Supplement

Infinity CentralStation Wide

WARNING

For a full understanding of the performance characteristics of this device, the user should carefully read this supplement and the related instructions for use before use of the device.

Infinity CentralStation Wide VG3.0

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Trademarks

– Infinity®

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is a trademark of Clorox.

Abbreviations

In the *Instructions for use Infinity CentralStation Wide SW VG1.n and Infinity M300,* the following information is added to the section “Abbreviations”:

For any abbreviations of parameters originating from source monitors, see the corresponding instructions for use.

Supplement overview

This supplement contains the instructions for use for *Infinity CentralStation Wide VG3.0*. Combine this supplement with the *Instructions for use Infinity CentralStation Wide SW VG1.n and Infinity M300* to form the complete set of instructions for use.

Infinity CentralStation (ICS) *VG3.0* includes the following enhancements:

- Mandatory reporting of adverse events
- Infinity CentralStation reboot or restart
- Alarms
  - Default minimum alarm volume when an M300/M300+ is offline
  - Selecting alarm tone patterns
- Report handling
  - Graphical and Tabular trend reports
  - Previewing reports
  - Adding the hospital name to report headers
  - Adding a logo to report headers
  - Specifying the output destination for reports (for printing and exporting)
  - Scheduled reports
  - Selecting patients for scheduled reports
- Configuring printers
- VentCentral Setup screen (default ventilator parameter settings)
- Hardware
  - ICS speakers (external USB speaker support)
  - ICS battery indicator icon
  - Canvys touchscreen and widescreen displays (HDMI capable display)
  - Mouse movement with dual-display configurations
  - Gen 4 CPU upgrade
- Additional language support

For a list of open-source software (OSS) and the respective licenses, see Open Source License Agreement at:

http://www.draeger.com/opensource

For your safety and that of your patients

Mandatory reporting of adverse events

Serious adverse events with this product must be reported to Dräger and the responsible authorities.

General safety information

The following WARNING, CAUTION, and NOTE statements apply to general operation of the medical device.

See the *Instructions for use Infinity CentralStation Wide SW VG1.n and Infinity M300* for additional safety information.

WARNING

Risk exists that waveforms and parameter boxes are disassociated during Main Screen Layout.

User may be unaware of disassociating a waveform from a parameter box during Main Screen Layout.

User can choose a default list of waveforms and parameter boxes that are associated.

WARNING

Risk of incorrect use.

Instructions for use must be kept accessible for the user.

WARNING

Dräger recommends using the ICS only as a remote monitoring device, and the bedside monitor for primary diagnosis.

WARNING

Any modification of this device or use other than that specified within this document may cause interference with other equipment or result in injury to the patient or user, including electric shock, burns, or death.

WARNING

Risk of patient removal from the Main screen.

Changing settings on the Main Screen Layout dialog could remove previously assigned beds.

A confirmation popup informs the user that the layout of at least one bed that is currently assigned to the Main Screen has been changed.

CAUTION

The Infinity CentralStation (ICS) does not have virus protection software and therefore relies on the firewall of your institution to prevent access to infected files. While setting up IT applications to access web sites, evaluate each web site with regard to possible virus infection.

Dräger recommends that users implement a firewall and install antivirus software to protect their devices from potential cybersecurity threats.

CAUTION

Risk of user misinterpreting patient information.

User may be unaware that alarms for arterial systolic and diastolic invasive pressures are disabled while in ECMO (Extracorporeal membrane oxygenation) mode.

See the source device instructions for use, for details regarding device-specific modes related to alarms.

NOTE

User misinterprets the meaning of a label.

The meaning of the label may be unclear.

See the source device instructions for use, for any abbreviations of parameters originating from the source device.

NOTE

User may misinterpret patient status.

The Bedview waveform and parameter box layout always follows the source bedside monitor and may differ from the Main Screen layout when a Parameter order template is in use.

Functional safety

The essential performance of a patient monitor is to provide a clinician with meaningful parameter values and alarm annunciation when the established parameter limits have been exceeded, or the ability to provide values is compromised. Risks associated with use of the monitor in light of these essential performance functions have been evaluated and mitigations implemented so that the residual risk is as low as reasonably practicable, provided routine maintenance and service recommendations are followed throughout the life of the product.

Security recommendations

Dräger makes the following security recommendations:

– Physical security of the patient monitors is recommended and is the responsibility of the operating organization.

– Physical security of the telecommunications closet is recommended and is the responsibility of the operating organization.

– Dräger recommends that operating organizations restrict physical access to unused ethernet ports on the ICS.

– Dräger recommends that operating organizations restrict physical access to unused USB and serial ports on the ICS.

– Dräger relies on the medical device isolation mechanism of the VLANs and the proper configuration, implementation, and use of the operating organization's security measures to prevent the introduction of malware onto the Infinity network.

Connections to IT networks

In an IT network, data can be exchanged by means of wired or wireless technologies. An IT network can be any data interface (e.g., RS232, LAN, USB, printer interface) that is described in standards and conventions.

During operation, this device can exchange information with other devices by means of IT networks and supports the following functions:

- Display of waveforms and parameter data
- Signaling of alarms
- Recording, storing, and printing
- Remote control (e.g., alarm management)
- Bed view by remote access
- Access to saved patient data
- Transfer of device settings and patient data

Connecting this device to a network that incorporates other devices or making subsequent changes to that network can lead to new risks for patients, users, and third parties. Before the device is connected to the network or the network is changed, these risks must be identified, analyzed, and evaluated, and appropriate measures taken.

Examples of subsequent changes to the network:

- Changing the network configuration
- Removing devices from the network
- Adding new devices to the network
- Performing upgrades or updates on devices that are connected to the network

Information about connecting to an IT network

Prerequisites

This device may be connected to the network by service personnel. The IT representative of the hospital must be consulted in advance.

