm

Masimo®, , Root®, and rainbow® are federally registered trademarks of Masimo Corporation.

Replica™, and Patient SafetyNet™ are trademarks of Masimo Corporation. All other trademarks and registered trademarks are property of their respective owners.

The use of the trademarks PATIENT SAFETYNET and PSN is under license from University HealthSystem Consortium.

© 2018 Masimo Corporation

Contents

About This Manual-----	5
Product Description, Intended Use and Contraindications-----	7
Product Description-----	7
Intended/Indications for Use -----	7
Contraindications-----	7
Safety Information, Warnings and Cautions -----	9
Safety Warnings and Cautions-----	9
Performance Warnings and Cautions-----	9
Cleaning and Service Warnings and Cautions -----	11
Compliance Warnings and Cautions-----	11
Chapter 1: Description -----	13
Overview -----	13
Chapter 2: Basic Setup and Use-----	15
Open the Replica Application-----	15
Identify System and Login-----	15
View Notifications -----	16
View Patient Data-----	17
Chapter 3: Operation-----	19
Getting Started -----	19
View System Data-----	20
Notifications Screen-----	21
Patients -----	25
Alarms and Messages -----	28
Advanced Features-----	30
Chapter 4: Troubleshooting-----	33
Troubleshooting Replica -----	33
Chapter 5: Specifications-----	37
Mobile Device Compatibility -----	37
Patient SafetyNet Compatibility -----	37
Symbols-----	37
Chapter 6: Service and Maintenance-----	39

Cleaning-----39

Contacting Masimo-----39

Index----- 41

About This Manual

This manual explains how to set up and use Replica™. Important safety information relating to general use of Replica 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.

WARNING: This is an example 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.

CAUTION: This is an example of a caution statement.

A *note* is given when additional general information is applicable.

Note: This is an example of a note.

Product Description, Intended Use and Contraindications

Product Description

Replica is a mobile device application that is intended to be used as part of the Patient SafetyNet system. Replica provides communication from Point-of-Care (PoC) devices through Patient SafetyNet to provide the following:

- Device parameters
- Measurement waveforms
- Trends
- Visual indication of device alarm status
- Alarm escalation and notification

Intended/Indications for Use

Patient SafetyNet is intended to be used as a supplemental alarm system communicating with multiple patient monitoring devices. Patient SafetyNet provides secondary display of physiological monitoring parameters. Patient SafetyNet enables the viewing and monitoring of patient physiological conditions. Patient SafetyNet is used in hospitals or hospital-type environments.

Contraindications

None

Safety Information, Warnings and Cautions

CAUTION: Replica is to be operated by, or under the supervision of, qualified personnel only. Read the manual, accessories directions for use, all precautionary information, and specifications before use. Refer to Operator's Manuals of Patient SafetyNet and any bedside Point of Care (PoC) devices connected to Replica for additional safety information, warnings, and cautions.

Safety Warnings and Cautions

WARNING: Do not use Replica mobile device if it appears or is suspected to be damaged.

WARNING: Do not adjust, repair, open, disassemble, or modify the Replica mobile device. Damage to the device may result in degraded performance and/or patient injury.

WARNING: Do not place the Replica mobile device in any position that might cause it to fall on the patient.

WARNING: The Replica mobile device should only be used in clinical environments in which it is approved to prevent patient injury or damage.

WARNING: Do not use the Replica mobile device in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide to avoid risk of explosion.

WARNING: Do not use the Replica mobile device during magnetic resonance imaging (MRI) or in an MRI environment.

WARNING: To protect against injury, follow the directions below:

- Avoid placing the Replica mobile device on surfaces with visible liquid spills.
- Do not place Replica mobile device near a patient.
- Do not use Replica mobile device during defibrillation.
- Do not soak or immerse the mobile device in liquids.
- Do not attempt to sterilize the mobile device.
- Do not attempt to clean the Replica mobile device while in use.

Performance Warnings and Cautions

WARNING: Replica should not be used as the sole basis for medical decisions. It must be used in conjunction with clinical signs and symptoms.

WARNING: Replica is intended to provide supplemental monitoring only. The connected device's alarms, used in conjunction with clinical signs and symptoms, are the primary sources for patient monitoring.

WARNING: Do not use unauthorized devices with Replica. Possible loss of performance may result.

WARNING: Use of high-frequency electrosurgical equipment in the vicinity of the Replica mobile device may produce interference and result in degraded performance.

WARNING: To ensure proper communication to Replica, routinely verify monitoring data is correctly displayed against the PoC device. If any measurement seems questionable, use the measurements on the PoC device.

WARNING: To ensure detection of supplemental notifications, follow the directions below:

- Do not disable the notification features on the Replica mobile device (i.e. sounds, vibrations, etc.).
- Check battery status prior to use.
- Periodically view Replica.

WARNING: Changes to the Replica mobile device software, including settings and upgrades, may impact performance and should be made by authorized personnel only.

WARNING: Only use Masimo authorized devices with Replica. Using unauthorized devices with Replica may result loss of performance or incorrect display of patient monitoring data.

CAUTION: The Replica mobile device is intended to operate across the facility's network. Unanticipated failure or alteration of network components (including but not limited to: disconnection or malfunctioning of a networking device/switch/router/ethernet cable) and/or the Patient SafetyNet system may result in loss of connectivity of Replica. Altering or making changes to the hospital network or to the Patient SafetyNet system should be done with proper knowledge.

CAUTION: The Quality of Service (QoS) of connectivity to the Replica may be affected by:

- Network failure
- Increased number of connected devices on the network
- Modifications to the network
- Presence of devices provided with radio transmitters
- Improper network configuration on PoC
- Signal priorities of the network
- Latency

CAUTION: To prevent tampering and ensure security, follow the directions below:

- Mobile device should be located with responsible personnel
- Mobile device should not be left unattended
- Security features on mobile device should be activated
- Unauthorized changes should not be made to the Replica mobile device

CAUTION: In order to establish and maintain Replica's minimum Quality of Service, the following network specifications should be met before and after installation:

- Wireless Network Connection
During Ping Test, passing result if:
 - a. At least 98% of packets have latency $\leq$ 100 milliseconds,
 - b. No more than 2 % packets loss, and
 - c. Primary access point signal strength at least -67 dBm

CAUTION: Failure to charge Replica promptly after a Low Battery notification may result in the device shutting down.

