

Vigilant Sentinel

Your Smart Infusion Status

Version 1.1



INSTRUCTIONS FOR USE



**FRESENIUS
KABI**

caring for life

Symbol descriptions



Warning (Refer to the Instructions For Use)



Warning



Fragile, handle with care



Keep away from rain



Humidity limitation



Batch code / number



This side up



CE mark



Refer to the Instructions For Use
Electronic Instructions for Use are available on
the Key 2 distribution website <https://key2.fresenius-kabi.com>



Name and address of the manufacturing facility



Name and address of manufacturer / Date of
manufacture (Year-Month-Day)



Product reference / part number



Temperature limitation



Atmospheric pressure limitation



General symbol for recyclable material



Eco packaging symbol



Warning: Warning of a potential hazard that could result in serious personal injury and/or product damage if the written instructions are not followed.



Caution: Warning of a potential hazard that could result in minor personal injury and/or product damage if the written instructions are not followed.



Information: Recommendations to be followed.

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1 Introduction

Vigilant Sentinel is an infusion visualization application that collects data from all pumps in a ward, and displays smart status information for each bed and each pump on a central station.

By providing a complete overview of all beds in a ward and the status of all infusions, it helps nurses to organize their daily activities efficiently. In particular, it helps to:

- Prioritize bed visits
- Plan for syringe and bag changes
- Be aware of sudden new priority conditions
- Find available pumps that can be used for another patient

The benefit for the nurses is reduced stress due to pump alarms, and reduced alarm fatigue.

1.1 Scope

These Instructions for Use (IFU) are applicable to the Vigilant Sentinel application.

Users of the Vigilant Sentinel application must read this manual before using Vigilant Sentinel. Failure to adhere to these instructions may result in damage to the equipment.

Before using the application, you must also read all the accompanying documents provided with the following devices:

- Agilia infusion pumps
- Agilia racks (Link+ Agilia)

1.2 Intended use

Vigilant Sentinel is an infusion visualization system designed to provide qualified healthcare personnel with a centrally aggregated view of infusion pumps' status within a hospital or hospital-type setting.

It is a secondary display system and is not intended to replace any part of the patient care and monitoring procedures already in place for infusion devices. It does not relieve healthcare personnel of their duty to closely monitor patients and infusions directly at the bedside.

Vigilant Sentinel is not a remote alarm management system, therefore caregivers should only rely on bedside pumps for alerts and alarms. Vigilant Sentinel is not intended to be used for diagnostic purposes.



WARNING

Vigilant Sentinel must not be relied upon as the primary method for monitoring infusions. It is the responsibility of the nurses, and of the medical staff generally, to regularly monitor the pumps at the patients' bedside.

1.3 Intended users

Vigilant Sentinel is intended for use by qualified and trained healthcare professionals, including nurses (primary users) and trained system administrators (secondary users).

It is assumed that the nurses are familiar with the Agilia pumps and Link+ racks used in their ward and compatible with Vigilant Sentinel. All compatible equipment is listed in *Compatibility matrix* on page 9.

1.4 Training

For training, contact your Fresenius Kabi sales representative. See the fill-in contact box at the end of these Instructions for Use (IFU).

NOTE: Typical initial training duration: 1 hour. We recommend that you attend a 20-minute refresher course once a year.

1.5 Intended patients

Vigilant Sentinel is an infusion visualization system intended for all kind of patients infused using a compatible pump.

1.6 Use environment

The Vigilant Sentinel application is intended for use in hospitals and hospital-like settings. It must be installed on a desktop PC located in a central nursing station with the supervisory equipment used by the medical staff. For ease of use, the PC can be equipped with a touch screen, in which case the keyboard and mouse are not required.

For the best view of the display screen, the recommended user position is in front of the screen with your eyes at the same level as the screen.



INFORMATION

Vigilant Sentinel must be installed, used, and maintained in accordance with the clinical practices, protocols, and rules, established and documented by the healthcare organization.

1.7 Vigilant Sentinel delivery

Vigilant Sentinel is delivered:

- On a CDROM
- On the Key 2 distribution website <https://key2.fresenius-kabi.com>

The product CDROM includes:

- The Vigilant Sentinel software
- User instructions and technical documentation in electronic format (accessible from the CDROM home page)
- A printed Getting Started Guide

From the Key 2 website, you can download:

- The Vigilant Sentinel software
- User instructions and technical documentation in electronic format (under the `doc` folder)

NOTE: Printed Instructions for Use (IFU) are available on request from the Key 2 distribution website <https://key2.fresenius-kabi.com>.

2 Warnings and Precautions

This section lists all the warning and precaution messages given throughout this guide. It is important to take special care to observe the indications given in these messages.



WARNING

Vigilant Sentinel must not be relied upon as the primary method for monitoring infusions. It is the responsibility of the nurses, and of the medical staff generally, to regularly monitor the pumps at the patients' bedside.



WARNING

Vigilant Sentinel associates a bed number with Link+ racks at the bedside. The pumps slotted in the racks are thus automatically associated with that bed. Therefore, you can move pumps from one Link+ rack to another, but you must not move a Link+ rack from one bed to another.



WARNING

If you need to move a Link+ rack from one bed to another, you must contact the hospital's technical support department to update the Vigilant Sentinel configuration.

The label on the Link+ rack must be changed to indicate the new bed name (room number + bed number).





WARNING

Vigilant Sentinel must only be used with the equipment listed in *Compatibility matrix* on page 9.

3 Vigilant Sentinel system

3.1 System components

Vigilant Sentinel infusion visualization system components are the following:

- Vigilant Sentinel software
- Fresenius Kabi volumetric pumps (represented by  on the Vigilant Sentinel display).
- Fresenius Kabi syringe pumps (represented by  on the Vigilant Sentinel display).
- Fresenius Kabi Link+ Agilia racks, that provide the pumps with a central power supply and wired Ethernet communication.

For a full list of compatible equipment, see *Compatibility matrix* on page 9.

Vigilant Sentinel can display infusion status information for a maximum of 24 beds with up to two Link+ racks per bed, representing up to 384 infusion pumps.

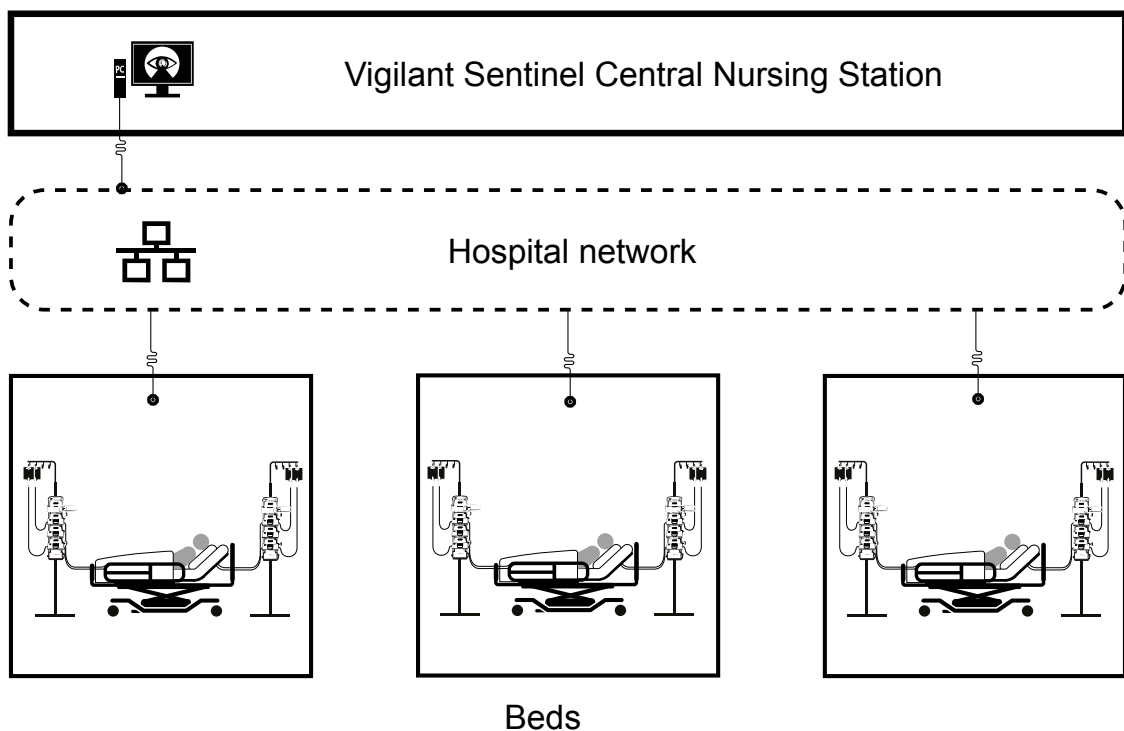
INFORMATION



- A Link+ rack can only be connected to one information system at a time. Before connecting a Link+ rack to the Vigilant Sentinel system, make sure it is not connected to another information system such as a PDMS. Failure to follow this recommendation can result in communication errors.
- For more information on Vigilant Sentinel application installation, contact your technical support department.

3.2 Principle of use

The diagram below shows how the Vigilant Sentinel system is set up in a hospital environment. From the Central Nursing Station, you can view the status of infusion pumps in the patients' rooms.



- Vigilant Sentinel software is installed on a PC (referred to as the "Vigilant Sentinel Central Nursing Station") that has a wired connection to the hospital network.
- The Link+ racks at the bedside have a wired connection to the hospital network.
- Vigilant Sentinel Central Nursing Station centralizes and displays pump information in near real-time.
- You can view pump information on the Vigilant Sentinel interface and organize the required actions at the bedside.



WARNING

Vigilant Sentinel associates a bed name (room number + bed number) with the Link+ racks at the bedside. The pumps slotted in the racks are thus automatically associated with that bed. Therefore, you can move pumps from one Link+ rack to another, but you must not move a Link+ rack from one bed to another. A label on the Link+ rack must indicate the room number and bed number.

3.3 Vigilant Sentinel communication network

Vigilant Sentinel communicates with Link+ racks over a wired network. All pumps communicate with the Link+ rack through infrared cells. The cell located at the back of the pump faces one on the Link+ rack when the pump is plugged onto a power connector on the rack.

The Link+ rack detects the presence of a pump even when it is off. It is displayed in Sentinel with the status **Off**.

When Agilia pumps that have WiFi enabled are plugged onto the Link+ rack, the following happens:

- If the pump is on: WiFi is automatically disabled and the pump can communicate only over the wired network.
- If the pump is off: it regularly emits a WiFi signal and can communicate with the Centerium server.

For further information on the uses of WiFi communication, see the IFU for the pump.

3.4 Time delays

The Vigilant Sentinel user interface displays information from the Link+ racks and connected pumps with a slight delay. You must take this delay into account to determine the priority of actions to be organized at the patient bedside.

Vigilant Sentinel polls the system periodically:

- Every 5 seconds to detect disconnections (pumps or Link+ racks) and pump status information
- Every 30 seconds to detect new Link+ racks

Thus, between the display on the pump or Link+ rack, and the display on Vigilant Sentinel central station, the time delays can be as follows:

- At startup, Vigilant Sentinel displays information on the Link+ racks in under 90 seconds.
- During operation:
 - After connecting a new Link+ rack, Vigilant Sentinel displays the rack status in under 60 seconds; after disconnecting a Link+ rack, the status is displayed in under 10 seconds.
 - After connecting a pump to a Link+ that is already present, or after disconnecting a pump, the status is displayed within 10 seconds.
 - Pump status is displayed on Vigilant Sentinel within 10 seconds from the display on the pump.
- Before stopping, there is a 90 second timeout (default value for 3 retries) before Vigilant Sentinel displays a network disconnected status or technical error status on a standby screen.