The following documents must be observed:

- Accompanying documents of this device
- Descriptions of the network

– Description of the network-based alarm systems

Dräger recommends complying with IEC 80001-1 (risk management for IT networks with medical devices).

LAN networks

– LAN networks are usually configured in a star topology. Individual devices can be combined into groups by means of layer-n-switches. Other data traffic is decoupled by means of separate VLAN networks. Configure the network settings of the device in accordance with these instructions for use and the network specifications.

– Specifications for LAN connections are described in the following standards:
  Wired networks: IEEE 802.3
  Wireless networks: IEEE 802.11 (b, g, n)

– If the device is used with a layer-2-switch or a layer-3-switch, the port settings must be configured on the network switch. Before the device is shipped, Dräger can configure the network settings of the device so that they are compatible with the specifications of the operating organization.

– This device exchanges data with other medical devices over the LAN network. The network must support the following transmissions and protocols:

– TCP/IP

– Unicast (static or dynamic addressing with the ARP or RARP network protocols)

– Multicast

– Broadcast

– IGMP (version 2)

  This device can join or leave an IP multicast group by using the IGMP network protocol.

VLAN networks

If data is being exchanged within a single physical network and a clinical information system is used, an independent VLAN network must be set up for the clinical information system. Additionally, at least one of the following independent VLAN networks must be set up:

– Network for medical devices for intra-hospital use

– Network for portable patient monitors

Consequences of using an unsuitable network

If the network does not meet the requirements, hazardous situations can result. The following situations can occur with this device:

- Due to unsafe distributed alarm system:
  - Alarms are not transmitted.
  - Alarms or data are delayed.
  - False alarms are indicated.
- During an interruption of the network connection:
  - Alarms are not transmitted.
  - Suppressed alarms or alarm tones are not reactivated, but remain suppressed.
- Without firewall and antivirus software:
  - Data are not protected.
  - Device settings are changed.
  - The device generates false alarms or no alarms.
- Data are sent incomplete, sent to the wrong device, or not sent at all.
- Patient data are intercepted, falsified, or damaged.
- Data have incorrect time stamps.
- An overload of the device due to very high network loads (e.g., caused by denial-of-service attacks) can lead to deactivation of the interface. The interface will only be available again after the device has been restarted. In rare cases, a warm boot may take place and may occur repeatedly.

Requirements for the electrical characteristics of connected devices and networks

The LAN interfaces and the serial interfaces are only suitable for the connection of devices or networks that have a rated voltage of at most 24 V DC on the network side and that meet the requirements of one of the following standards:

- IEC 60950-1: Ungrounded SELV circuits
- IEC 60601-1 (as of 2nd edition): Touchable secondary circuits

Device symbols

The following table lists additional Dräger hardware device symbols.

Symbol	Description
	Not made with natural rubber latex
	Eurasian conformity mark
	Unique Device Identifier, barcode
	China RoHS mark
	Acceptable storage temperatures
	Acceptable humidity range
	Acceptable atmospheric pressure range
	Lot/batch number
	Safety certification mark

Infinity CentralStation reboot or restart

When the ICS must be rebooted or restarted, Dräger recommends that patients connected to monitors are to be supervised by clinical personnel during the reboot or restart process.

NOTE
A restart will automatically close and reopen only the Infinity CentralStation application. A reboot, or manual power cycling, will power cycle the Infinity CentralStation computer and restart all applications and processes.

The ICS is the primary monitoring device for the M300/M300+. If M300/M300+ monitoring devices are monitored on only one ICS, they will not be actively monitored during a reboot or restart. When monitoring devices are offline, the ICS cannot capture full-disclosure data. This results in data gaps. While offline, monitoring devices continue to capture trends in their local database. If a reboot or restart is necessary, Dräger recommends moving all monitoring devices to a secondary ICS temporarily to ensure continued patient monitoring during the downtime. Once the original ICS is back online:

– The ICS automatically resumes patient monitoring and backfills trends saved in the local database of all monitoring devices.

– The M300/M300+ devices can be safely moved back to the original ICS to continue monitoring. When moving M300/M300+ devices back to the original ICS, a Question dialog appears to confirm the move. Once confirmed, the devices are moved back to the original ICS and removed from the secondary one.

Restarting the ICS application, instead of rebooting or manually power cycling the ICS computer, is a much faster method and thus recommended.

To restart the ICS application:

1 Select ***System setup*** from the ***Main screen*** menu bar.

2 Select the ***Biomed*** tab.

3 Enter the password, and click ***OK***.

4 Select the ***System console*** tab.

5 Type ***restartcentral*** in the console window, and press ***Enter***.

NOTE
Rebooting or manually power cycling the ICS computer should be considered a final course of action.

Alarms

Default minimum alarm volume when an M300/M300+ is offline

On the ***Telemetry defaults*** > ***Alarms*** > ***Device settings*** tab, the ***Minimum selectable alarm volume if offline [%]*** selection settings are 10, 20, 30, 40, 50 (default), 60, 70, 80, 90, or 100. The factory default is 50%.

Alarm tones

Alarm tones (***IEC fast*** and ***IEC slow***) can be set to use either cardiac-type sound (default) or ventilation-type sound.

Telemetry defaults > Alarms > Device settings page

Users select ICS alarm tone patterns individually by alarm grade (low, medium, and high). Alarms for a given alarm grade sound at the ICS using the selected alarm tone pattern. Select alarm tone patterns using the ***Alarm pattern*** option on the ***System setup*** > ***Alarms*** page. Available alarm tone pattern selections for non-telemetry beds include:

– ***Infinity***

– ***IEC fast Cardiac*** (default)

– ***IEC slow Cardiac***

– ***IEC fast Other***

– ***IEC slow Other***

Use the ***Telemetry defaults*** > ***Alarms*** > ***Device settings*** page to select M300/M300+ alarm tone patterns. Available M300/M300+ alarm tone pattern selections include:

– ***Infinity***

– ***IEC fast***

– ***IEC slow***

Optical alarms

Message banners for optical alarm signals can be read by the user from distances of up to 1 meter (approximately 3.3 feet) from the Infinity CentralStation display. Flashing parameter field signals are intended to be recognized by the user from distances of up to 4 meters (approximately 13 feet).