Note: All batteries lose capacity with age, thus the amount of run time at Low Battery will vary depending upon the age of the battery.

Note: Patient monitoring data displayed on the Replica mobile device is based upon the time stamp provide by the PoC device. The mobile device times may not be synchronized to the PoC device.

Cleaning and Service Warnings and Cautions

WARNING: Do not autoclave, pressure sterilize, or gas sterilize the Replica mobile device.

WARNING: To reduce the risk patient cross-infection, clean the Replica mobile device if it comes in contact with patients.

Note: The Replica mobile device installation must be completed by Masimo or an authorized service department.

Compliance Warnings and Cautions

WARNING: Any changes or modifications not expressly approved by Masimo shall void the warranty for this equipment and could void the user's authority to operate the equipment.

WARNING: Disposal of product - Comply with local laws in the disposal of the Replica mobile device and/or its accessories.

WARNING: When using devices with wireless features outside the United States, consideration should be taken to local government frequency allocations and technical parameters to minimize the possibility of interference to/from other wireless devices.

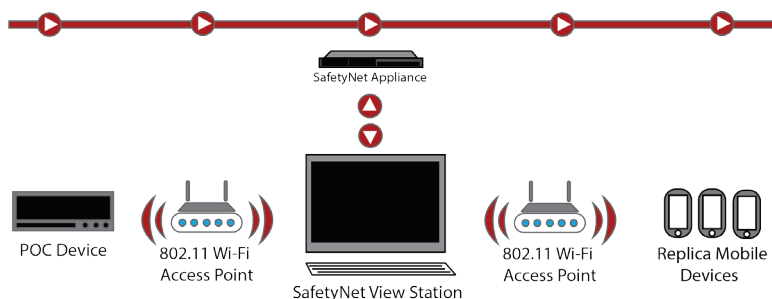
WARNING: In accordance with international telecommunication requirements, the frequency band of 2.4 GHz and 5.15 to 5.25 GHz is only for indoor usage to reduce potential for harmful interference to co-channel mobile satellite systems.

Note: Refer to the mobile device's Operator's Manual for FCC compliance information.

Chapter 1: Description

Overview

Replica is a software application for mobile devices that connects to Patient SafetyNet systems on the hospital network, to provide supplemental remote monitoring of patient PoC device data. Replica also provides two-way notifications through Patient SafetyNet, allowing clinicians to accept or forward the notifications related to alarms in order to aid in the coordination of care. If a notification is forwarded using Replica, Patient SafetyNet automatically sends the notification to the next available clinician.



The Replica operating instructions are intended to provide the necessary information for proper use. Do not operate Replica without completely reading and understanding these instructions.

The Replica and Patient SafetyNet Supplemental Alarm Notification System should not be used as the primary sources for patient monitoring. The standalone PoC audible and visual alarms, used in conjunction with clinical signs and symptoms, are the primary sources for determining that an alarm condition exists.

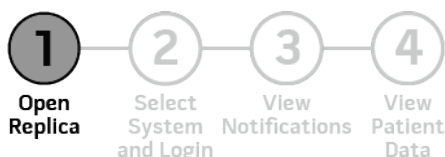
General knowledge and an understanding of the features and functions of the Patient SafetyNet Supplemental Alarm Notification System are a prerequisite for proper use. Refer to the ***Operator's Manual for Patient SafetyNet***.

The following instructions assume that the Replica application and Patient SafetyNet Supplemental Alarm Notification System are installed and ready for use.

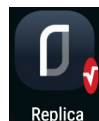
Chapter 2: Basic Setup and Use

The following steps outline basic setup and use for Replica. For complete information, refer to **Chapter 3: Operation** on page 19.

Open the Replica Application



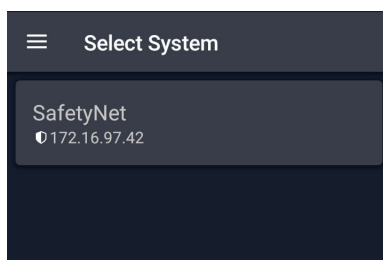
From the mobile device home screen, press/select the icon to start Replica. For complete information about starting Replica, see **Getting Started** on page 19.



Identify System and Login

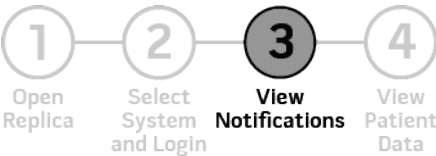


1. From the *Select System* screen, press/select a desired system to view.
2. Enter the username and password used to login to Patient SafetyNet.
3. Press/select the *LOGIN* button to connect to the system.



For complete information about systems and logging in, see **Select a System and Login** on page 19.

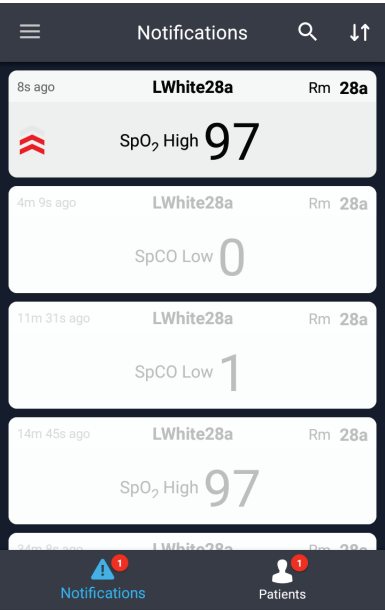
View Notifications



After successfully logging in and connecting to a system, the *Notifications* screen displays by default.

Notifications can be Accepted or Forwarded directly from this screen by:

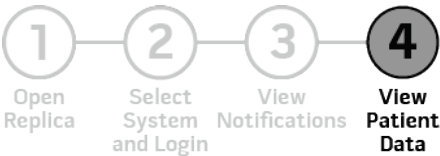
- Swiping the notification to the left and selecting Accept or Forward.
- Press/select the notification and selecting Accept or Forward.