For information on the time between occurrence of alarm conditions and occurrence of message on pump, refer to the relevant IFU for the pump.



INFORMATION

The time delays specified in this section are dependent on the conformance with Vigilant Sentinel system installation recommendations and on the hospital's overall network performance.

3.5 Compatibility matrix

Vigilant Sentinel infusion visualization system is validated for use with the following equipment and software versions.

Compatible equipment	Vigilant Sentinel V1.0	Vigilant Sentinel V1.1
Link+4 / Link+6 / Link+8	V 3.0	V 3.0
Volumat Standard Agilia	Not supported	V 1.2e
Volumat MC Agilia	V 2.3f	V 2.3f

Compatible equipment	Vigilant Sentinel V1.0	Vigilant Sentinel V1.1
Agilia VP	Not supported	V 1.4 and later versions up to and including 2.2.x
Agilia VP MC		
Injectomat Standard Agilia	Not supported	V 2.5g
Injectomat MC Agilia	V 4.3h	V 4.3h
Injectomat TIVA Agilia	Not supported	V 4.3h
Agilia SP	Not supported	V 1.6a and later versions up to and including 2.2.x
Agilia SP MC		
Agilia SP TIVA		

3.6 Compliance with standards

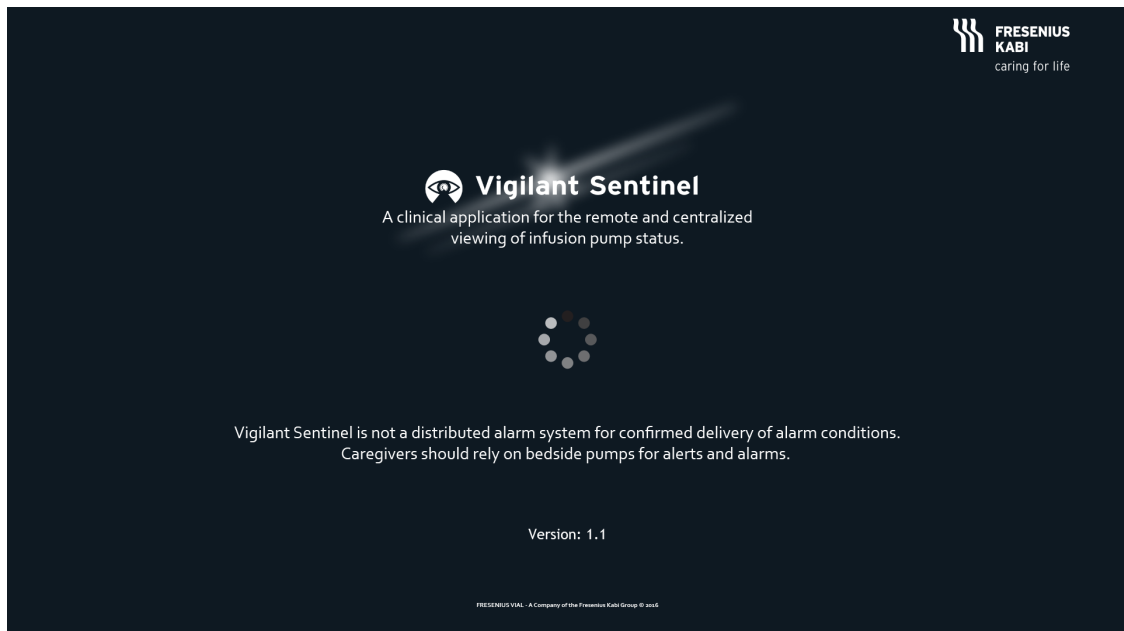
The Agilia pumps and Link+ racks provided by Fresenius Kabi that are part of the Vigilant Sentinel infusion visualization system are compliant with applicable standards. Compliance with these standards is described in the IFUs for the Agilia pumps and Link+ Agilia racks.

The requirements for the PC used as the Vigilant Sentinel central station are described in the Vigilant Sentinel installation instructions.

4 Starting and shutting down Vigilant Sentinel

4.1 Starting Vigilant Sentinel

1. On the Vigilant Sentinel host PC, log on with the dedicated user account for Vigilant Sentinel (configured by the system administrator).



The application automatically starts. The splash screen is displayed.

2. Wait while the application checks the connection with the Link+ racks over the hospital network.



- If the connection test is successful, the ward view is displayed as shown above.
 - If connection errors are detected, Vigilant Sentinel displays the list of Link+ racks that are affected.
 - If connection errors are detected with all Link+ racks, after three retries of 30 seconds (default values), Vigilant Sentinel displays a Network disconnected status.
3. If connection errors with Link+ racks are detected, and you know that these racks have been temporarily disconnected, click **Continue** at the bottom of the page.
The ward view is displayed. Disconnected Link+ racks are greyed out in the bedside view.
 4. If Vigilant Sentinel displays a screen showing Network disconnected, contact your technical support department.

4.2 Shutting down Vigilant Sentinel

In normal use, Vigilant Sentinel must run permanently and must not be shut down. If needed, contact your technical support department for more information about shutting down the application.

5 Using the Vigilant Sentinel interface


The Vigilant Sentinel user interface consists of the following views:

- The ward view: provides high-level status for each bed in the ward
- Empty container view: indicates time left before end of container (syringe or bag) for each pump with a known remaining time
- Bedside view first level: provides summary information on each pump at the bedside
- Bedside view second level: provides pump status and detailed infusion parameters for infusing pumps

5.1 Displaying the ward view

The ward view shows all beds in a ward to help you to identify the beds that require action and the order of priority for visiting them. It displays summary information for up to 24 beds.

Display the ward view as follows:

1. Log on to Vigilant Sentinel to display the ward view, or navigate to the ward view by clicking the Ward icon  in the upper left-hand corner of any bedside view.
The ward view is displayed.



Legend

- 1 Bed summary (× number of beds)
- 2 2-way button to navigate between ward view and empty container view
- 3 Access to information about the software

The bed summary indicates the bed name, and shows information on the pump with highest-priority action, or if several infusions are in progress, the pump with the lowest remaining time.



Legend

- 1 Drug name
- 2 Infusion remaining time / Pump type
- 3 Bed name (5 characters)
- 4 Progress bar representing remaining time

2. If nurse action is required, you can:

- Select the bed that requires action in the Vigilant Sentinel interface to view more details. See *Displaying the bedside view (first level)* on page 15.
- Go to the patient's bedside to organize the necessary action, in accordance with your hospital's practices, protocols, and rules.

INFORMATION



- For more information on reading the bed summary, see *Status information on ward view* on page 26.
- For more information on symbols displayed, see *Display and symbols* on page 24.
- For more information on pump status, refer to the relevant IFU for the pump.

5.2 Displaying the empty container view

The empty container view shows all infusions in the ward that are approaching the end of container, or are empty, when the remaining time is known and displayed in the other views of Vigilant Sentinel. The infusions are ordered by time left before end of syringe or bag, with the shortest time at the top of the list.

The purpose of this view is to help you anticipate empty syringes and bags and, if necessary, to prepare the new syringes and bags needed to complete the prescribed dose.



INFORMATION The empty container view does not show mid-term or short-term action status for pumps. Keep watch of the condensed ward view for any new priority conditions on pumps or on beds in the ward.

Display the empty container view as follows:

1. On the ward view, click the 2-way button located at the bottom of the window, in the center.
The empty container view is displayed.



Legend

1. Infusion progress bars
2. 2-way button to navigate between ward view and empty container view
3. Access to information about the software
4. Scroll button showing number of hidden lines below

2. Plan for syringe and bag replacements based on the information displayed, and on the patient prescriptions.
3. For details on a specific infusion, you can:
 - Click the progress bar to display the bedside view second level.
 - Go to the patient's bedside to check the status on the pump, replace a syringe or bag, or complete the infusion, in accordance with your hospital's practices, protocols, and rules.
4. If the condensed ward view shows a new short-term or mid-term action, you can:
 - Select the bed that requires action in the condensed ward view to display directly the corresponding bedside view.
 - Go to the patient's bedside to resolve the status on the pump, in accordance with your hospital's practices, protocols, and rules.

INFORMATION



- For more examples of pump infusion status, see *Status information on bedside view (2nd level)* on page 33.
- For information on the condensed ward view, see *Status information on condensed ward view* on page 30.
- For more information on symbols displayed, see *Display and symbols* on page 24.

5.3 Displaying the bedside view (first level)

The bedside view (first level) shows a selected bed to help you to identify the specific pumps that require action. It shows:

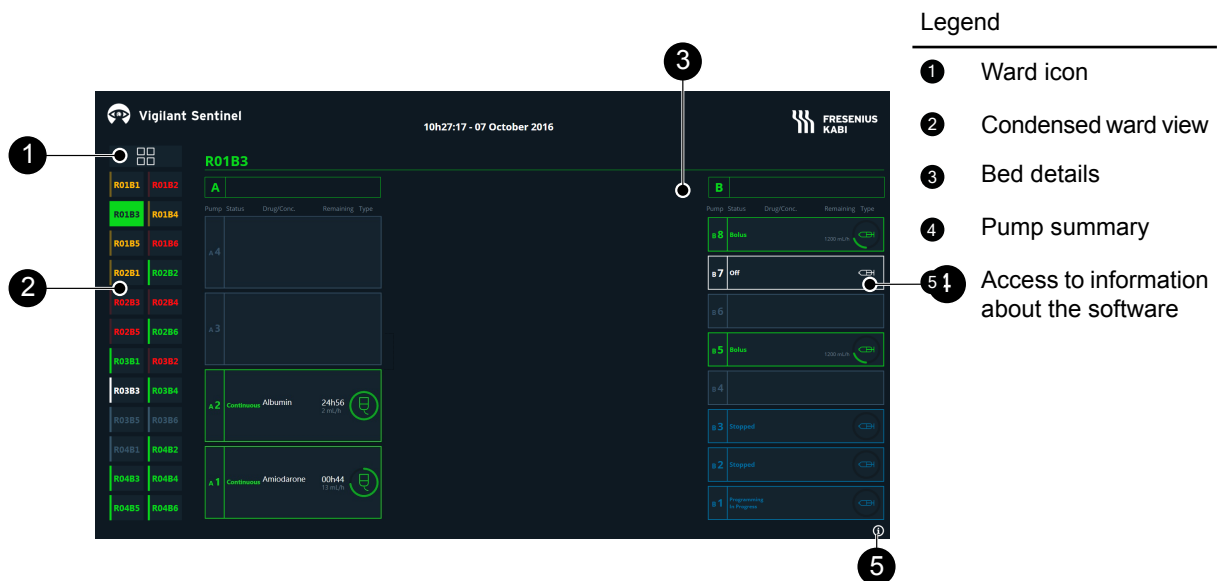
- The Link+ racks at the bedside (up to two, A and B as identified by the labels on the racks, in accordance with the Vigilant Sentinel Installation instructions)
- The rack slot numbers, and the pumps if present
- High level infusion status for each pump

It also displays a condensed ward view so that you don't lose sight of potential emergencies at other beds.