Alarm functionality should be verified by generating a high-priority, medium-priority, and low-priority alarm condition and confirming optical alarm signals and acoustic alarm signals at the Infinity CentralStation.

Configuring the alarm settings of the patient

The following settings can be accessed from the BedView ***Alarms*** > ***Device settings*** page:

– For patient monitors:
  – Volume for external device alarm
– For M300/M300+ telemetry:
  – Volume for M300/M300+ speaker alarm
  – Selectable for M300/M300+ VGn only:
    - Priority for SpO_2 sensor off alarm
    - Priority for ECG leads off alarm
    - Priority for critical battery alarm

Alarm volume range

Alarm priority level	Minimum alarm volume	Maximum alarm volume
High	39 – 55 dB	64 – 81 dB
Medium	42 – 52 dB	67 – 79 dB
Low	41 – 54 dB	65 – 79 dB

System setup > *Alarms* page

Selection	Settings	Description
External device alarm audio	***On***, ***Off*** *(default)*	The ICS can be configured to annunciate acoustic alarm signals from external devices. The alarm message from an external device always appears on the main screen.
ICS speakers	Go to ***System setup*** > ***Alarms***. One of the following settings is displayed: – USB – Internal speaker on or Internal speaker off – Analog **Note**: This field is read only. Speaker selection is done at installation and may be changed by contacting DrägerService.	Indicates the type of speaker selected — ***USB*** or ***Analog*** and if the internal speaker is on or off.

Visual surveillance alarm signals

CAUTION
With a Delta/DeltaXL patient monitor, if a low-priority alarm occurs while a medium or high-priority alarm is audio paused (silenced), the surveillance alarm message and banner are temporarily removed until the audio pause times out.

Report handling

Trends/Data > Trends graph and Trends table pages

The ***Trends/Data*** dialog window lets users generate and print patient trend reports in either a graphical trend format or a tabular trend format. Users can generate the following trend reports containing all parameters in the current report setup for a patient:

– A Graphical trend report that displays stored trend data based on a trends graph. It is compiled using settings from the ***Trends/Data*** > ***Trends graph*** page and the ***Trends graph*** setup page.

– A Tabular trend report that displays stored trend data based on a trends table. It is compiled using settings from the ***Trends/Data*** > ***Trends table*** page and the ***Trends table*** setup page. For more information on Tabular trend report settings and formatting, see “Tabular trend report settings” and “Tabular trend report formatting” below.

For a complete description of the ***Trends graph*** page and ***Trends table*** page, their functions, how to access them, and how to customize their content, see the *Instructions for use Infinity CentralStation Wide SW VG1.n and Infinity M300*.

Users can manually generate, preview, and print trend reports from the ***Trends graph*** page and the ***Trends table*** page, respectively. For more information about previewing reports, see "Previewing reports" on page 22.

Users can also schedule trend reports for automatic generation from the ***System setup*** > ***Scheduled reports*** page. For more information about the ***Scheduled reports*** page, see "System setup > Scheduled reports page" on page 27.

Tabular trend report settings

The Tabular trend report is a multi-parameter report containing all trended parameters in the full disclosure database. Unless otherwise specified, the following settings match those on the ***Trends table*** page:

– Selected Trend table parameters, their display order, and their data values at each time interval.

– Initial time interval between the trend table columns, which is 1, 5, 10, 15 (default), 30, or 60 minutes.

– Report duration, which is 2, 4, 8, 12, or 24 hours.

– Report start time is the interval column time minus the duration.

– Initial end time is the interval closest in time to the current anchored cursor time. Users can also select the report end time using the cursor location.

Tabular trend report formatting

The Tabular trend report includes the following row and column formatting:

– Report header, which includes the report title, hospital name, patient name and ID, date of birth, care unit and bed labels, admission date, type of implant, report start and end times, and report generation time.

– Separate parameter and units-of-measure columns.

– Up to nine time interval columns on a page labeled in HH:MM:SS format.

  When the number of intervals exceeds the maximum number of columns on a page, the additional intervals appear in labeled columns below the previous set of interval columns.

– Report footer, which includes a comments area for handwritten comments, signature area, signature date area, and page number.

The Tabular trend report appears in a horizontal format, and prints with a landscape orientation. Be sure to send Tabular trend reports to a printer that is capable of printing in landscape mode.