Note: The number of current, unanswered notifications displays next to the *Notifications* icon.

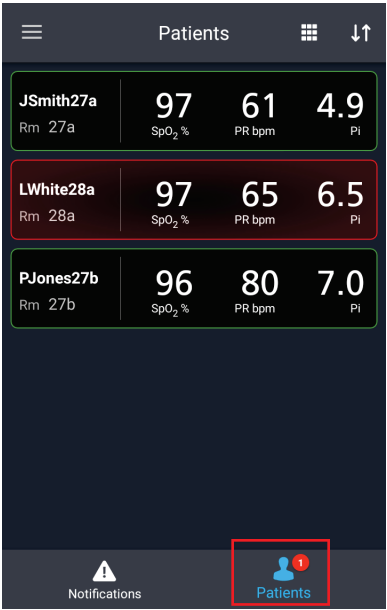
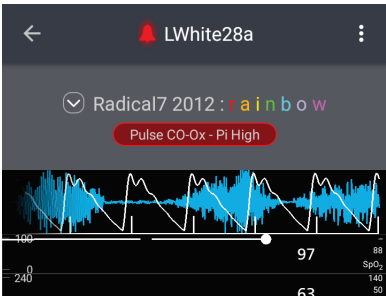
For complete information about Notifications, see **Notifications Screen** on page 21.

View Patient Data



Press/select the *Patients* icon at the bottom of the Replica screen to view patient data (shown at right).

Press/select the desired patient to view patient data (shown below).



Note: The number of patients currently alarming displays next to the *Patients* icon.

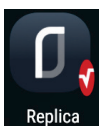
For complete information about patient data, see **Patients** on page 25.

Chapter 3: Operation

Getting Started

To operate Replica on the mobile device:

1. Ensure the battery for the mobile device is fully charged before using.
Note: For charging instructions and battery life information, refer to the mobile device's Operator's Manual or Directions For Use.
2. If the mobile device is OFF, turn it ON. Refer to the mobile device's Operator's Manual or Directions For Use.
3. Ensure the mobile device is on the same network as the intended system to be connected with. Refer to the mobile device's Operator's Manual or Directions For Use.
4. From the home screen, press/select the icon to start Replica.

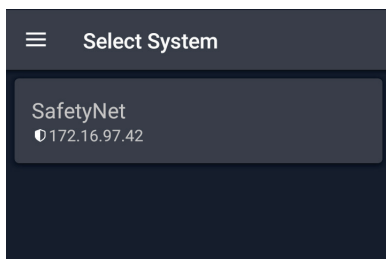


5. Once the Replica application opens the *Select System* screen displays. See **Select a System and Login** on page 19.

CAUTION: To prevent unauthorized modification of software, enable security settings on the mobile device. Refer to the mobile device's Operator's Manual or Directions For Use.

Select a System and Login

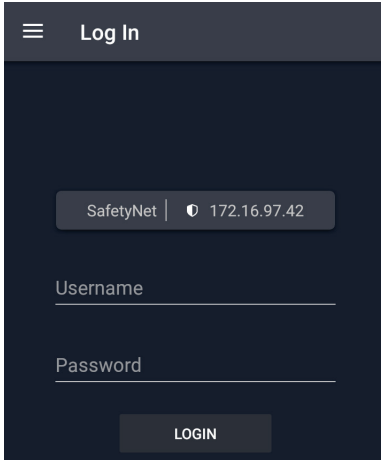
1. From the available options on the *Select System* screen, press/select a desired system to view.



Note: If a desired system is not listed, or no systems are shown (the *Select a System* screen displays *No Systems Added*), a system can be added by pressing/selecting the **Add System** button . See **Add a System** on page 30.

2. Enter the same username and password credentials used for logging into the Patient SafetyNet System that Replica is connected.

Note: The username and password are created through Patient SafetyNet. If the username and/or password are forgotten, contact the system administrator for assistance.



3. Press/select the *LOGIN* button to connect to the system.
4. A pop-up screen appears with status of the connection of Replica with the selected system.
5. When Replica successfully connects to the system, the *Notifications* screen displays. See **View System Data** on page 20.

Note: If the device cannot connect, Replica continues to attempt a connection until *Cancel* is pressed/selected.

Note: If a connection attempt is made to an incompatible version of Patient SafetyNet, a message appears displaying the incompatible version vs the Replica version required. Ensure the correct version of Patient SafetyNet is installed, and re-attempt to connect to the system.

If a different system connection is desired, see **Advanced Features** on page 30.

Logout of the Connected System

1. To logout of the selected system, press/select the Back arrow  at the bottom edge of the mobile device screen until a pop-up displays to confirm to logout (or cancel).
2. Press/select *OK* to logout.

View System Data

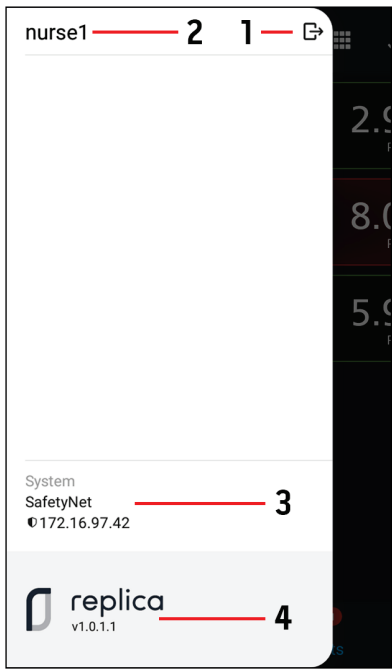
After successfully logging in and connecting to a system, the *Notifications* screen displays by default. Select the *Notifications* or *Patients* icon at the bottom of the Replica screen to view the desired information.

Note: The number of current, unanswered notifications displays next to the *Notifications* icon. The number of patients currently alarming displays next to the *Patients* option.