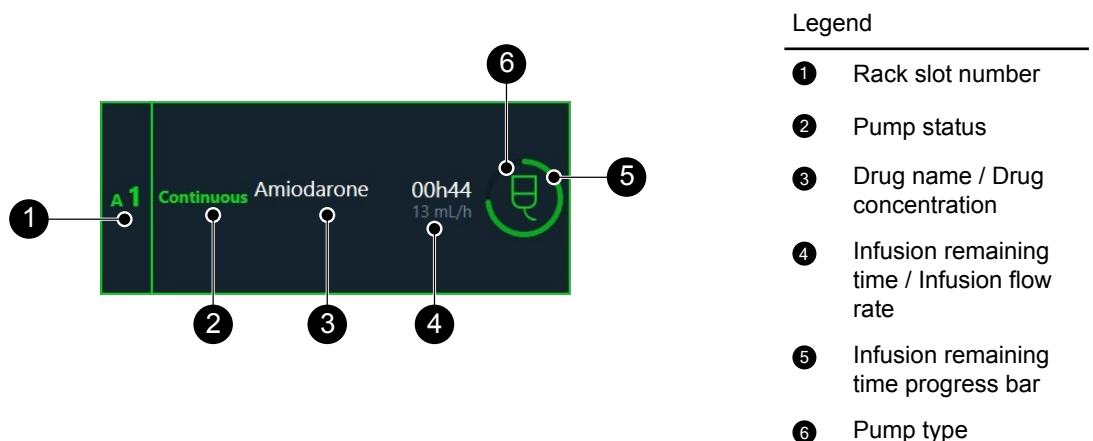
Display the first level bedside view as follows:

1. In the ward view, click a bed.

The bedside view (first level) is displayed. The condensed ward view warns you about any new action required at ward level.



The pump summary indicates the slot number in the rack, and shows high-level infusion information.



2. If new action is required on the condensed ward view, choose one of the following options:

- On the Vigilant Sentinel interface, in the condensed ward view, select the bed that requires action to display directly the corresponding bedside view.
- Go to the patient's bedside to resolve the status on the pump, in accordance with your hospital's practices, protocols, and rules.

3. If action is required on a pump, you can:

- Click the pump to view detailed status.
- Go to the patient's bedside to resolve the status on the pump, in accordance with your hospital's practices, protocols, and rules.



INFORMATION

- For more examples of pump summary, see *Status information on bedside view (first level)* on page 31.
- For information on the condensed ward view, see *Status information on condensed ward view* on page 30.
- For more information on symbols displayed, see *Display and symbols* on page 24.

5.4 Displaying the bedside view (second level)

On the second level bedside view, you can view infusion details for a selected pump at the patient's bedside:

- Drug name
- Concentration
- Infusion mode
- Dilution
- Dose rate
- Flow rate
- VTBI
- Dose infused
- Volume infused
- Remaining volume
- Remaining time
- End time
- Patient weight
- Pressure

Display the second level bedside view as follows:

1. In the ward view, click a bed.
The bedside view (first level) is displayed.
2. In the bedside view, click a pump.
You can click on a green, yellow, or red pump. Blue, white and grey pumps are not available for selection.

Legend

- 1 Infusion details
- 2 Current status tab

The screenshot displays the Vigilant Sentinel interface. On the left, a list of pumps is shown with status indicators (green, yellow, red, blue, white, grey). Pump R01B3 is highlighted in green. The central panel shows the selected pump's details: Amiodarone, Continuous infusion mode, 13 mL/h flow rate, 9.27 mL VTBI, 0.73 mL volume infused, 00h43 remaining time, 10h43 - 07 Oct 2016 end time, 0 mmHg pressure, and 24h55 concentration. The right panel shows other pumps with their status (e.g., e8 Status, e7 OFF, e6, e5 Status, e4, e3 Stopped, e2 Stopped, e1 Programming in Progress). Callout 1 points to the 'Amiodarone' header, and callout 2 points to the 'CURRENT STATUS' tab.

The pump infusion details are displayed. The current status tab displays messages that indicate any short-term or mid-term action that is required.

3. If short-term or mid-term action is required, go to the patient's bedside to resolve the status on the pump, in accordance with your hospital's practices, protocols, and rules.






INFORMATION

- For more examples of pump infusion status, see *Status information on bedside view (2nd level)* on page 33.
- For more information on pump status, refer to the relevant IFU for the pump.
- For more information on symbols displayed, see *Display and symbols* on page 24.





5.5 Navigating between views

To navigate between views in the Vigilant Sentinel interface, you can click:

- Any live area on the current view
- The ward icon  present on the bedside views and on the empty container view
- The two-way navigation button present on the ward view  and the empty container view 

The ward view is the Vigilant Sentinel default display. This means that when any other view is displayed, with no action after a certain time limit, Vigilant Sentinel automatically displays the ward view again. This time limit is at the maximum, and by default, 30 seconds.

To actively change views, follow these steps:


1. On the ward view, click either:
 - Any bed to open the corresponding bedside view.
 - The two-way navigation button  to display the empty container view.
2. On the bedside view first level, click either:
 - Any pump to view the corresponding pump details (bedside view 2nd level).
 - Any bed on the condensed ward view to open the corresponding bedside view.
 - The ward icon  to display the ward view.
3. On the bedside view 2nd level, click either:
 - Any other pump to view the pump details.
 - Any bed on the condensed ward view to open the corresponding bedside view.
 - The ward icon  to display the ward view.
4. On the empty container view, click either:
 - Any infusion progress bar to display the corresponding pump details (bedside view 2nd level).
 - Any bed on the condensed ward view to open the corresponding bedside view.
 - The two-way navigation button  to display the ward view.

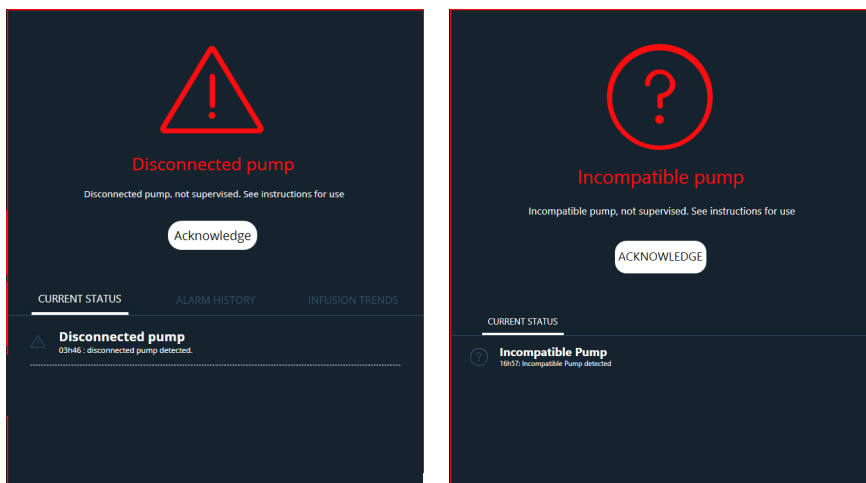
NOTE: You can navigate to the empty container view from the ward view only.

5.6 Acknowledging short-term action status

When a pump is disconnected from a rack, or when an incompatible pump is slotted on the rack, Vigilant Sentinel generates a short-term action status that requires an acknowledgement. The status can be acknowledged from the Vigilant Sentinel Central Station.




To acknowledge a disconnected pump or incompatible pump:

1. In the ward view, click the bed displaying a short-term action status (priority:  Red) due to a disconnected pump or incompatible pump.
The bedside view is displayed.
2. In the bedside view, click the pump showing the short-term action status message.
The pump details are displayed in the upper section of the central part of the screen.



3. If needed, go to the patient's bedside to check pump status because Vigilant Sentinel cannot display it.
4. Click **Acknowledge**.

The short-term action status is acknowledged. This means that the status changes to information (blue or grey):

- **Incompatible pump:** on the bedside view, the corresponding slot turns to  Blue (bright) and the status message changes from Incompatible pump to Unsupervised pump. The inhibited alarm symbol  is displayed on the bedside view, and on the ward view. No data is available for display on Vigilant Sentinel.
- **Disconnected pump:** the pump is considered absent and the corresponding slot turns to  Grey (no action required). If the pump is still in use after disconnection, the infusion data is not available for display on Vigilant Sentinel.


5.7 Displaying software information

The software information screen displays important product information:

- CE mark
- Product name and version number
- GTIN product identifier
- Name and address of manufacturer

NOTE: The GTIN product identifier combined with the software version number define a Unique Device Identification (UDI). It is also provided in a data matrix and in a readable text format available on the product labels.

To display the software information screen:

- From the ward view or any of the bedside views, click the information icon  in the bottom right-hand corner of the display.

The Vigilant Sentinel software information screen is displayed.

6 Conventions used by Vigilant Sentinel








Vigilant Sentinel displays status information using a combination of the following elements:

- A color code
- A symbol
- An informative message
- An audio signal (depending on your system configuration)

This section explains the meaning of the color codes and symbols, as well as the priority ranking used by Vigilant Sentinel. For illustrations of the messages that can be displayed on each view with their meanings, see *Interpreting information displayed by Vigilant Sentinel* on page 26.

6.1 Color code

The colors below are used on the Vigilant Sentinel display to indicate the priority of actions to organize at the bedside:

Priority	Color	Information to nurse
High	 Red	The nurse needs to organize short-term action at the bedside.
Medium	 Yellow	The nurse needs to organize mid-term action at the bedside.
Information	 Green	No nurse action is needed at the bedside: pump(s) with fluid delivery in progress.
Information	 Blue (dull)	On the bedside view only: nurse action is in progress (new infusion in preparation or infusion suspended).
	 Blue (bright)	<ul style="list-style-type: none">■ On the ward view: a blue symbol can be displayed in the bed summary on any background color, indicating the presence of an unsupervised pump.■ On the bedside view: unsupervised pump (incompatible pump acknowledged).
Information	 White	The nurse can use available pump(s) for another patient.
Information	 Grey	<ul style="list-style-type: none">■ On the ward view: nurse action not required at the bedside, no running infusion.■ On the bedside view: empty slot, no pump present.

6.2 Priority ranking in Vigilant Sentinel

Vigilant Sentinel continuously checks that the system is operational because it is a prerequisite for displaying pump infusion status. The operation of the system is described in *Principle of use* on page 8.

In addition, Vigilant Sentinel sorts all the data received from the pumps, discards information that is not relevant in terms of nurse action, and assigns priorities to the data to be displayed on the central station.

Thus, the messages displayed on Vigilant Sentinel are sorted and prioritized based on:

- System condition
- Relevance for nurse action
- Stage of operation of the pump (installation in progress, programming in progress, infusion in progress, stopped)
- Number and type of messages to display in the event of multiple priority conditions

6.2.1 System condition

Vigilant Sentinel regularly checks the system is operational and reports information such as:

- Pump connections or disconnections, and incompatible pumps connected to the system
- Link+ connections or disconnections, and incompatible Link+ racks connected to the system
- Interruptions in communication over the system network, or communication errors detected

- Network congestion
- Interruptions in Link+ power supply

In Vigilant Sentinel, any event that affects the system condition is reported with a higher priority than the pump condition. The reason is that if the system is not operational, it cannot guarantee to relay pump information reliably.