System setup > Recorders/Reports page

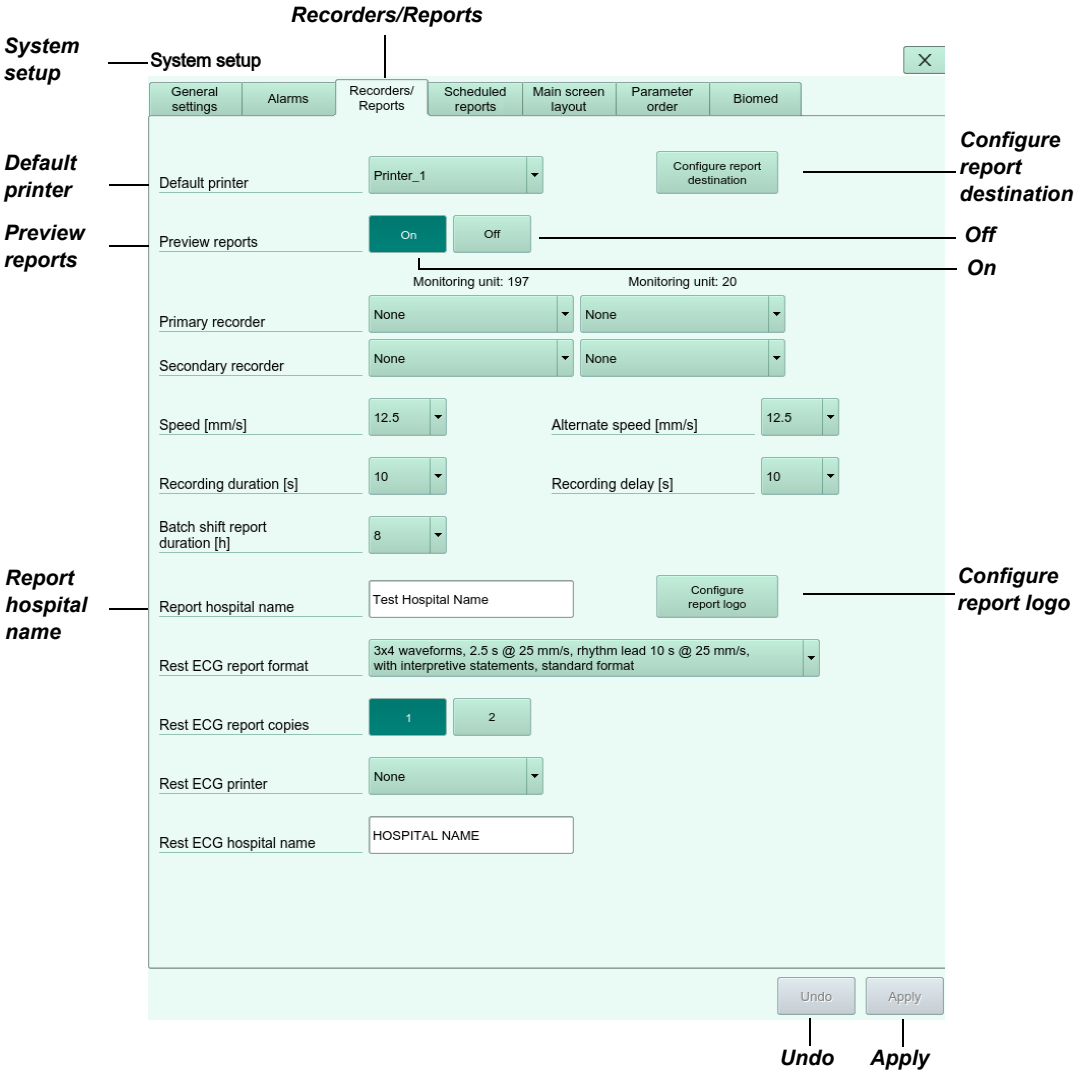
The ***System setup > Recorders/Reports*** page provides additional configuration settings for:

– Previewing reports,

– Adding the hospital name and logo or other image to reports, and

– Specifying the output destination for generated reports.

The following illustration shows the ***System setup > Recorders/Reports*** page.



Previewing reports

The ***Preview reports*** option on the ***System setup > Recorders/Reports*** page lets users enable report preview for available reports from the ***Trends/Data*** dialog window. Use the ***On*** button to enable report preview, and the ***Off*** button to disable it.

Available reports include:

– Graphical trend report

– Tabular trend report

– Full disclosure report

– Events report

NOTE

The ***Preview reports*** option setting becomes the default in BedView.

To enable print preview:

1 Press the ***System setup...*** button on the main screen.

The ***System setup*** page appears.

2 Go to the ***Recorders/Reports*** tab.

3 Next to ***Preview reports***, click the ***On*** button.

4 Click ***Apply***.

To preview a report for a patient:

1 With ***Preview reports*** enabled, select the patient's viewport on the main screen.

2 Press the ***Trends/Data*** button.

The ***Trends/Data*** dialog window opens.

3 On any ***Trends/Data*** tab, press the ***Reports...*** button.

4 Select the desired report and duration.

The ICS generates a preview of the selected report.

To print a report from the preview, click  . If ***Export manual reports:*** in the ***Configure report destination*** dialog is enabled, the user is also prompted to export the report to a file. For more information, see "Specifying the output destination for reports" on page 24.

Adding the hospital name to report headers

The ***Report hospital name*** option on the ***System setup > Recorders/Reports*** page lets the user display a hospital name in the header of reports.

To display the hospital name on reports:

1 Press the ***System setup...*** button on the main screen.

  The ***System setup*** page appears.

2 Go to the ***Recorders/Reports*** tab.

3 Enter the hospital name in the ***Report hospital name*** field.

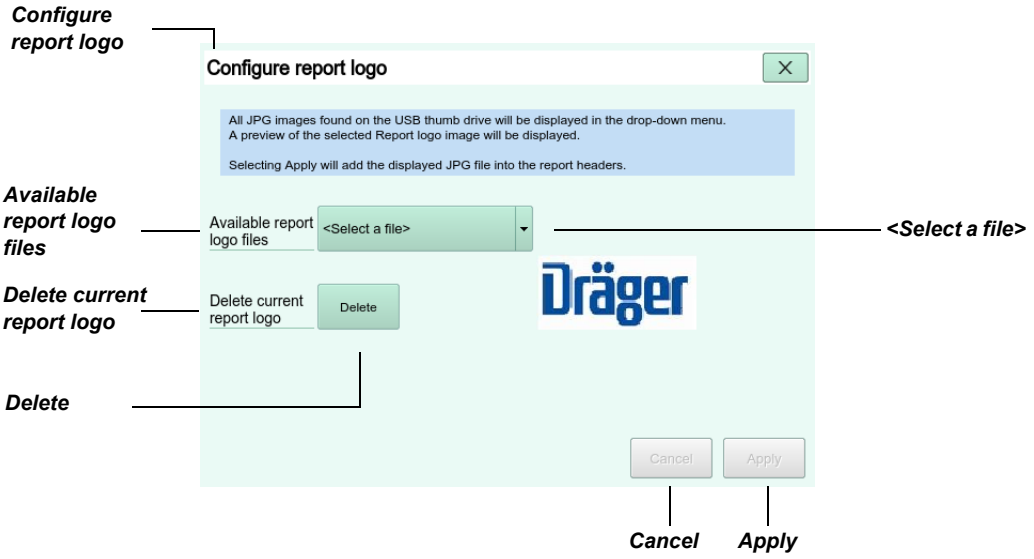
4 Click ***Apply***.