Side Menu

The side menu displays the logged in user (respondent), Replica software version number, currently connected system, and allows the ability to log Replica out of the current connected system. To view the side menu, while on the *Notifications* or *Patients* screen, swipe right from the left edge of the Replica screen. To close, swipe left on the side menu.



- 1 - Log Out of Connected System
- 2 - Logged in User Name
- 3 - Connected System
- 4 - Replica Software Version

Notifications Screen

The *Notifications* screen is viewed by pressing/selecting the *Notifications* icon at the bottom of the Replica screen. See **View System Data** on page 20. The *Notifications* screen displays any active notifications for the assigned system Replica is connected to. If no notifications are present, the *Notifications* screen displays *No Notifications*. The mobile device can be set

to provide a vibration and/or audible alert when a notification is received. Refer to the mobile device's Operator's Manual or Directions For Use.

CAUTION: The user must be identified as a Respondent in Patient SafetyNet to receive notifications. Refer to the *Operator's Manual for Patient SafetyNet* for complete information.

The screenshot shows a mobile application interface titled "Notifications". It displays a list of four notifications. Each notification card contains the following information: elapsed time since notification, patient name, room number, vital sign measurement, and a response area. Red lines and numbers 1-7 point to specific UI elements:

- 1 - Elapsed Time Since Notification*
- 2 - Current Notification State
- 3 - Completed Notification
- 4 - Patient Label
- 5 - Message Example
- 6 - Response Area
- 7 - Room Number

The notifications shown are:

- 12s ago, JSmith27a, Rm 27a, SpHb High 14.0, [One Red Arrow]
- 3m 37s ago, LWhite28a, Rm 28a, SpO₂ High 97, [Two Red Arrows]
- 17m 46s ago, LWhite28a, Rm 28a, SpCO Low 0, [Three Red Arrows]
- 25m 8s ago, LWhite28a, Rm 28a, SpCO Low 1, [No Arrows]

* In relation to connected system time, not the mobile device time.

Notification State

The current notification state is indicated by the color of the arrows at the left end of the notification.

- One Red - Initial notification.
- Two Red - Second notification, escalated.
- Three Red - Third notification, re-escalated.
- No arrows - Notification is completed or has been silenced on the PoC device.

Search Notifications

Notifications can be searched by pressing/selecting the search icon at the top of the Replica screen and entering a patient label or room number.

Sort Notifications

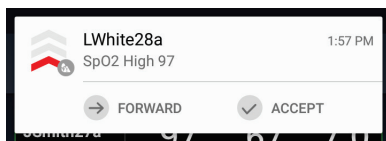
Notifications can be sorted by *Time* or *Escalation* by pressing/selecting the sort icon . When sorted by *Escalation*, the notifications are listed by severity.

Notification Popup

When a notification occurs while viewing patient data, or while not viewing the Replica app on the mobile device, the assigned respondents (as determined by the *Assignment* settings in Patient SafetyNet) are notified through an alert screen pop-up.

For notifications to appear, they must be enabled through the mobile device settings. Refer to the mobile device's Operator's Manual or Directions For Use to enable notifications for Replica.

The notification can be accepted or forwarded directly from the popup. See **Accept or Forward Notifications** on page 23. Refer to the Operator's Manual for Patient SafetyNet for complete respondent assignment information.



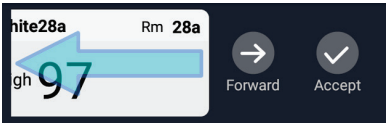
Accept or Forward Notifications

When a respondent receives notification due to an alarm/alert on Replica, they can either Accept or Forward the notifications. If the notification is accepted from the mobile device but no action is taken at the PoC, then the notification escalates according to the institution's pre-determined escalation time to the next level of assigned clinician. If the notification is forwarded then the notification is sent immediately, by-passing the pre-determined escalation time, to the next available respondent as determined by Patient SafetyNet.

Note: Notifications can also be accepted or forwarded directly from the notification popup.

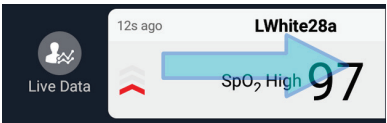
Swipe Left on Notification

Swiping left on the notification displays a shortcut to accept or forward a notification by pressing/selecting the *Accept* or *Forward* buttons.



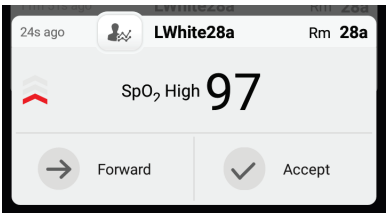
Swipe Right on Notification

Swiping right on the notification displays a shortcut to view the *Patient Data* screen by pressing/selecting the *Live Data* button.



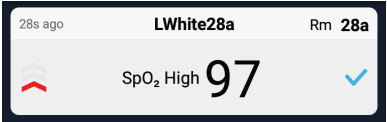
Press/Select Notification

Press/select the notification on the *Notifications* screen to display options to accept or forward the notification, or view the *Patient Data* screen by pressing/selecting the patient icon.



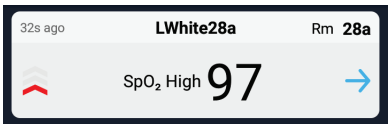
Accept Notification

When accepted, *Accept* is highlighted and the corresponding *Notification* displays a checkmark.



Forward Notification

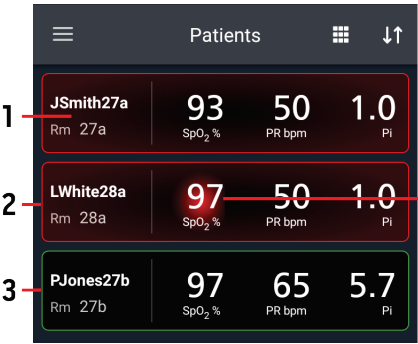
When forwarded, *Forward* is highlighted and the corresponding *Notification* displays an arrow.



Patients

The *Patients* screen is viewed by pressing/selecting the *Patients* icon at the bottom of the Replica screen. See **View System Data** on page 20. The *Patients* screen displays all admitted patients (along with parameters and any current alarms/alerts) assigned to the logged in user (respondent) for the system Replica is connected to.