Some system conditions detected by Vigilant Sentinel result in closing down the ward view and bedside views, and displaying a standby screen. These are:

- Communication not established with all Link+ devices when none of the Link+ devices in the system is connected
- Network disconnected, please contact your technical support
- Vigilant Sentinel is experiencing delays updating the system

Other system conditions detected by Vigilant Sentinel do not affect proper operation. These result in displaying a specific error message. For example:

- Link+ disconnected (high priority)
- Incompatible pump (high priority until acknowledged)
- Disconnected pump (high priority if previously infusing)
- Pump off (information)

These system conditions are aggregated with the pump statuses to report for a bed based on the ranking rules for multiple priority conditions explained in *Multiple priority conditions* on page 23.

For the full list of system messages with their priority level, see *Sentinel display reference* on page 44.

6.2.2 Relevance for nurse action

Pump messages and alerts that are not relevant for determining immediate or future action required at the patient bedside are not displayed on the Vigilant Sentinel central station.

Pump messages and alerts that are discarded report low priority conditions or information-only signals. The tables below show the list of pump messages and alerts, the conditions that trigger them and the reason why they are discarded in Vigilant Sentinel.

Syringe pump messages not displayed on Vigilant Sentinel

Pump display ¹	Conditions for activation	Reason for discarding
Low flow rate	During infusion programming, lower soft limit exceeded.	A nurse is already present and programming the pump.
Lower soft min		
High flow rate	During infusion programming, upper soft limit exceeded.	A nurse is already present and programming the pump.
Upper soft max		
Hard limit reached	During infusion programming, cannot exceed hard low limit or hard high limit.	
Empty syringe mode	At the end of an infusion, indicates the possibility to empty the tip of the syringe. It is an option in the pump configuration.	The end of infusion short-term action is displayed on Vigilant Sentinel without the options specific to each pump's configuration.
Power disconnection	Pump disconnected from mains power supply.	Main power supply is from Link+. Vigilant Sentinel displays Link+ off mains if necessary.
Keyboard locked Unlock keypad to continue	Pump keypad manually locked by nurse.	Action on keyboard has no effect. A nurse who requires access knows how to unlock it.
Night mode	Pump visual and audio alerts dimmed and muted. Mode manually set by nurse.	Not relevant for infusion supervision.

¹ For further information on relevant messages for the pump in use, see the IFU for the pump.


Volumetric pump messages not displayed on Vigilant Sentinel

Pump display ²	Conditions for activation	Reason for discarding
Automatic restart after occlusion	The pump automatically restarts when a brief occlusion occurs.	The occlusion condition on the pump does not last longer than 20 seconds. Vigilant Sentinel displays a short-term action status if restart fails.
Low flow rate Underflow (drop sensor)	During infusion programming, lower soft limit exceeded.	A nurse is already present and programming the pump.
Lower soft min		
High flow rate Overflow (drop sensor)	During infusion programming, upper soft limit exceeded.	A nurse is already present and programming the pump.
Upper soft max		
Hard limit reached	During infusion programming, cannot exceed hard low limit or hard high limit.	
OCS failure!!!	The occlusion test system detected a failure.	A nurse is already present and priming the pump.
Connect drop sensor!!!	When drop sensor is compulsory, message displayed at startup when drop sensor is not connected.	A nurse is present starting the infusion.
No drop sensor!!!	Drop sensor Not required but is connected during infusion or when the infusion is stopped .	
Stop for new infusion!	VTBI is complete and KVO mode is active.	Treated by Vigilant Sentinel like an end of infusion (high priority).
Power disconnection	Pump is disconnected from mains.	Main power supply is from Link+. Vigilant Sentinel displays Link+ off mains if necessary.
Keyboard locked-Unlock keypad to continue	Manually locked by nurse.	Action on keyboard has no effect. A nurse who requires access knows how to unlock it.
Night mode	Manually set by nurse.	Not relevant for infusion supervision.














6.2.3 Stage of operation of pump

Priority alerts on pumps are translated into short-term and mid-term action statuses in Vigilant Sentinel, and sometimes into information-only messages. The priority and color code assigned by Vigilant Sentinel is determined by the stage of operation of the pump. For example, pump alerts that are emitted during pump installation and programming are not displayed on Vigilant Sentinel to avoid sending immediately a nurse to a bedside where there is already a nurse present.

The table below shows how pump alerts are translated into short-term actions, medium term actions, or information messages on the Vigilant Sentinel central station.


Pump stage of operation	Type of pump alert	Status on Sentinel
Power on	Erxxx (message) !!! Technical error	 Red Technical error - short-term action
	All medium and high priority alerts marked !!! or !!	Not displayed

² For further information on relevant messages for the pump in use, see the IFU for the pump.

Pump stage of operation	Type of pump alert	Status on Sentinel
Installing bag or syringe	Battery alerts: <ul style="list-style-type: none"> ■ Battery alarm!!! ■ Very low battery!!! 	 Red Low battery - short-term action
	Erxxx (message) !!! Technical error	 Red Technical error - short-term action
	Battery pre-alarm!!	 Yellow Low battery - mid-term action
	Installation alerts such as: <ul style="list-style-type: none"> ■ Syringe installation!!! ■ Plunger head alarm!!! ■ Disengagement mechanism!!! ■ Remove completely syringe! ■ Install set!!! ■ Check set installation!!! ■ Door opened!!! ■ Set / air installation!!! ■ Air bubble!!! ■ Air alarm!!! 	 Blue (dull) Installation in progress - information After 20 seconds,  Yellow Incomplete action - mid-term action
	All medium and high priority alerts marked !!! or !!	Not displayed
Programming an infusion	Battery alerts: <ul style="list-style-type: none"> ■ Battery alarm!!! ■ Very low battery!!! 	 Red Low battery - short-term action
	Erxxx (message) !!! Technical error	 Red Technical error - short-term action
	Battery pre-alarm!!	 Yellow Low battery - mid-term action
	Validation alerts: <ul style="list-style-type: none"> ■ Check settings!! ■ Waiting settings!! ■ Waiting start!! ■ No validation ■ Audio alarm (Volumat) 	 Blue (dull) Programming in progress - information After 20 seconds,  Yellow Incomplete action - mid-term action
	All medium and high priority alerts marked !!! or !!	No display
Running infusion	All high priority conditions marked !!!	 Red Short-term action status with matching message
	All medium priority conditions marked !!	 Yellow Mid-term action status with matching message
	Information messages	 Blue (dull) Paused, stopped or delayed infusion - information

6.2.4 Multiple priority conditions

When Vigilant Sentinel reports multiple priority conditions for the same bed, these can all be viewed on the bedside view 1st level or 2nd level. However, in the ward view and condensed ward view, they are aggregated and summarized into a single square representing the bed.

The total number of priority conditions for the bed is indicated in a bell on the ward view, for example  if there are three priority conditions requiring action. The color of the bell, red or yellow, indicates the highest priority among the conditions reported.

For example, if a Link+ rack is off mains, the Vigilant Sentinel central station can still communicate with the pumps. On the ward view, the mid-term action status for the Link+ is aggregated with the status of the pumps. The count displayed in the bell is incremented for each pump condition that requires mid-term or short-term action. The status of pumps racked on the Link+ with infusions running normally is not visible on the ward view.

However, in some cases, due to a priority condition on the Vigilant Sentinel system, pump information is not available. The system condition is the only condition reported.



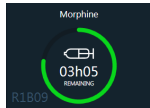

For example, if a Link+ rack is disconnected from the network, the short-term action status for the Link+ is the only condition reported due to the interruption in communication between the pumps racked on the Link+ and the Vigilant Sentinel central station. The status of pumps racked on the Link+, whether infusing normally or requiring mid-term or short-term action is not visible on any of the views.

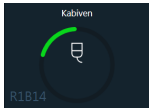
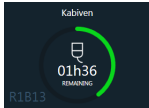

For illustrations of how multiple alarms are aggregated and summarized on the ward view and on the condensed ward view, see *Status information on ward view* on page 26 and *Status information on condensed ward view* on page 30 respectively.

6.3 Time Display in Vigilant Sentinel

In most cases, the time displayed on the pump itself is the time shown on all views in Vigilant Sentinel. However, there is one exception: when an infusion is programmed with a limit on a syringe pump, the time shown on the pump is the time before the end of the programmed dose. If this dose is greater than the syringe capacity, the empty container view displays the time left before the end of the syringe whereas the bedside view displays the time left before the end of dose, like the pump itself.

The table below summarizes how time information is displayed on Vigilant Sentinel.













Type of pump	Type of infusion	Remaining time on pump	Ward view and bedside views	Empty container view
Syringe pump	No programmed limit	Known - end of syringe	Same as pump. Example: 	Same as pump. Example: 
	Programmed limit = syringe capacity	Known - end of dose	Same as pump. Example: 	Same as pump because end of dose = end of syringe
	Programmed limit > syringe capacity			Calculated time before end of syringe . Example: 

Type of pump	Type of infusion	Remaining time on pump	Ward view and bedside views	Empty container view
Volumetric pump	No programmed limit	Unknown	Unknown. Example: 	No display
	Programmed limit (always < or = bag capacity)	Known - end of dose	Same as pump. Example: 	Same as pump. Example: 

NOTE: Infusions are displayed on the empty container view when the time left before the end of container is under a certain threshold. The default setting for this threshold is one hour.

6.4 Display and symbols

The symbols below are used on Vigilant Sentinel to indicate the type of action to organize at the bedside:

Symbol	Description
	Rack not connected to the mains power supply
	Rack disconnected from the hospital network
	Several devices require short-term or mid-term action (device type can be volumetric pump, syringe pump, and/or rack)
	Volumetric pump in normal operation
	Syringe pump in normal operation
	Occlusion status (volumetric pump)
	Occlusion status (syringe pump)
	Other pump status or Vigilant Sentinel short-term/mid-term action status (such as door open or pump disconnected from rack)
	Pump low battery
	Incompatible pump
	Alarm inhibited following acknowledgement of incompatible pump
	Establishing connection with Vigilant Sentinel

6.5 Audio signals

Vigilant Sentinel can be configured to emit an audio signal to attract the attention of the nurse when action might be required. The audio signal warns about a change in status towards a greater level of priority. This warning signal can be configured:

- For ward level only
- For bed level only
- For both ward level and bed level

If necessary, ask your hospital's technical support department for information on the audio signal configuration in Vigilant Sentinel.

7 Interpreting information displayed by Vigilant Sentinel


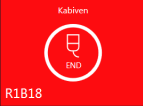



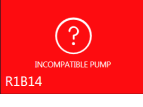
This section provides examples of the status information displayed on:

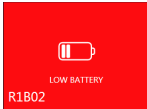

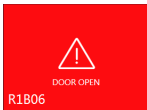
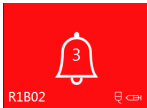
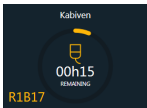


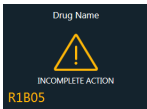
- The ward view, see *Status information on ward view* on page 26.
- The condensed ward view, see *Status information on condensed ward view* on page 30.
- The bedside view, see *Status information on bedside view (first level)* on page 31.
- The bedside view with pump details, see *Status information on bedside view (2nd level)* on page 33.