Adding a logo to report headers

The ***Configure report logo*** button on the ***System setup > Recorders/Reports*** page displays the ***Configure report logo*** dialog. This dialog lets users select a JPG file, from a USB drive, that contains a logo or other image to display in the header of reports.

NOTE
Include a logo in the header of any report type, except for Rest ECG reports.

The following illustration shows the ***Configure report logo*** dialog.



JPG images should have an aspect ratio of 2:1 (twice as wide as high), as they are scaled to approximately 400 x 200 pixels in report headers.

To display a logo or other image in the header of printed reports:

1 Press the ***System setup...*** button on the main screen.

The ***System setup*** page appears.

2 Go to the ***Recorders/Reports*** tab.

3 Click the ***Configure report logo*** button.

The ***Configure report logo*** dialog opens.

4 Select a JPG file from the ***<Select a file>*** drop-down list, which displays the list of available files found on the USB drive. If a USB drive is not installed in the USB port, this option is grayed out.

A preview of the selected image (in an approximate size) appears in the dialog.

5 Click ***Apply***.

The JPG file is copied to the system and the image is displayed in the header of reports.

To delete the currently selected image (as shown in the preview):

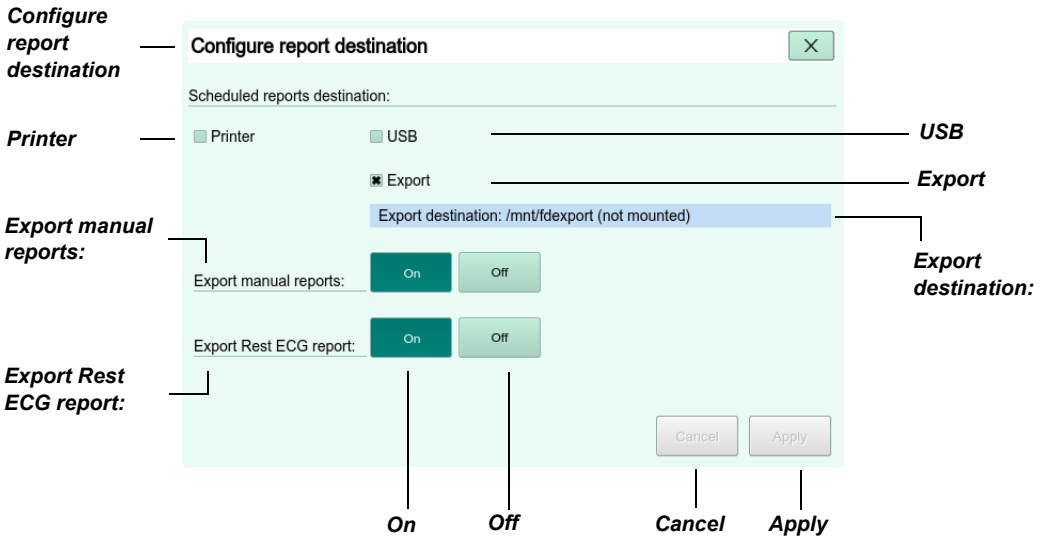
– Click the ***Delete*** button for the ***Delete current report logo*** option.

The JPG file is deleted from the system, and the image no longer appears in report headers.

Specifying the output destination for reports

The ***Configure report destination*** button on the ***System setup > Recorders/Reports*** page displays the ***Configure report destination*** dialog. This dialog lets users specify the output destination for scheduled reports and manually generated reports, including Rest ECG reports. Report destinations include printer, file location, or both.

The following illustration shows the ***Configure report destination*** dialog.



The following table lists the available settings on the ***Configure report destination*** dialog. Your selection takes effect upon selection of the ***Apply*** button.

Selection	Settings	Description
Printer check box		Sends scheduled reports to the default printer, if defined on the ***System setup > Recorders/Reports*** page. At least one printer must be configured for printing reports. Otherwise, this option is grayed out.
USB check box		Sends scheduled reports, manually generated reports, and Rest ECG reports to the root folder of a USB drive installed in the USB port. The folder path is displayed in ***Export destination***.
Export check box		Sends scheduled reports, manually generated reports, and Rest ECG reports to the **/mnt/fdexport** folder on a mounted file share configured by specialized service personnel. The folder path is displayed in ***Export destination***.

Selection	Settings	Description
Export manual reports:	***On***, ***Off*** (default)	Enables the export of manually generated reports to the ***Export destination*** location. Choose ***On*** to enable the export of these reports, and ***Off*** to disable it.
Export Rest ECG report:	***On***, ***Off*** (default)	Enables the export of Rest ECG reports to the ***Export destination*** location. Choose ***On*** to enable the export of these reports, and ***Off*** to disable it.

NOTE
Either the ***USB*** check box or the ***Export*** check box must be selected before the user can enable the ***Export manual reports*** and ***Export Rest ECG report*** options.

To enable the automatic export of reports, and specify the output destination for reports:

1 Press the ***System setup...*** button on the main screen.

The ***System setup*** page appears.