- Patients can be sorted by *Label* or *Room* by pressing/selecting the sort icon  at the upper-right corner of the Replica screen.
- Patients can be displayed in list or grid view by pressing/selecting the view icon  at the top of the Replica screen.



Patient List View

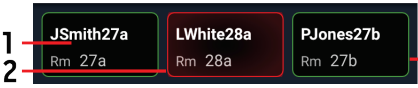
1* - Patient Label and Room Number.

2* - Tile glow and border color corresponds to alarm.

3* - No alarms (Green border, no highlighted parameters).

4 - Red or Yellow glow behind parameter when alarming.

* When in grid view, only these items display.



Patient Grid View

The border color of the Patient displays one of several colors:

- Green: Successful admission and connection with PoC device.
- Yellow: Successful connection to the device. This would include statuses, notifications, modifiers, notification devices not assigned to patient, or patients

that have not been successfully admitted to the system. See the *Operator's Manual for Patient SafetyNet* for complete information.

- Red: Device alarming.
- Gray: Disconnected device.

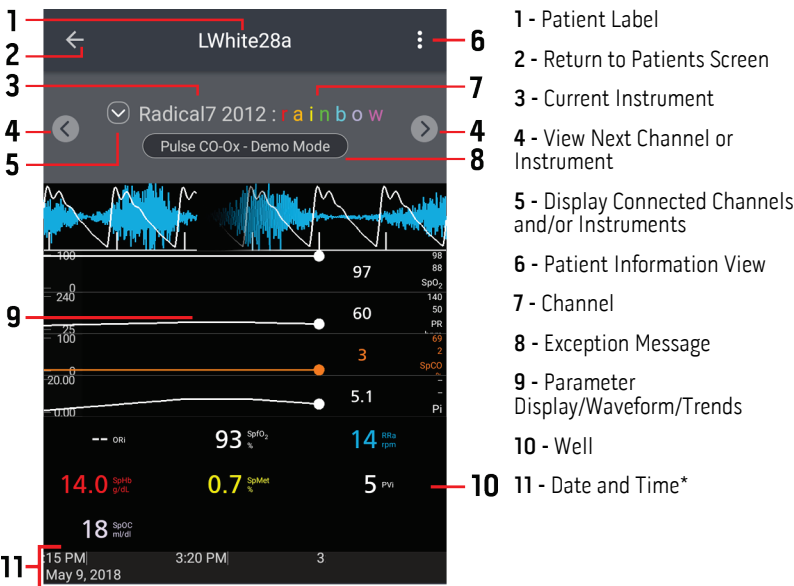
Patient Screen

To view a specific patient's data, perform one of the following:

- Press/select the patient from the available options on the *Patients* screen.
- Swipe right on the patient notification tile on the *Notifications* screen. See **Accept or Forward Notifications** on page 23.

Once selected, the patient label displays at the top of the Replica screen. This is the label assigned when the patient is admitted to the system. When connected, the rainbow channel displays by default (in this example, Radical-7 is the instrument).

Note: If rainbow is not available, only Radical-7 displays.

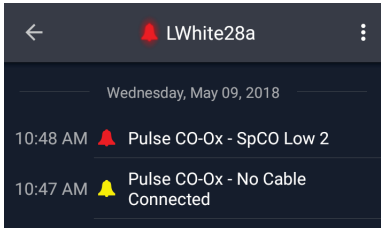


* Connected system date and time, not the mobile device date and time.

Patient Information View

Different patient information can be viewed by pressing/selecting the Patient Information View icon  at the top right corner of the Replica screen.

- Live Data - Patient monitoring parameter data and available instruments/channels (*Patient Screen*).
- Info - Patient name, room number, and Patient label (if all data has been entered into the connected system).
- Timeline - Any interactions or exception messages or events from the last 12 hours, with date and time, relayed through the connected system (shown below).

**Timeline View**

Customize Windows

Parameters can be moved in and out of the well and trends can be zoomed in/out of, and panned.

Expand/Minimize Parameter

Parameters not displayed in the *Parameter Display* are displayed in the *Well*. Windows can be customized by expanding and minimizing parameters and measurements. When a parameter is expanded (moved to the *Parameter Display*), it is shown in the *Parameter Display* with its trend. When a parameter is minimized (moved to the *Well*), it is only displayed in the *Well* with its Numeric Value and Parameter Label.

- To move a parameter from the *Well* to the *Parameter Display*, press/select and hold on the parameter and drag it to the *Parameter Display*.
- To remove a parameter from the *Parameter Display* back to the *Well*, press/select and hold on the parameter and drag it to the *Well*.

Note: The ability to expand/minimize parameters does not apply to all instrument windows.

Trends

- Zoom In/Out - Using a pinch gesture with two fingers, zoom in and out of the parameter trend data.
- Pan - Using a swipe gesture with one finger, pan left or right on the parameter trend data.

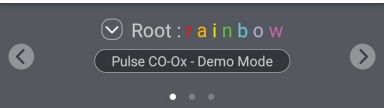
Note: The trend data timeline is based on the system date and time, not the mobile device date and time.

Instruments

The instruments available for viewing through Replica match those assigned to the patient by the connected system when the patient is admitted. "Root" may display multiple times depending on the number of devices connected to it. The devices connected to Root are recognized as channels.

The number of white dots under the instrument name correspond to the number of currently connected instruments and/or channels available to view patient data.

To switch between instrument/channel data screens, swipe left or right on the instrument name or press/touch the arrows on each side. Parameters for the selected instrument display for the patient.

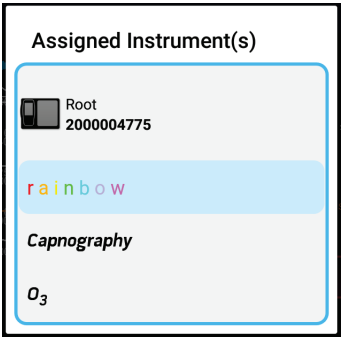


Example: If only "Root : rainbow" is available on the connected system, only "Root : rainbow" is displayed as an option on Replica. If a SedLine module is connected to the system, then "Root : SedLine" also appears as a selection on Replica.