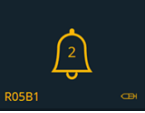
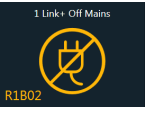
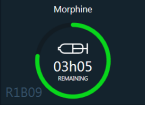
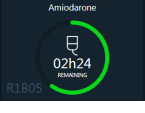
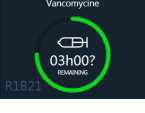

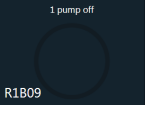

7.1 Status information on ward view

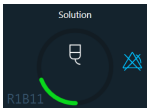
The ward view displays summary information on all beds in the ward. The Vigilant Sentinel application creates this summary based on a priority ranking (see *Priority ranking in Vigilant Sentinel* on page 19) between the system status and the pump status.

The following table provides examples of summary information that can be displayed for a bed.

Display	Trigger	Information to nurse
Flashing red background 	One Link+ rack is disconnected from the network.	<ul style="list-style-type: none"> ■ Contact your technical support department to resolve the network issue. ■ No pump data is available for display on Vigilant Sentinel. ■ Short-term action at the bedside is required to check pumps.
Flashing red background 	<ul style="list-style-type: none"> ■ An infusion has ended on a volumetric pump. ■ No other devices require short-term action. 	Short-term action at the bedside is required to stop the pump or to program another infusion.
Flashing red background 	<ul style="list-style-type: none"> ■ An infusion has ended on a syringe pump. ■ No other devices require short-term action. 	
Flashing red background 	<ul style="list-style-type: none"> ■ There is an occlusion on a volumetric pump. ■ No other devices require short-term action. 	Short-term action at the bedside is required to clear the occlusion.
Flashing red background 	<ul style="list-style-type: none"> ■ There is an occlusion on a syringe pump. ■ No other devices require short-term action. 	
Flashing red background 	<ul style="list-style-type: none"> ■ An incompatible pump is present. ■ No other devices require short-term action. 	<ul style="list-style-type: none"> ■ Replace the pump with a compatible pump ■ Acknowledge the status, as explained in <i>Acknowledging short-term action status</i> on page 17

Display	Trigger	Information to nurse
Flashing red background 	<ul style="list-style-type: none"> The battery is very low on one pump. No other devices require short-term action. 	Short-term action at the bedside is required to restore power supply from mains to the pump.
Flashing red background 	<ul style="list-style-type: none"> There is a high priority condition on the Vigilant Sentinel system. The message below the warning symbol can be: communication error, disconnected pump, unknown mode, topology error, Link+ incompatible, technical error. No other devices require short-term action. 	<ul style="list-style-type: none"> Contact your technical support department to resolve the issue. Short-term action at the bedside is required to check pumps.
Flashing red background 	<ul style="list-style-type: none"> There is a high-priority condition on one pump. The message below the warning symbol can be: syringe installation, bag installation, free flow, underflow, overflow, disengagement mechanism, door open, air, technical error, no drop sensor, drop sensor. No other devices require short-term action. 	<ul style="list-style-type: none"> Short-term action at the bedside is required to check the pump. For further details on pump condition, see relevant IFU for the pump.
Flashing red background 	Multiple actions required with at least one short-term action (in this example, total of 3 short/mid-term actions).	Short-term action at the bedside is required. Click the icon to display the bedside view with summary information for each pump.
Flashing yellow animated object 	<ul style="list-style-type: none"> An infusion is nearly ended on a volumetric pump. In this example, the infusion will end in 15 minutes. No other device requires short-term or mid-term action. 	Mid-term action at the bedside is required for the infusion that is nearly ended.
Flashing yellow animated object 	<ul style="list-style-type: none"> An infusion is nearly ended on a syringe pump. In this example, the infusion will end in 18 minutes. No other device requires short-term or mid-term action. 	
Flashing yellow object 	<ul style="list-style-type: none"> The battery is low on one pump. No other devices require short-term action. 	Mid-term action at the bedside is required to restore power supply from mains to the pump.
Flashing yellow object 	Medium priority condition reported by the Vigilant Sentinel system. Message displayed is: incomplete action.	Mid-term action at the bedside is required to validate the pump installation, the infusion programmed but not started, or the new settings on the pump. For detailed instructions, see the relevant IFU for the pump.

Display	Trigger	Information to nurse
Flashing yellow object 	Multiple mid-term actions required (in this example, total of 2 mid-term actions).	Mid-term action at the bedside is required. Click the icon to display the bedside view with summary information for each pump.
Flashing yellow object 	The Link+ rack is disconnected from the mains.	Mid-term action at the bedside is required to plug the Link+ power cord into the mains. Pumps are operating on battery.
Animated green object 	<ul style="list-style-type: none"> Running infusion on a syringe pump with known remaining time (in this example, 3 hours and 5 minutes). No pump requires short-term or mid-term action. 	No action required at the bedside: pump(s) with fluid delivery in progress.
Animated green object 	<ul style="list-style-type: none"> Running infusion on a volumetric pump with known remaining time (in this example, 2 hours and 24 minutes). No pump requires short-term or mid-term action. 	
Animated green object 	<ul style="list-style-type: none"> Running infusion on a syringe pump with known remaining time (in this example, 3 hours). At least one other pump is infusing with unknown remaining time. No pump requires short-term or mid-term action. 	
Animated green object 	<ul style="list-style-type: none"> The infusion remaining time is unknown for all pumps with fluid delivery in progress. No pump requires short-term or mid-term action. 	
White 	<ul style="list-style-type: none"> No pump requires short-term or mid-term action. No pump with fluid delivery in progress. At least one pump available. 	Available pump(s) can be used for another patient. NOTE: Link+ racks must not be moved.
Grey 	<ul style="list-style-type: none"> No pump requires short-term or mid-term action. No pump with fluid delivery in progress. No pump available. 	No action is required at the bedside.

Display	Trigger	Information to nurse
<p>Blue icon on any color background</p> 	<ul style="list-style-type: none"> ■ Incompatible pump acknowledged. ■ At least one pump with fluid delivery in progress. ■ No pump requires short-term or mid-term action. 	<p>Action is required at the bedside to monitor the unsupervised pump.</p>

INFORMATION



- The progress bar is full until the infusion remaining time reaches a configurable threshold. Once the remaining time reaches the threshold, the progress bar starts to empty. This threshold can be configured at 1 hour, 2 hours or 4 hours remaining time (1 hour is the default value).
- Depending on your system configuration, an audio signal warns you about a change in status to a greater level of priority.
- For more information on configuring the remaining time progress bar or the audio signal, contact your technical support department.



WARNING

Vigilant Sentinel associates a bed number with Link+ racks at the bedside. The pumps slotted in the racks are thus automatically associated with that bed. Therefore, you can move pumps from one Link+ rack to another, but you must not move a Link+ rack from one bed to another.

7.2 Status information on empty container view

The empty container view displays:

- All running infusions programmed in continuous, secondary, ramp, sequence or TIVA mode with a known time before end of syringe or bag **and** this known time is under a set threshold
- All ended infusions that might require an immediate change of container
- A progress bar for each infusion that represents the time left before the end of container



The infusions are ordered by increasing time before end of syringe or bag.

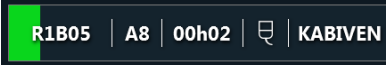
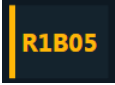

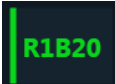
INFORMATION



- The empty container view does not display alarm conditions on the pump or on the Link+ racks. You must watch the condensed ward view on the left hand side of the screen for new mid-term and short-term action status.
- If a running infusion is interrupted due to an alarm condition on the pump, the infusion disappears from the empty container view.


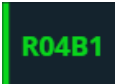
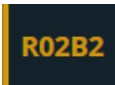

The table below shows examples of infusions displayed on the empty container view, with the information on possible actions required.

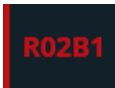

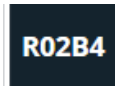
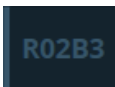
Display	Trigger	Information to nurse
<p>Progression bar empty (black)</p>  <p>The condensed ward view flashes red:</p> 	<p>Empty syringe</p>	<p>Short term-action required at the bedside to complete the ended infusion or change the syringe.</p>

Display	Trigger	Information to nurse
<p>Progress bar nearly empty</p>  <p>The bed on the condensed ward view flashes yellow (if no higher priority action on bed):</p> 	Near end of infusion	<p>Mid-term action at the bedside required.</p> <ul style="list-style-type: none"> You must plan to visit bed and do action required You can view pump details
<p>Progress bar green</p>  <p>The bed on the condensed ward view is green (if no higher priority action on bed):</p> 	Infusion in progress	No mid-term action at the bedside required.

7.3 Status information on condensed ward view

The condensed ward view displays summary information on all beds in the ward while a selected bed is displayed. The following table provides examples of summary information for beds on the condensed ward view.

Display	Trigger	Information to nurse
<p>Highlighted object (any color)</p> 	<p>Selected bed The corresponding bed is selected in the bedside view.</p>	Indicates selected bed.
<p>Green left vertical bar</p> 	<ul style="list-style-type: none"> No device requires short-term or mid-term action. At least one pump is infusing. 	No action is required at the bedside.
<p>Flashing yellow left vertical bar</p> 	<p>Previously required mid-term action</p> <ul style="list-style-type: none"> No device requires short-term action. At least one device requires mid-term action. 	Mid-term action at the bedside is required (the action was already reported by Vigilant Sentinel before the bedside view was displayed).
<p>Flashing highlighted yellow object</p> 	<p>New mid-term action</p> <ul style="list-style-type: none"> No device requires short-term action. At least 1 device requires mid-term action. 	Mid-term action at the bedside is required (the action was reported by Vigilant Sentinel after the bedside view was displayed).

Display	Trigger	Information to nurse
Flashing red left vertical bar 	Previously required short-term action <ul style="list-style-type: none">At least one device requires short-term action.	Short-term action at the bedside is required (the action was already reported by Vigilant Sentinel before the bedside view was displayed).
Flashing highlighted red object 	New short-term action <ul style="list-style-type: none">At least one device requires short-term action.	Short-term action at the bedside is required (the action was reported by Vigilant Sentinel after the bedside view was displayed).
White left vertical bar 	<ul style="list-style-type: none">No pump that requires short-term or mid-term action.No pump with fluid delivery in progress.At least 1 pump available.	Available pump(s) can be used for another patient. NOTE: Link+ racks must not be moved.
Grey left vertical bar 	<ul style="list-style-type: none">No pump that requires a short-term or mid-term action.No pump with fluid delivery in progress.No pump available.	No action is required at the bedside: no running infusion.







WARNING

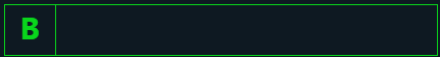
Vigilant Sentinel associates a bed number with Link+ racks at the bedside. The pumps slotted in the racks are thus automatically associated with that bed. Therefore, you can move pumps from one Link+ rack to another, but you must not move a Link+ rack from one bed to another.

7.4 Status information on bedside view (first level)

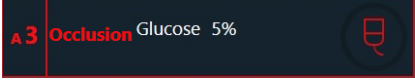


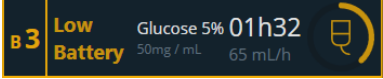
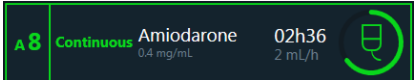



The bedside view displays summary information on the Link+ racks and the pumps at the bedside.