2 Go to the ***Recorders/Reports*** page.

3 Click the ***Configure report destination*** button.

The ***Configure report destination*** dialog opens.

4 Specify the output destination settings.

5 Click ***Apply***.

Based on the specified settings, reports are automatically:

– Sent to the default printer (if the printer is defined and the ***Printer*** check box is selected), and

– Saved to a ***USB*** drive, or

– Exported to a mounted file share.

Clinical log entries

A patient name is required to print a report. A patient ID is required to export a report to a file location; it is not required to print a report.

A clinical log entry is created whenever a PDF report is:

– Printed or saved to a file location,

– Not printed because the patient name is missing, or

– Not saved because the patient ID is missing.

System setup > Scheduled reports page

The ***System setup > Scheduled reports*** page lets users enable and configure the automatic generation of reports for one or more patients monitored within the shift reporting time. Scheduled reports can include one or more of the following reports:

– Shift report

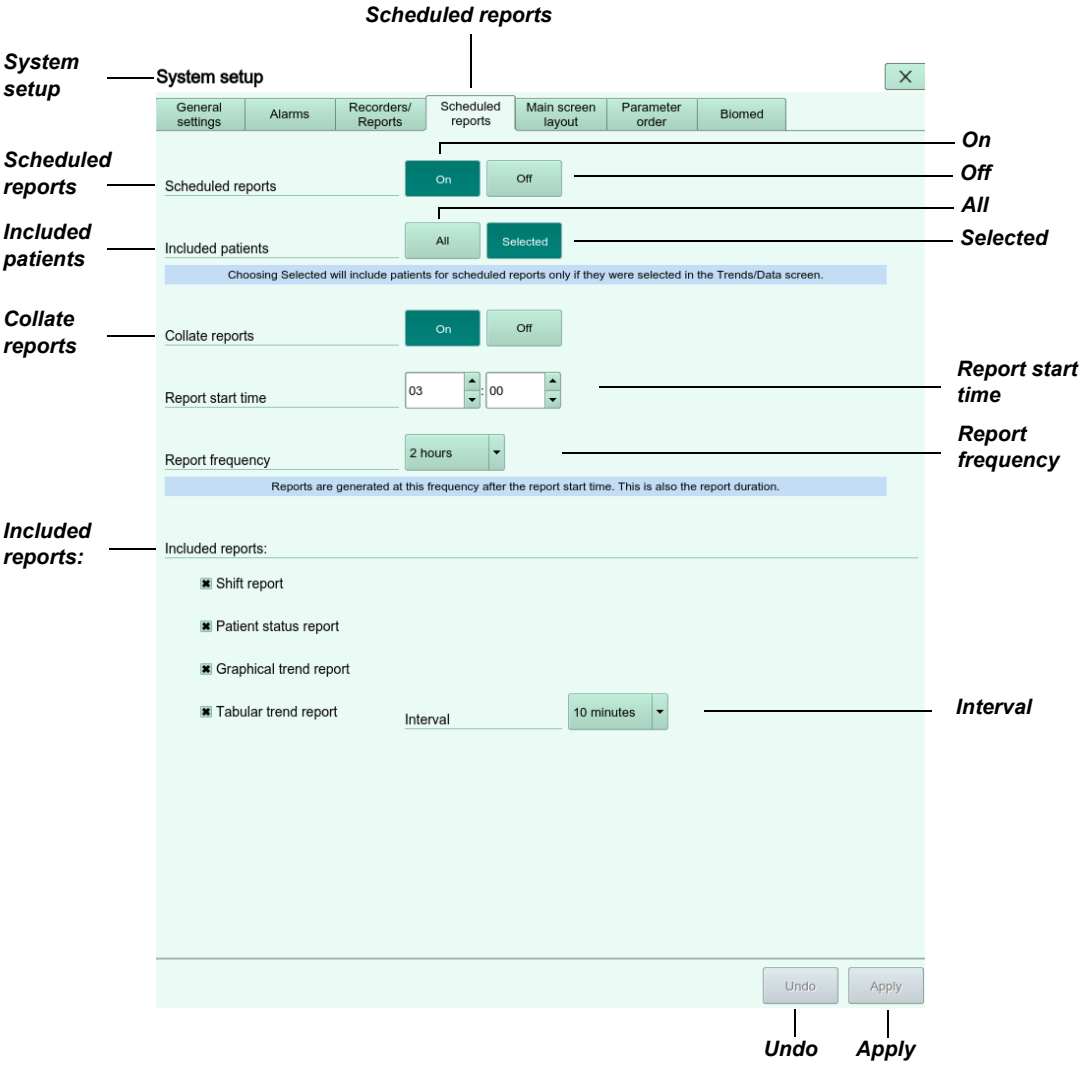
– Patient status report

– Graphical trend report

– Tabular trend report

Users can generate scheduled reports for patients individually or in collated sets. They can also automatically print or save an electronic copy of these reports by configuring an output destination for reports. These reports can be used for medical review or stored with a patient's other paper or electronic medical records. For more information, see "Specifying the output destination for reports" on page 24.

The following illustration shows the ***System setup > Scheduled reports*** page.



The following table lists the available settings on the ***Scheduled reports*** page. Your selection takes effect upon selection of the ***Apply*** button.