To view available instruments/channels, press/select the down arrow  next to the instrument name. See **Patient Screen** on page 26.

Once selected, the *Assigned Instrument(s)* screen appears showing all connected instruments. In this example, Root is the instrument and rainbow, Capnography and O₃ are the channels.

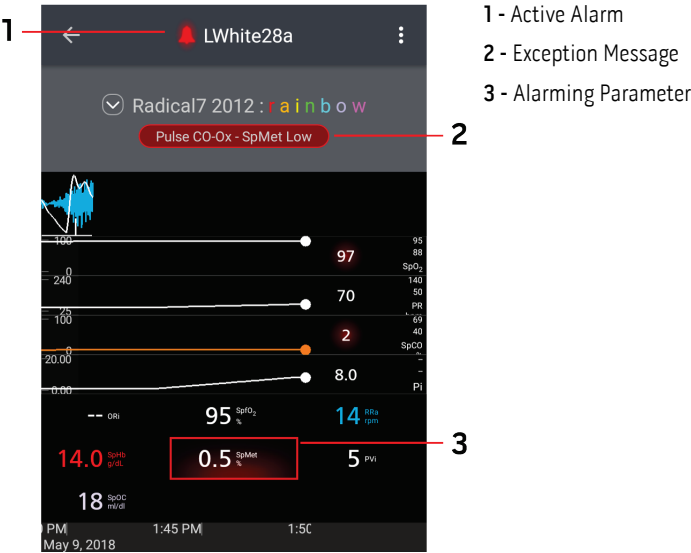
To close the *Assigned Instrument(s)* screen, press/select the back arrow at the bottom of the mobile device screen.



Alarms and Messages

When a patient is actively alarming, an alarm icon appears to the left of the patient label at the top of the *Patient* screen. The parameter that corresponds to the alarm is highlighted. Exception messages appear below the instrument name. When the alarming parameter is in the well, the parameter is also surrounded in Red.

Neither Replica nor the mobile device provide audible alarms, only visual alarms.



Replica Messages

The following section lists possible messages, the potential cause, and next steps.

Message	Potential Causes	Next Steps
No Systems Added	No system has been added to Replica.	Add a system to Replica. See Add a System on page 30.
No Patient(s) Admitted	Current user does not have any patients assigned.	If patients are expected, ensure Replica is connected to the correct system. See Select a System and Login on page 19.
No Devices Added	No instruments are currently connected and monitoring the patient on the connected system.	If patient data is expected, ensure Replica is connected to the correct system. See Select a System and Login on page 19.
No Server Connection	Replica is not connected to the server.	Ensure the mobile device is within range of the wireless network for connection to the system. See Chapter 4: Troubleshooting on page 33.

Message	Potential Causes	Next Steps
<i>Failed: Bad Username/Password</i>	Incorrect Username or Password entered.	- Ensure the correct Username and Password are used when logging in to Replica. - If the Username and/or Password has been forgotten, contact the system administrator.
<i>Unable to connect due to incompatible protocol versions. The app protocol version is X.X.X.X, while the system protocol version is X.X.X.X.</i>	Displayed when attempting to connect to a system with an incompatible protocol version.	Contact the hospital Patient SafetyNet administrator.
<i>Reconnecting</i>	Reconnection is in progress after a failed connection or remote disconnect.	Ensure the mobile device is within range of the wireless network for connection to the system. See Chapter 4: Troubleshooting on page 33.

Advanced Features

Connect to a Different System

Change Systems

- To change the selected system, press/select the Back arrow  at the bottom edge of the mobile device screen until a pop-up displays to confirm to logout (or cancel).
- Press/select *OK* to logout.
- Press/select the Back arrow  again to display the *Select System* screen.
- Press/select the same or a different system from the *Select System* screen and log into that system. See **Select a System and Login** on page 19.

Add a System

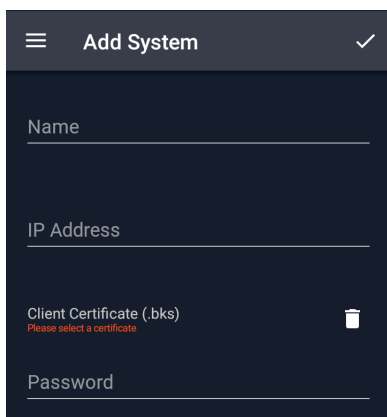
A Patient SafetyNet system must be added to the Replica App before logging in. The system added must be on the same network as the mobile device or data is not displayed.

WARNING: The software settings of the Replica mobile device should be made by authorized personnel only.

Note: If the system is not on the same network as the mobile device, it can be added, but Replica will not be able to connect it to view data or receive notifications until both are connected to the same network.

To add a new system to the *Select System* screen, perform the following procedure:

1. Press/select the *Add System* button . The *Add System* screen displays.



2. Enter a unique name, label, or identifier in the *Name* field. This feature is useful when multiple systems are listed and available for connection.
3. Enter the *IP Address* for the system.
4. A certificate is required when connecting a system, press/select *Please select a certificate*. Choose the necessary certificate from the certificates available on the mobile device. If the required certificate is not found on the device, a certificate must be loaded onto the mobile device. The certificate must be on the mobile device to be able to upload to Replica.
Note: If a certificate needs to be added to the device, this should be performed by a Masimo representative.
5. After selecting a certificate, Replica will return to the *Add System* screen.
6. Enter the password for the certificate.
7. Press/select the check mark in the top-right corner of the screen to add the system.
8. The system will be added to the *Add System* screen.
9. To view the system on Replica, see **Select a System and Login** on page 19.

Modify/Remove a System

To modify system details or remove a system from Replica, from the *Select System* screen, press/select and hold on the selected system to view the *Edit System* screen.

Modify System Details

1. While viewing the *Edit System* screen, change the system details as desired.

2. When changes are complete, press/select the check mark at the upper right corner of the screen to save the changes.
3. Replica exits the *Edit System* screen and the *Select System* screen displays.