The following table shows the type of information that can be displayed for a Link+ rack.

Link+ rack status	Trigger	Information to nurse
Flashing red object 	The Link+ rack is disconnected from the hospital network.	Short-term action on the Link+ rack is required.
Steady red object 	The Link+ rack is not compatible with Vigilant Sentinel.	Short-term action on the Link+ rack is required.
Steady red object 	There is an error in the Vigilant Sentinel configuration.	Short-term action on the Link+ rack is required.
Flashing yellow object 	The Link+ rack is not connected to the mains power supply.	Mid-term action on the Link+ rack is required.

Link+ rack status	Trigger	Information to nurse
Steady green object 	The Link+ rack is in normal operation.	No action required.

The following table provides examples of summary information that can be displayed for a pump.

Pump information	Trigger	Information to nurse
Flashing red object 	<ul style="list-style-type: none"> The pump is stopped. Vigilant Sentinel is reporting an occlusion short-term action status. Remaining time is not known and flow rate is zero. 	Short-term action on the pump is required.
Flashing red, end of infusion 	<ul style="list-style-type: none"> The infusion is finished. 	
Flashing red animated circle 	<ul style="list-style-type: none"> The infusion is finished. Vigilant Sentinel is reporting an end of infusion short-term action status. A KVO rate is maintained and remaining time is zero. 	
Flashing yellow object 	<ul style="list-style-type: none"> The pump is infusing. Vigilant Sentinel is reporting a low battery mid-term action status. 	Mid-term action on the pump is required.
Fixed green circle, remaining time displayed 	<ul style="list-style-type: none"> The infusion remaining time is known. 	No action is required at the bedside.
Animated green circle, remaining time not displayed 	<ul style="list-style-type: none"> The infusion remaining time is unknown. 	
Blue (dull) 	<ul style="list-style-type: none"> There is a new or suspended infusion on this pump. 	Action is in progress.
Blue (dull) 	<ul style="list-style-type: none"> The infusion on this pump was stopped. 	Infusion stopped.

Pump information	Trigger	Information to nurse
Blue (bright) 	<ul style="list-style-type: none"> Following acknowledgement of an incompatible pump, this pump is unsupervised. 	No data is available for display on Vigilant Sentinel.
White 	<ul style="list-style-type: none"> The pump is available. 	Pump is available for another patient. NOTE: Link+ racks must not be moved.
Grey 	<ul style="list-style-type: none"> No pump is connected on the corresponding rack slot. 	Another pump can be used on the empty rack slot.

INFORMATION



- The progress bar is full until the infusion remaining time reaches a configurable threshold. Once the remaining time reaches the threshold, the progress bar starts to empty. This threshold can be configured at 1 hour, 2 hours or 4 hours remaining time (1 hour is the default value).
- Depending on your system configuration, an audio signal warns you about a change in status to a greater level of priority.
- For more information on configuring the remaining time progress bar or the audio signal, contact your technical support department.



WARNING

Vigilant Sentinel associates a bed number with Link+ racks at the bedside. The pumps slotted in the racks are thus automatically associated with that bed. Therefore, you can move pumps from one Link+ rack to another, but you must not move a Link+ rack from one bed to another.

7.5 Status information on bedside view (2nd level)

The bedside view 2nd level displays detailed information for a selected pump. This section shows the infusion information at the following stages:

- Infusion running: green display
- Near end of infusion: yellow display
- End of infusion: red display

Running infusion

1 AQUACHLORAL SUPPRETTES 0.4 mg/mL

Infusion mode	Continuous
Dilution	400 mg / 1000mL
Dose rate	400 µg/h
Flow rate	2 mL/h
VTBI	120 mL
Dose infused	5200 µg
Volume infused	26 mL
Remaining volume	3000 mL
Remaining time	00h50
End time	11h05 - 13 Apr 2017
Patient weight	65 kg
Pressure	15 mmHg

2

3

4

5 00h50 REMAINING

6 DOSE RATE 400 µg/h FLOW RATE 2 mL/h

Legend

- 1 Drug name
- 2 Infusion parameters (values displayed when available)
- 3 Status information (empty when no nurse action required)
- 4 Pump symbol with color indication (green for a running infusion)
- 5 Remaining time as displayed on pump itself
- 6 Dose rate and flow rate

Near end of infusion

1 AQUACHLORAL SUPPRETTES 0.4 mg/mL

Infusion mode	Continuous
Dilution	400 mg / 1000mL
Dose rate	400 µg/h
Flow rate	2 mL/h
VTBI	120 mL
Dose infused	5200 µg
Volume infused	26 mL
Remaining volume	3000 mL
Remaining time	00h10
End time	13h48 - 14 Apr 2017
Patient weight	65 kg
Pressure	15 mmHg

2

3

4

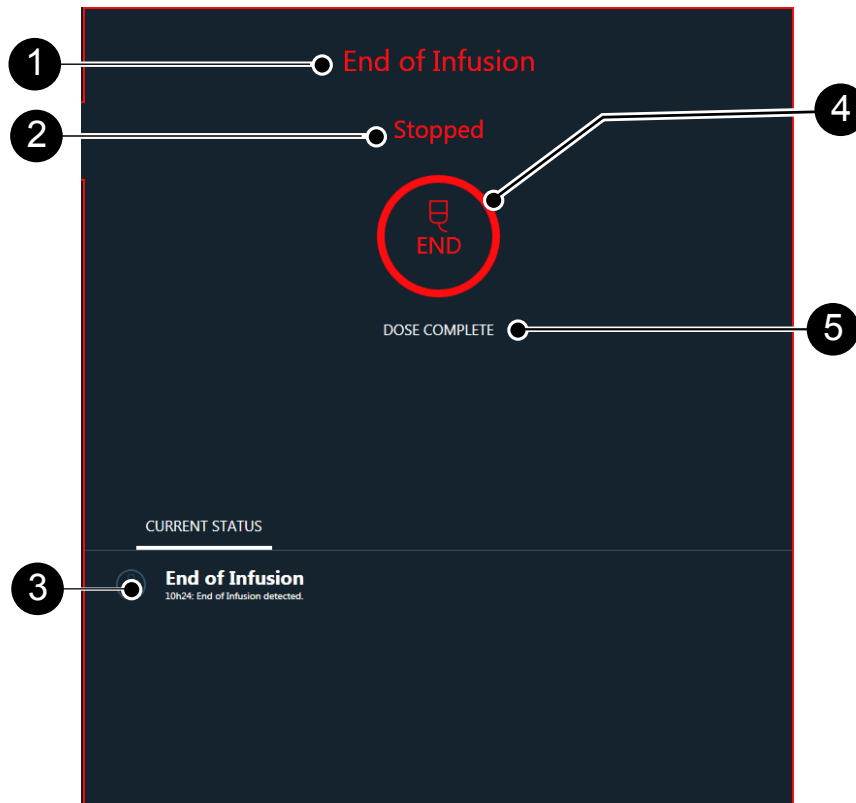
5 00h10 REMAINING

6 DOSE RATE 400 µg/h FLOW RATE 2 mL/h

Legend

- 1 Drug name
- 2 Infusion parameters (values displayed when available)
- 3 **Status information with time stamp indicating action required**
- 4 Pump symbol with color indication (yellow for an infusion approaching end time)
- 5 Remaining time as displayed on pump itself
- 6 Dose rate and flow rate

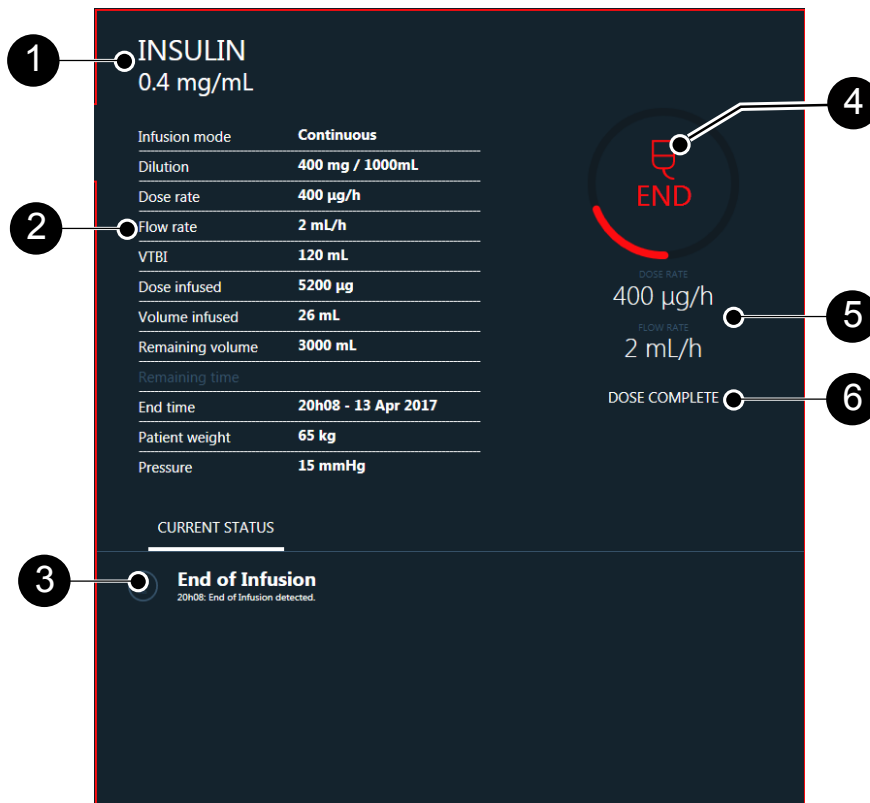
End of infusion



Legend

- ① Screen title **End of Infusion** in red
- ② Indication in red that pump is stopped
- ③ **Status information with time stamp indicating action required**
- ④ Pump symbol with color indication (**red for an infusion that has ended**)
- ⑤ Indication of **dose complete or incomplete** in relation to programmed dose

End of infusion with KVO



Legend

- ① Drug name
- ② Infusion parameters (values displayed when available)
- ③ **Status information with time stamp indicating action required**
- ④ Pump symbol with color indication (red for an infusion that has ended with **animated circle indicating KVO in progress**)
- ⑤ Dose rate and flow rate
- ⑥ Indication of **dose complete or incomplete** in relation to programmed dose

For complete information on pump and system messages reported in the bedside view 2nd level, see *Sentinel display reference* on page 44.

8 Maintaining the Vigilant Sentinel system

The Vigilant Sentinel requires regular checks and maintenance, and in particular:

- *Checking that Vigilant Sentinel is functional* on page 36
- *Cleaning the display screen* on page 36
- *Updating the Vigilant Sentinel system configuration* on page 36
- *Ensuring electromagnetic compatibility* on page 36

8.1 Checking that Vigilant Sentinel is functional

In normal operation, the information displayed on the Vigilant Sentinel central station is refreshed every 10 seconds at most. You must perform periodically, for example each month, a functional check on the system as follows:

1. Check the time at the top of the Vigilant Sentinel screen. It is normally updated every second.
2. Check that the application is not frozen by clicking on an item on the screen to display a different view.
3. Simulate a high priority condition on an identified pump and check that the associated message is displayed on the corresponding bed on the Vigilant Sentinel central station within 10 seconds.
4. Contact the hospital's technical support department if you suspect that Vigilant Sentinel is not operating correctly.