Selection	Settings	Description
Scheduled reports	***On***, ***Off*** (default)	Enables the generation of scheduled reports. Choose ***On*** to enable scheduled reports. Choose ***Off*** to disable scheduled reports.
Included patients	***All*** (default), ***Selected***	The patients to include in the scheduled reports. Choose ***All*** to include all patients listed on the Trends/Data (census) page that are assigned to the local ICS. The listed patients are preselected and cannot be modified. They include patients who were monitored during the time covered by the report, even if they were not actively monitored at the time the report was generated. Choose ***Selected*** to include one or more patients listed on the Trends/Data (census) page. For more information, see "Selecting patients for scheduled reports" on page 30.
Collate reports	***On***, ***Off*** (default)	Enables the collation of selected reports for each patient. That is, specifies how selected reports for each patient are assembled. Choose ***On*** to combine all selected reports for each patient into one file. In this case, the label "collated" is added to the file name. Choose ***Off*** to separate selected reports for each patient into individual files.
Report start time	1 minute to 24 hours (default is 08:00)	The initial report start time (in hours and minutes).
Report frequency	2, 4, 8 (default), 12, or 24 hours	The frequency at which reports are generated after the report start time. This is also the report duration.
Included reports:	Available reports include: – Shift report – Patient status report – Graphical trend report – Tabular trend report	The reports to include in the set of scheduled reports for each patient.
Interval	1, 5, 10, 15 (default), 30, or 60 minutes	The interval between trend columns in Tabular trend reports, when included in the set of scheduled reports.

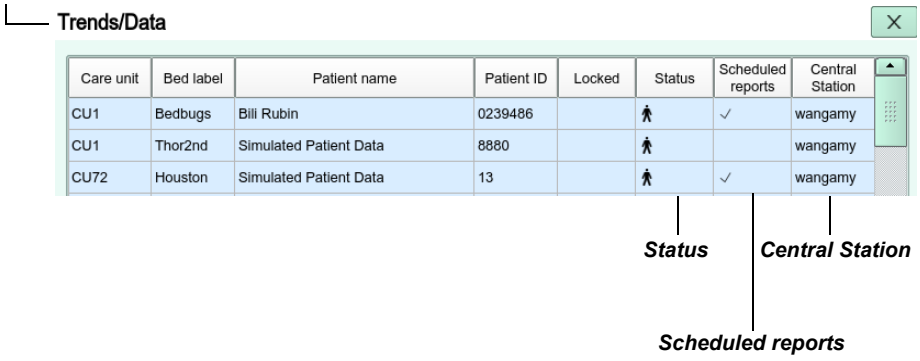
Selecting patients for scheduled reports

The ***Trends/Data*** (census) page displays a table containing all available patients with a disclosure record in either the ICS's own monitoring unit(s), or in one or more configured monitoring units.

Users can select one or more patients from this table to include in the scheduled reports generated as defined on the ***System setup > Scheduled reports*** page. Selected patients can be active or inactive, and must be assigned to the local ICS.

The following illustration shows a fragment of the ***Trends/Data*** (census) page.

Trends/Data



To select one or more patients:

1 Press the ***Trends/Data*** button on the main screen.

  The ***Trends/Data*** (census) page appears.

2 Select patients by clicking in the table cell in the ***Scheduled reports*** column.

  A check mark appears for each patient selected. To clear the check mark, click in the cell again.

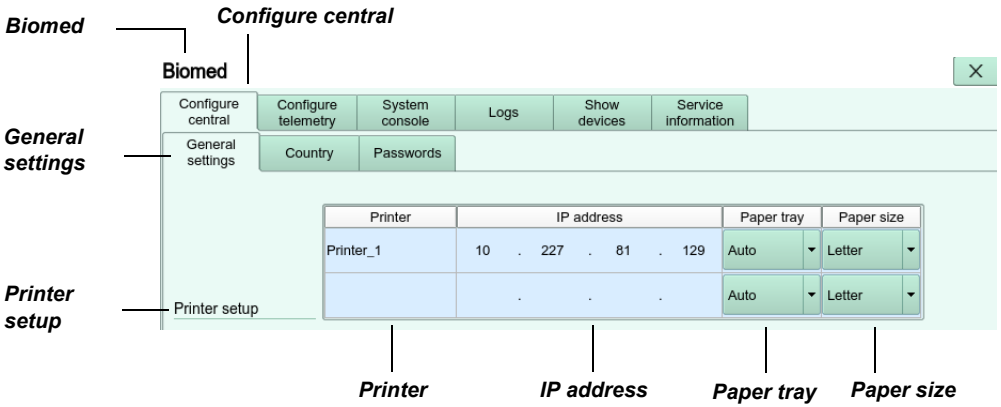
NOTE

The ***Status*** column indicates whether the patient is active or inactive. The ***Central Station*** column identifies the ICS to which each patient is assigned.

Configuring printers

Users can configure up to two printers, independently, in the Printer setup section of the ***Biomed > Configure central > General settings*** page. In addition to setting the printer names and IP addresses, users can also select the paper tray and paper size for each printer.

The following illustration shows the ***Printer setup*** section of the ***Biomed > Configure central > General settings*** page.



The ***Printer setup*** section includes the following additional settings:

– The ***Paper tray*** drop-down list, which lets users select:
  – A paper tray from the printer's available paper trays, or
  – Auto (default), which automatically selects the paper tray for the selected paper size.
– The ***Paper size*** drop-down list, which lets users select either of the following paper sizes:
  – Letter (default), which measures 215.9 mm x 279.4 mm (or 8.5 in x 11.0 in).
  – A4, which measures 210 mm x 297 mm (or 8.27 in x 11.69 in).

Parameter order

The following illustration shows the ***Parameter order*** dialog, which lets the user configure the order of parameters and how they display on the ***Main screen***.