Remove a System

1. While viewing the *Edit System* screen, press/select the trash can icon  in the upper right corner of the screen.
2. When prompted to "Delete System?", press/select OK or Cancel.
 - If Cancel is selected, the system is NOT removed and Replica remains on the *Edit System* screen.
 - If OK is selected, the system is removed and Replica returns to the *Select System* screen.

Chapter 4: Troubleshooting

Troubleshooting Replica

The following section lists possible symptoms, the potential cause, and next steps.

Symptom	Potential Causes	Next Steps
<i>Replica mobile device does not turn on.</i>	- Depleted Battery. - Internal failure.	- Connect mobile device to battery charger and charge battery. Refer to the mobile device's Operator's Manual or Directions For Use. - Contact Masimo Service. See Contacting Masimo on page 39.
<i>Replica mobile device turns off.</i>	- Depleted Battery. - Internal failure.	- Connect mobile device to battery charger and charge battery. Refer to the mobile device's Operator's Manual or Directions For Use. - Contact Masimo Service. See Contacting Masimo on page 39.
<i>Replica stops responding.</i>	- Mobile device is out of range of the network. - Replica operation has stopped.	- Ensure the mobile device is within range of the wireless network for connection to the system. - Restart Replica and login to the system. See Select a System and Login on page 19. If problem persists, contact Masimo Service. See Contacting Masimo on page 39.
<i>Replica mobile device does not communicate with Patient SafetyNet.</i>	- Mobile device is out of range of the network. - External device is not compatible. - Wi-Fi is not turned on and/or not correctly configured. - Location does not have wireless availability. - Connected network is not available. - Mobile device software updates are required. - Internal failure.	- Ensure the mobile device is within range of the wireless network for connection to the system. - Check mobile device compatibility. See Chapter 5: Specifications on page 37. - Check that the wireless feature for mobile device is on and correctly configured. Refer to the mobile device's Operator's Manual or Directions For Use. - Check wireless availability for location. - Check network settings and availability. - Update the mobile device software. Refer to the mobile device's Operator's Manual or Directions For Use. - Contact Masimo service. See Contacting Masimo on page 39.

Symptom	Potential Causes	Next Steps
<i>Incorrect patient data is displayed</i>	• Incorrect user currently logged into Replica. • Connected to incorrect system. • System settings have changed. • Incorrect patients assigned to user.	• Ensure the correct user is logged into Replica. See Select a System and Login on page 19. • Ensure Replica is connected to the correct system. See Select a System and Login on page 19. • Restart Replica and login to the system. See Select a System and Login on page 19. • Ensure correct patients are assigned to user. See the Operator's Manual for Patient SafetyNet for complete information.
<i>NO patient data is displayed</i>	• Incorrect user currently logged into Replica. • Connected to incorrect system. • Mobile device is connected to the incorrect network. • System settings have changed. • Incorrect patients assigned to user. • Wi-Fi is not correctly configured. • Connected network is not available. • Mobile device settings are incorrect. • Internal failure.	• Ensure the correct user is logged into Replica. See Select a System and Login on page 19. • Ensure Replica is connected to the correct system. See Select a System and Login on page 19. • Check that the mobile device is connected to the correct network. Refer to the mobile device's Operator's Manual or Directions For Use. • Restart Replica and login to the system. See Select a System and Login on page 19. • Ensure correct patients are assigned to user. See the Operator's Manual for Patient SafetyNet for complete information. • Check that the wireless feature is correctly configured. Refer to the mobile device's Operator's Manual or Directions For Use. • Check network settings and availability. • Ensure the mobile device settings allow proper operation of Replica notifications. Refer to the mobile device's Operator's Manual or Directions For Use. • Contact Masimo service. See Contacting Masimo on page 39.
<i>Patient notifications do not appear during events</i>	• Active alarm has been suspended from Patient SafetyNet or PoC device. • Incorrect user currently logged	• If an active alarm is suspended from Patient SafetyNet or PoC device, notifications may not appear. • Ensure the correct user is logged into Replica. See Select a System and Login on page 19. • Ensure Replica is connected to the correct

Symptom	Potential Causes	Next Steps
	into Replica. • Connected to incorrect system. • System settings have changed. • Incorrect patients assigned to user. • Mobile device is out of range of the network.	system. See Select a System and Login on page 19. • Restart Replica and login to the system. See Select a System and Login on page 19. • Ensure correct patients are assigned to user. See the Operator's Manual for Patient SafetyNet for complete information. • Ensure the mobile device is within range of the wireless network for connection to the system.
<i>Time and date displayed on the mobile device does not match the PoC device.</i>	• Time and date setting on the mobile device is not set to the same as the PoC device.	• Set the time and date on the mobile device to the same time and date as the PoC device. Refer to the mobile device's Operator's Manual or Directions For Use. Note: The time and date for Replica data matches the PoC device, no matter the time/date settings on the mobile device.

Chapter 5: Specifications

Mobile Device Compatibility

Item	Specification*
Operating System	Android 5.0 (Lollipop)

* For complete specifications, refer to the mobile device's Operator's Manual or Directions For Use.

Patient SafetyNet Compatibility

Item	Specification
Software Version	v5.5.0.0 or above

Symbols

Symbols	Definition
	Follow Instructions for use
	Non-Sterile
	Not made with natural rubber latex
	Instructions/Directions for Use/Manuals are available in electronic format @ http://www.Masimo.com/TechDocs Note: eIFU is not available for CE mark countries.

Chapter 6: Service and Maintenance

Cleaning

To properly clean the mobile device, refer to the mobile device's Operator's Manual or Directions For Use.

Contacting Masimo

Masimo Corporation
52 Discovery
Irvine, California 92618

Tel: +1 949 297 7000
Fax: +1 949 297 7001

Limited Warranty

Masimo warrants to the initial buyer only that these products, when used in accordance with the directions provided with the Products by Masimo, will be free of defects in materials and workmanship for a period of six (6) months. The foregoing is the sole and exclusive warranty applicable to the products sold by Masimo to buyer. Masimo expressly disclaims all other oral, express or implied warranties, including without limitation any warranties of merchantability or fitness for particular purpose. Masimo's sole obligation and buyer's exclusive remedy for breach of any warranty shall be, at Masimo's option, to repair or replace the product.