8.2 Cleaning the display screen

The screen of the Vigilant Sentinel central station must be cleaned regularly to ensure the information displayed is clearly visible.

1. If the Vigilant Sentinel central station is equipped with a touch screen, lock the screen or turn it off.
2. Using an anti-static cloth and an appropriate product, wipe the screen to remove any dust or stains.
3. In the case of a touch screen, unlock the screen or turn it back on.

Refer to the user manual of the screen for information on cleaning and maintaining it.

8.3 Updating the Vigilant Sentinel system configuration

At all times, the Vigilant Sentinel system configuration must reflect the real number of beds in the ward and the real positions of Link+ racks next to the beds. You must contact your system administrator to update the Vigilant Sentinel configuration if you need to:

- Add a bed to be supervised by Vigilant Sentinel
- Add a Link+ rack next to a bed
- Move a Link+ rack from one bed to another
- Permanently remove a Link+ rack that will no longer be used in the ward

8.4 Ensuring electromagnetic compatibility

You must ensure the electromagnetic compatibility of all components of the Vigilant Sentinel system within their respective operating environments. These components include:

- Agilia pumps listed in *Compatibility matrix* on page 9
- Link+ Agilia racks listed in *Compatibility matrix* on page 9
- The PC used as the Vigilant Sentinel central station
- The network infrastructure: network cables and hub

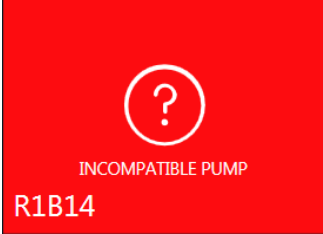

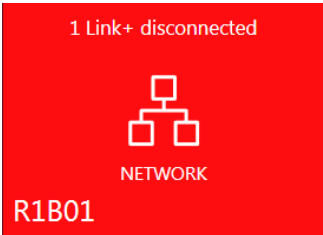
The equipment supplied by Fresenius Kabi, namely the pumps and the Link+ racks are tested and qualified in relation to electromagnetic emissions and electromagnetic immunity. The recommended operating environment for these devices, including clearances from other radiating equipment, is documented in their respective IFUs.

It is the responsibility of IT system administrators (from Fresenius Kabi and customer IT department) to ensure that the operating environment for the Vigilant Sentinel system is in conformance with the conditions described in these IFUs.

The IT system administrators must also ensure that the network infrastructure and the PC used as the Vigilant Sentinel central station are in conformance with the requirements listed in the Vigilant Sentinel installation instructions.

9 Troubleshooting

The table below lists the common issues reported by Vigilant Sentinel with recommendations on how to solve them.

Issue	Cause	Recommended action
<p>"Incompatible pump" is displayed.</p> 	<p>A Fresenius Kabi pump is plugged on the rack, but it is not compatible with Vigilant Sentinel.</p>	<ul style="list-style-type: none"> ■ You can acknowledge the status by selecting the pump, and clicking Acknowledge in the bedside view. ■ Remove the pump in accordance with hospital protocols
<p>When Vigilant Sentinel starts up, a page is displayed with a list of Link+ devices that are not communicating with the system.</p>	<p>Vigilant Sentinel cannot connect to the Link+ racks that are listed.</p>	<ul style="list-style-type: none"> ■ If you know that these racks have been disconnected for good reason such as maintenance or cleaning, click Continue at the bottom of the page. ■ Otherwise, contact the hospital's technical support department.
<p>"Link - Off Mains" is displayed.</p> 	<p>The rack is not powered from the mains. The pumps are operating on battery.</p>	<ul style="list-style-type: none"> ■ Plug the rack power supply cord into a wall socket.
<p>In ward view "Link disconnected / NETWORK" is displayed.</p> 	<p>Loss of communication between a rack at bedside and the hospital network.</p>	<ul style="list-style-type: none"> ■ Check the Ethernet connection at the bedside. ■ If the Ethernet cable is properly connected, contact the hospital's technical support department.
<p>On a standby screen, Vigilant Sentinel displays "An internal error occurred, please contact your Technical Support."</p>	<p>Application not functioning. The ward view is not accessible.</p>	<ul style="list-style-type: none"> ■ Contact the hospital's technical support department.
<p>On a standby screen, Vigilant Sentinel displays "Vigilant Sentinel is experiencing delays updating the display."</p>	<p>Congestion in data transmission. The ward view is not accessible.</p>	<ul style="list-style-type: none"> ■ Click Retry at the bottom of the screen. ■ Contact the hospital's technical support department.
<p>On a standby screen, Vigilant Sentinel displays "Network disconnected, please contact your Technical Support."</p>	<p>The ward view is not accessible.</p>	<ul style="list-style-type: none"> ■ Contact the hospital's technical support department.
<p>The display is frozen.</p>	<p>Application not functioning.</p>	<ul style="list-style-type: none"> ■ Contact the hospital's technical support department.

Issue	Cause	Recommended action
The information reported by Vigilant Sentinel is not consistent with the device installation at the bedside.	A rack has been moved to another bed than the one indicated on the Link+ label.	■ Contact the hospital's technical support department.
The audio signals emitted by Vigilant Sentinel prevent correct identification of the alarms emitted by the pumps.	The audio signal is too loud. It can be disabled in the Vigilant Sentinel Configuration Editor.	■ Contact the hospital's technical support department.
The audio signal of Vigilant Sentinel is not working.	The audio signal is not enabled in Vigilant Sentinel or not properly configured on the Central Station PC.	■ Contact the hospital's technical support department.
Vigilant Sentinel causes disruption to an external networked system by overloading the network.	Dependent upon the affected system.	■ Contact the hospital's technical support department to shut down Vigilant Sentinel to confirm it is the source of the problem.
Host PC for Vigilant Sentinel transmits malware to other applications on the network.	Host PC for Vigilant Sentinel is infected.	■ Contact the hospital's technical support department.

10 Storage

10.1 CD storage and transport conditions

Keep the Vigilant Sentinel CD-ROM in its original packaging. Respect the following conditions for storage and transport:

- Temperature: -10°C to +60°C
- Pressure: 500 hPa to 1060 hPa
- Relative humidity: 10% to 90% without condensation

After software installation, store the Vigilant Sentinel CD-ROM in its original packaging. Close the packaging when not in use, and store it in accordance with the recommendations above.

10.2 Preparing the CD for storage

- After software installation, store the Vigilant Sentinel CD-ROM in its original packaging.
- Close the packaging when not in use, and store it in accordance with the recommendations above.

11 Warranty

11.1 General warranty

Fresenius Kabi guarantees that this product is free from defects in material and workmanship during the period defined by the accepted sales conditions.

11.2 Limited warranty

To benefit from the materials and workmanship guarantee from our Fresenius Kabi sales representative or authorized agent, make sure to observe the following conditions:

- The software must have been used according to the instructions described in this document and in other accompanying documents.
- The CD must not have been damaged while being stored or repaired, and must not show signs of improper handling.
- The CD must not have been altered by unqualified personnel.
- The serial number (SN) must not have been altered, changed or erased.

If one or more of these conditions have been violated, Fresenius Kabi will prepare a repair estimate covering all required parts and labor.

To repair or return a device, contact your Fresenius Kabi sales representative.



INFORMATION

If the CD is damaged, it must be returned to the manufacturer in the original packaging.

12 Recycling

Vigilant Sentinel packaging is reusable.

Vigilant Sentinel hardware components (packaging, CD-ROM and documents) are recyclable at end-of-life.



INFORMATION

Discard materials in accordance with local regulations.

13 Glossary

hPa	Hectopascals
IFU	Instructions for Use
IT	Information Technology
KVO	Keep Vein Open
PC	Personal Computer
PDMS	Patient Data Management System
RJ45	Ethernet Interface Connector
SN	Serial Number
VTBI	Volume to be Infused
DHCP	Dynamic Host Configuration Protocol

A Sentinel display reference

This reference section provides a complete overview of all types of messages displayed on Vigilant Sentinel:

- *Syringe pump messages and corresponding Vigilant Sentinel messages on page 44*
- *Volumetric pump messages and corresponding Vigilant Sentinel messages on page 46*
- *Vigilant Sentinel system events and priorities on page 50*



INFORMATION

The ward view illustrations shown in the tables below are valid when the priority condition displayed is the only event to report for the bed. If there are multiple priority conditions, they are collectively represented by a bell symbol that indicates the number of priority conditions, as explained in *Status information on ward view* on page 26.


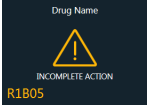

Syringe pump messages and corresponding Vigilant Sentinel messages

Compatible syringe pumps ³	Ward view	Bedside view 1st level	Current Status field on bedside view 2nd level
<ul style="list-style-type: none"> ■ End of infusion!!! ■ End of volume limit!!! ■ End of volume/time!!! ■ End of dose/time!!! 			End of infusion detected Nurse action: Short-term action required at the bedside to complete the infusion or change the syringe.
Occlusion!!!			Occlusion short-term action detected Nurse action: Short-term action required at the bedside to clear the occlusion because the infusion is stopped.
Interrupting a running infusion: Disengagement mechanism!!!			Disengagement mechanism Nurse action: Short-term action required at the bedside to check the syringe installation.
<ul style="list-style-type: none"> ■ Erxxx (message)!!! ■ Force sensor 			Technical error Nurse action: Contact your technical support department.
<ul style="list-style-type: none"> ■ Battery!!! ■ Very low battery!!! 			Low battery short-term action Nurse action: Short-term action required at the bedside to check that the Link+ rack supporting the pump is connected to the mains. If it is, contact your technical support department.


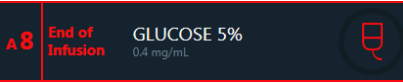
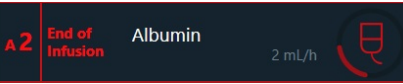


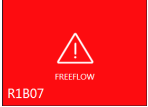
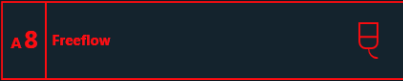
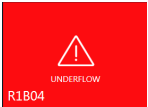


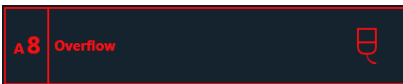
³ This table shows the messages for all syringe pumps that are coupled with an audio alarm. For further information on relevant messages for the pump in use, see the IFU for the pump.

Compatible syringe pumps ³	Ward view	Bedside view 1st level	Current Status field on bedside view 2nd level
Interrupting a running infusion: <ul style="list-style-type: none"> ■ Syringe clamp!!! ■ Flange!!! ■ Plunger head!!! 			Syringe installation Nurse action: Short-term action required at the bedside to check the syringe installation.
<ul style="list-style-type: none"> ■ End of infusion pre-alarm!! ■ Near end of volume/time!! ■ Near end of dose/time!! 			Near end of infusion detected Nurse action: If there are no short-term actions required, go to bedside to change the syringe or complete the infusion.
Occlusion pre-alarm!!			Occlusion mid-term action detected Nurse action: If there are no short-term actions required, go to bedside to clear the occlusion.
Battery pre-alarm!!			Low battery mid-term action detected Nurse action: If there are no short-term actions required, go to bedside to check that the Link+ rack supporting the pump is connected to the mains. If it is, contact your technical support department.
Volume/time			There is currently no short-term or mid-term action for this pump Nurse action: No bedside action required. Check remaining time before end of infusion.
<ul style="list-style-type: none"> ■ Simple bolus ■ Programmed bolus 			
Loading dose			

³ This table shows the messages for all syringe pumps that are coupled with an audio alarm. For further information on relevant messages for the pump in use, see the IFU for the pump.