Exclusions

The warranty does not apply to any non-Masimo branded product or any software, even if packaged with the Product, or any Product that was: (a) not new or in its original packaging when supplied to purchaser; (b) modified without Masimo's written permission; (c) supplies, devices, or systems external to the Product; (d) disassembled, reassembled, or repaired by anyone other than a person authorized by Masimo; (e) used with other products, like new sensors, reprocessed sensors, or other accessories, not intended by Masimo to be used with the Product; (f) not used or maintained as provided in the operator's manual or as otherwise provided in its labeling; (g) reprocessed, reconditioned, or recycled; and (h) damaged by accident, abuse, misuse, liquid contact, fire, earthquake or other external cause.

No warranty applies to any Product provided to Purchaser for which Masimo, or its authorized distributor, is not paid; and these Products are provided AS-IS without warranty.

Limitation of Warranty

Except as otherwise required by law or altered by the purchase agreement, the above warranty is the exclusive warranty that applies to the Product and software media, and Masimo does not make any other promises, conditions, or warranties regarding the Product. No other warranty applies, express or implied, including without limitation, any implied warranty of merchantability, fitness for a particular purpose, satisfactory quality, or as to the use of reasonable skill and care. See the licensing terms for the terms and conditions that apply to and Software accompanying the Product. Additionally, Masimo will not be liable for any

incidental, indirect, special, or consequential loss, damage, or expense arising from the use or loss of use of any Products or Software. In no event shall Masimo's liability arising from any Product or Software (under contract, warranty, tort, strict liability, or otherwise) exceed the amount paid by purchaser for the Product or Software. The above limitations do not preclude any liability that cannot legally be disclaimed by contract.

Sales & End-User License Agreement

This document is a legal agreement between you ("purchaser") and Masimo Corporation ("Masimo") for the purchase of this Product ("Product") and a license in the included or embedded Software ("Software") except as otherwise expressly agreed in a separate contract for the acquisition of this Product, the following terms are the entire agreement between the parties regarding your purchase of this Product. If you do not agree to the terms of this agreement, promptly return the entire Product, including all accessories, in their original packages, with your sales receipt to Masimo for a full refund.

Restrictions

1. **Copyright Restrictions:** The Software and the accompanying written materials are copyrighted. Unauthorized copying of the Software, including Software that has been modified, merged, or included with other software, or the written materials is expressly forbidden. Purchaser may be held legally responsible for any copyright infringement that is caused or incurred by Purchaser's failure to abide by the terms of this Agreement. Nothing in this License provides any rights beyond those provided by 17 U.S.C. §117.
2. **Use Restrictions:** Purchaser may physically transfer the Product from one location to another provided that the Software is not copied. Purchaser may not electronically transfer the Software from the Product to any other device. Purchaser may not disclose, publish, translate, release, distribute copies of, modify, adapt, translate, reverse engineer, decompile, disassemble, or create derivative works based on the Software or the written materials.
3. **Transfer Restrictions:** In no event may Purchaser transfer, assign, rent, lease, sell, or otherwise dispose of the Product or the Software on a temporary basis. Purchaser shall not assign or transfer this License, in whole or in part, by operation of law or otherwise without Masimo's prior written consent; except that the Software and all of Purchaser's rights hereunder shall transfer automatically to any party that legally acquires title to the Product with which this Software is included. Any attempt to assign any rights, duties or obligations arising hereunder other than as set forth in this paragraph shall be void.
4. **U.S. Government Rights:** If Purchaser is acquiring Software (including the related documentation) on behalf of any part of the United State Government, the following provisions apply: the Software and documentation are deemed to be "commercial software" and "commercial computer software documentation," respectively pursuant to DFAR Section 227.7202 FAR 12.212, as applicable. Any use, modification, reproduction, release, performance, display or disclosure of the Software (including the related documentation) by the U.S. Government or any of its agencies shall be governed solely by the terms of this Agreement and shall be prohibited except to the extent expressly permitted by the terms of this Agreement.

Index

A

About This Manual • 5
Accept or Forward Notifications • 23, 26
Add a System • 19, 29, 30
Advanced Features • 20, 30
Alarms and Messages • 28

C

Chapter 1
 Description • 13
Chapter 2
 Basic Setup and Use • 15
Chapter 3
 Operation • 15, 19
Chapter 4
 Troubleshooting • 29, 30, 33
Chapter 5
 Specifications • 33, 37
Chapter 6
 Service and Maintenance • 39
Cleaning • 39
Cleaning and Service Warnings and Cautions • 11
Compliance Warnings and Cautions • 11
Connect to a Different System • 30
Contacting Masimo • 33, 34, 39
Contraindications • 7

E

Exclusions • 39

G

Getting Started • 15, 19

I

Identify System and Login • 15

www.masimo.com

Instruments • 28
Intended/Indications for Use • 7

L

Limitation of Warranty • 39
Limited Warranty • 39
Logout of the Connected System • 20

M

Mobile Device Compatibility • 37
Modify/Remove a System • 31

N

Notification Popup • 23
Notifications Screen • 16, 21

O

Open the Replica Application • 15
Overview • 13

P

Patient SafetyNet Compatibility • 37
Patient Screen • 26, 28
Patients • 17, 25
Performance Warnings and Cautions • 9
Product Description • 7
Product Description, Intended Use and Contraindications • 7

R

Replica Messages • 29
Restrictions • 40

S

Safety Information, Warnings and Cautions • 9
Safety Warnings and Cautions • 9

Sales & End-User License Agreement • 40

Select a System and Login • 15, 19, 29, 30, 31, 33, 34

Side Menu • 21

Symbols • 37

T

Troubleshooting Replica • 33

V

View Notifications • 16

View Patient Data • 17

View System Data • 20, 21, 25

THIS PAGE INTENTIONALLY BLANK

THIS PAGE INTENTIONALLY BLANK



39506/LAB-9886C-0718