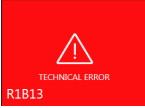




Compatible syringe pumps ³	Ward view	Bedside view 1st level	Current Status field on bedside view 2nd level
Before starting an infusion: <ul style="list-style-type: none"> ■ Syringe clamp ■ Flange ■ Plunger head 	No display		No display
		After 20 seconds: 	Incomplete action detected Nurse action: Mid-term action required at the bedside to validate the pump installation, the infusion programmed but not started, or the new settings on the pump.

Volumetric pump messages and corresponding Vigilant Sentinel messages

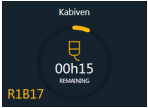
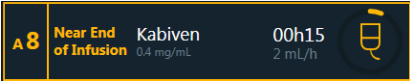
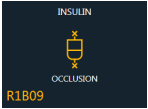
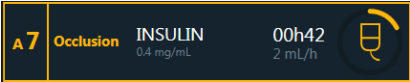


Compatible volumetric pumps ⁴	Ward view	Bedside view 1st level	Current Status field on bedside view 2nd level
<ul style="list-style-type: none"> ■ End of infusion!!! ■ End secondary alarm!!! 		 With KVO 	End of infusion detected Nurse action: Short-term action required at the bedside to complete the infusion or change the bag.
<ul style="list-style-type: none"> ■ Downstream occlusion!!! ■ Upstream occlusion!!! 			Occlusion short-term action detected Nurse action: Short-term action required at the bedside to clear the occlusion because the infusion is stopped.
Uncontrolled flow!!!			Free flow detected Nurse action: Short-term action required at the bedside to resolve the problem because the infusion is stopped.
<ul style="list-style-type: none"> ■ No drop detected by drop sensor ■ Underflow!!! 			Underflow detected Nurse action: Short-term action required at the bedside to resolve the problem because the infusion is stopped.
Overflow!!!			Overflow detected Nurse action: Short-term action required at the bedside to resolve the problem because the infusion is stopped.

³ This table shows the messages for all syringe pumps that are coupled with an audio alarm. For further information on relevant messages for the pump in use, see the IFU for the pump.

⁴ This table shows the messages for all volumetric pumps that are coupled with an audio alarm. For further information on relevant messages for the pump in use, see the IFU for the pump.

Compatible volumetric pumps ⁴	Ward view	Bedside view 1st level	Current Status field on bedside view 2nd level
Interrupting a running infusion: <ul style="list-style-type: none"> ■ Clamp missing ■ Set not detected by upstream pressure sensor ■ Set not detected by downstream pressure sensor ■ Set not installed correctly ■ Install set!!! ■ Check set installation!!! ■ Set/air installation!!! 			Bag installation detected Nurse action: Short-term action required at the bedside to check the bag installation because the infusion is stopped.
During a running infusion: Door opened!!!			Door open detected Nurse action: Short-term action required at the bedside to resolve the problem because the infusion is stopped.
<ul style="list-style-type: none"> ■ Air bubble!!! ■ Air alarm (air presence or air detection failure) ■ Air alarm!!! 			Air detected Nurse action: Short-term action required at the bedside to resolve the problem because the infusion is stopped.
Erxxx (message)!!!			Technical error short-term action detected Nurse action: Contact your technical support department.
<ul style="list-style-type: none"> ■ Battery alarm!!! ■ Very low battery!!! 			Low battery short-term action Nurse action: Short-term action required at the bedside to check that the Link+ rack supporting the pump is connected to the mains. If it is, contact your technical support department.
Connect drop sensor!!!			No drop sensor detected Nurse action: Short-term action required at the bedside to resolve the problem because the infusion is stopped.
No drop sensor!!!			Drop sensor detected Nurse action: Short-term action required at the bedside to resolve the problem because the infusion is stopped.

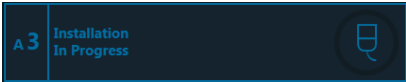
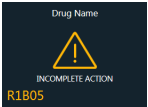
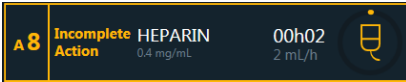
⁴ This table shows the messages for all volumetric pumps that are coupled with an audio alarm. For further information on relevant messages for the pump in use, see the IFU for the pump.

Compatible volumetric pumps ⁴	Ward view	Bedside view 1st level	Current Status field on bedside view 2nd level
Near end of infusion!!			Near end of infusion detected Nurse action: If there are no short-term actions required, go to bedside to change the bag or complete the infusion.
Occlusion pre-alarm!!			Occlusion mid-term action detected Nurse action: If there are no short-term actions required, go to bedside to clear the occlusion.
Battery pre-alarm!!			Low battery mid-term action detected Nurse action: If there are no short-term actions required, go to bedside to check that the Link+ rack supporting the pump is connected to the mains. If it is, contact your technical support department.

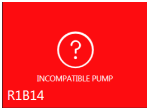
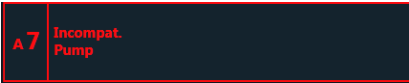

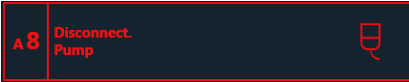



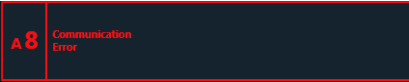
⁴ This table shows the messages for all volumetric pumps that are coupled with an audio alarm. For further information on relevant messages for the pump in use, see the IFU for the pump.

Compatible volumetric pumps ⁴	Ward view	Bedside view 1st level	Current Status field on bedside view 2nd level
<ul style="list-style-type: none"> ■ Volume/time ■ Volume/flowrate ■ Time/flowrate ■ Volume/Time/flowrate ■ Standalone flowrate/Basic Infusion ■ Drop by min ■ Programming mode: dose/time 			<p>There is currently no short-term or mid-term action for this pump</p> <p>Nurse action: No bedside action required. Check remaining time before end of infusion.</p>
<ul style="list-style-type: none"> ■ Simple bolus ■ Programmed bolus 			
Secondary			
Loading dose			
Ramp			
Sequence			





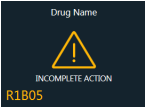
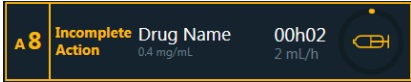
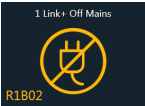

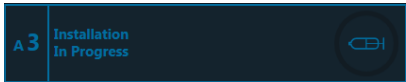

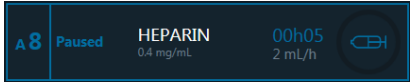
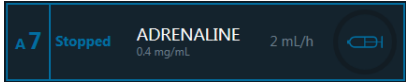
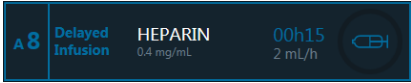
⁴ This table shows the messages for all volumetric pumps that are coupled with an audio alarm. For further information on relevant messages for the pump in use, see the IFU for the pump.


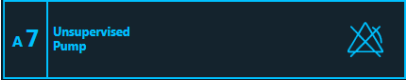
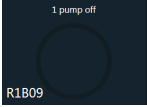


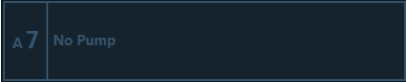
Compatible volumetric pumps ⁴	Ward view	Bedside view 1st level	Current Status field on bedside view 2nd level
Before starting an infusion: <ul style="list-style-type: none"> ■ Clamp missing ■ Set not detected by upstream pressure sensor ■ Set not detected by downstream pressure sensor ■ Set not installed correctly ■ Install set!!! ■ Check set installation!!! ■ Set/air installation!!! 	No display		No display
			Nurse action: Mid-term action required at the bedside to validate the pump installation, the infusion programmed but not started, or the new settings on the pump.

Vigilant Sentinel system events and priorities

Ward view	Bedside view 1st level	Current Status field on bedside view 2nd level
		Incompatible pump detected Nurse action: Acknowledge the incompatible pump or replace it by a compatible pump.
		Disconnected pump detected Nurse action: Acknowledge the disconnected pump to confirm intentional disconnection, or, if the pump is connected, contact your technical support department to resolve a potential communication error.
		Unknown mode detected Nurse action: Contact your technical support department.
		Communication error detected Nurse action: Contact your technical support department.
No display	No display	Pump X has encountered an unexpected error, please contact your Technical Support Nurse action: Contact your technical support department.

⁴ This table shows the messages for all volumetric pumps that are coupled with an audio alarm. For further information on relevant messages for the pump in use, see the IFU for the pump.

Ward view	Bedside view 1st level	Current Status field on bedside view 2nd level
		No display Nurse action: Contact your technical support department.
		No display Nurse action: Contact your technical support department.
		No display Nurse action: Contact your technical support department.
No display	No display	Link+ X encountered a technical error, please contact your Technical Support Nurse action: Contact your technical support department.
		Incomplete action detected Nurse action: Validate the pump installation, the infusion programmed but not started, or the new settings on the pump.
		No display Nurse action: Plug the power supply cord of the Link+ rack into the mains.
No display		Installation in progress Nurse action: None. Action already in progress at the bedside: syringe or bag being installed.
No display		Programming in progress Nurse action: None. Action already in progress at the bedside: syringe or bag being installed.
No display		Paused - Stopped - Delayed infusion Nurse action: None. Action already in progress at the bedside: a running infusion has been paused, stopped, or delayed.
		
		

Ward view	Bedside view 1st level	Current Status field on bedside view 2nd level
 <p>Ward view screenshot for R1B14. The screen displays 'No infusing pump' at the top, a large circular graphic in the center, and 'R1B14' at the bottom left. A small icon of a pump with a cross through it is visible on the right side.</p>	 <p>Bedside view 1st level screenshot for R1B14. The screen displays 'A 7' in a blue box, 'Unsupervised Pump' in the center, and a pump icon with a cross through it on the right.</p>	<p>No display Nurse action: None. You are informed that a non-supervised pump is in use. No data is available for display on Vigilant Sentinel.</p>
 <p>Ward view screenshot for R1B09. The screen displays '1 pump off' at the top, a large circular graphic in the center, and 'R1B09' at the bottom left.</p>	 <p>Bedside view 1st level screenshot for R1B09. The screen displays 'A 8' in a blue box, 'Off' in the center, and a 'CBI' icon on the right.</p>	<p>No display Nurse action: None. You are informed that a pump is available for another patient.</p>
 <p>Ward view screenshot for R1B11. The screen displays 'No infusing pump' at the top, a large circular graphic in the center, and 'R1B11' at the bottom left.</p>	 <p>Bedside view 1st level screenshot for R1B11. The screen displays 'A 7' in a blue box, 'No Pump' in the center.</p>	<p>No display Nurse action: None. You are informed that a slot is available for use.</p>

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Release notes

Date	Software version	Description
December 2016	1.0	Creation
June 2017	1.1	Addition of empty container view and of new compatible pumps
December 2017	1.1	Minor updates for delivery on Key 2 distribution website

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Fresenius Kabi AG
61346 Bad Homburg
Germany



Fresenius Vial S.A.S
Le Grand Chemin
38590 Brézins
France



0123

First CE Mark:
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www.fresenius-kabi.com

Local contacts for servicing

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