To access the ***Parameter order*** dialog:

1 Select ***System setup...*** on the main menu bar.

2 Select the ***Parameter order*** tab.

3 Next to ***Template***, in the pull-down box***,*** select from 25 predefined templates.

4 In the ***Name*** field, enter a name for the template you selected in step “3”.

5 Next to ***Display mode***, select:

- ***Auto*** – ***Unavailable waveforms and parameters from the source device will not be displayed.***
- ***Manual*** – ***Unavailable waveforms and parameters from the source device will display blank. Only the first 11 parameters from the source device are available for display. Only the first 11 parameters from the source device are available for display***

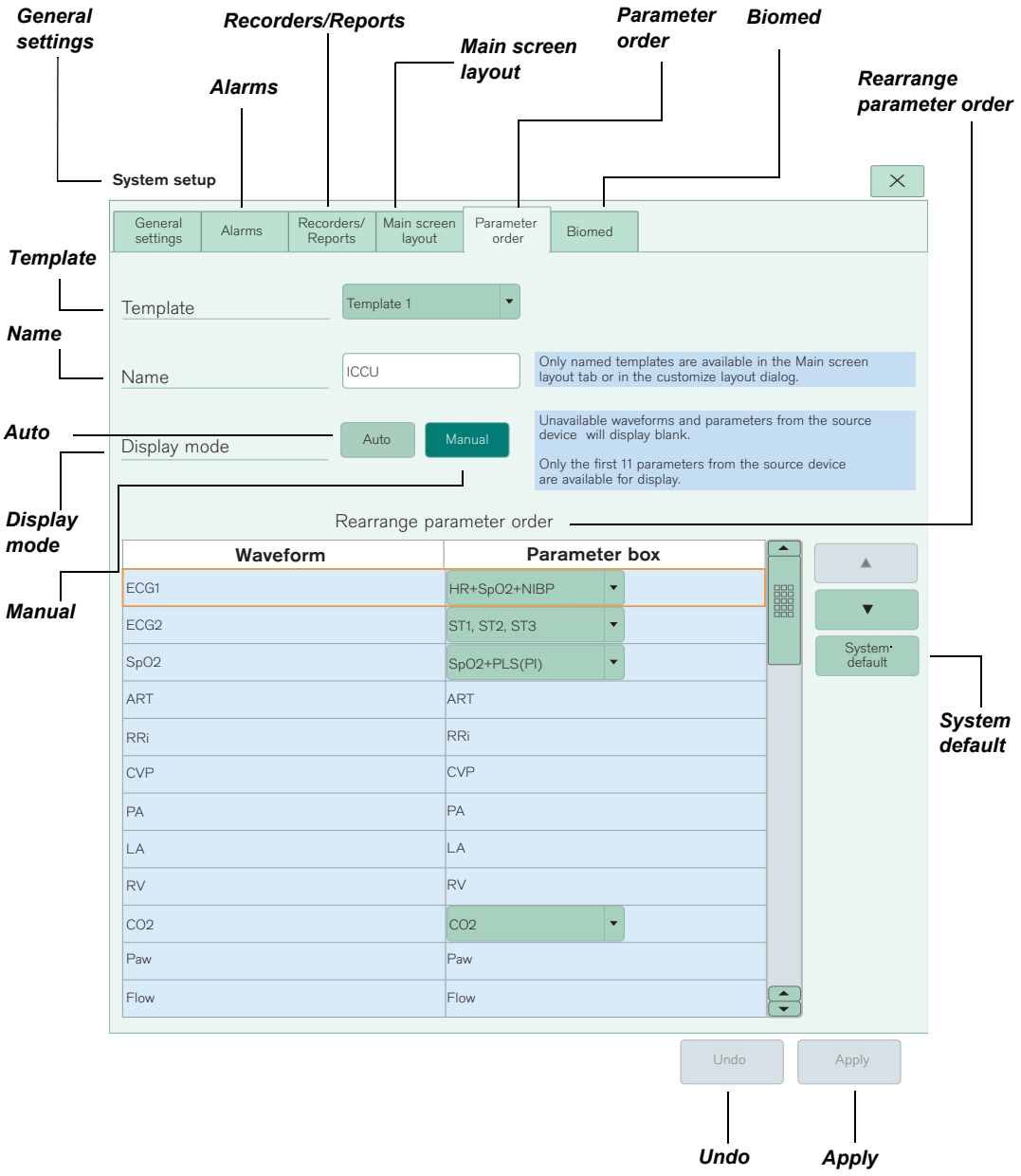
6 Under ***Rearrange parameter order***, use the up and down arrows to organize the waveforms under ***Waveform***, and parameters under ***Parameter box***. Multiple parameter boxes can be selected and moved at one time, using drag and drop functionality.

7 Click ***Apply*** to save the selections.

NOTE
Only named templates are available in the ***Main screen layout*** tab or in the customize layout dialog.

NOTE
If a template is active on the ***Main screen***, the template name can be modified but cannot be deleted.

NOTE
Select the ***System default*** button to reset to the factory default settings.


General settings
Recorders/Reports
Alarms
Main screen layout
Parameter order
Biomed
Rearrange parameter order
System setup
General settings
Alarms
Recorders/ Reports
Main screen layout
Parameter order
Biomed
Template
Name
Auto
Display mode
Manual
Template
Template 1
Name
ICCU
Only named templates are available in the Main screen layout tab or in the customize layout dialog.
Auto
Manual
Display mode
Unavailable waveforms and parameters from the source device will display blank.
Only the first 11 parameters from the source device are available for display.
Rearrange parameter order
Waveform
Parameter box
ECG1
HR+SpO2+NIBP
ECG2
ST1, ST2, ST3
SpO2
SpO2+PLS(PI)
ART
ART
RRi
RRi
CVP
CVP
PA
PA
LA
LA
RV
RV
CO2
CO2
Paw
Paw
Flow
Flow
System default
System default
Undo
Apply
Undo
Apply

Main screen layout

The following illustration shows the ***Main screen layout*** dialog, where the user can configure up to four screen layout views.

To access the ***Main screen layout*** dialog:

1 Select ***System setup...*** on the ***Main screen***.

2 Select the ***Main screen layout*** tab.

3 Next to ***Select layout****,* choose ***Layout 1***.

NOTE
The button with the (*) indicates the layout ***Name*** currently in use and displayed.

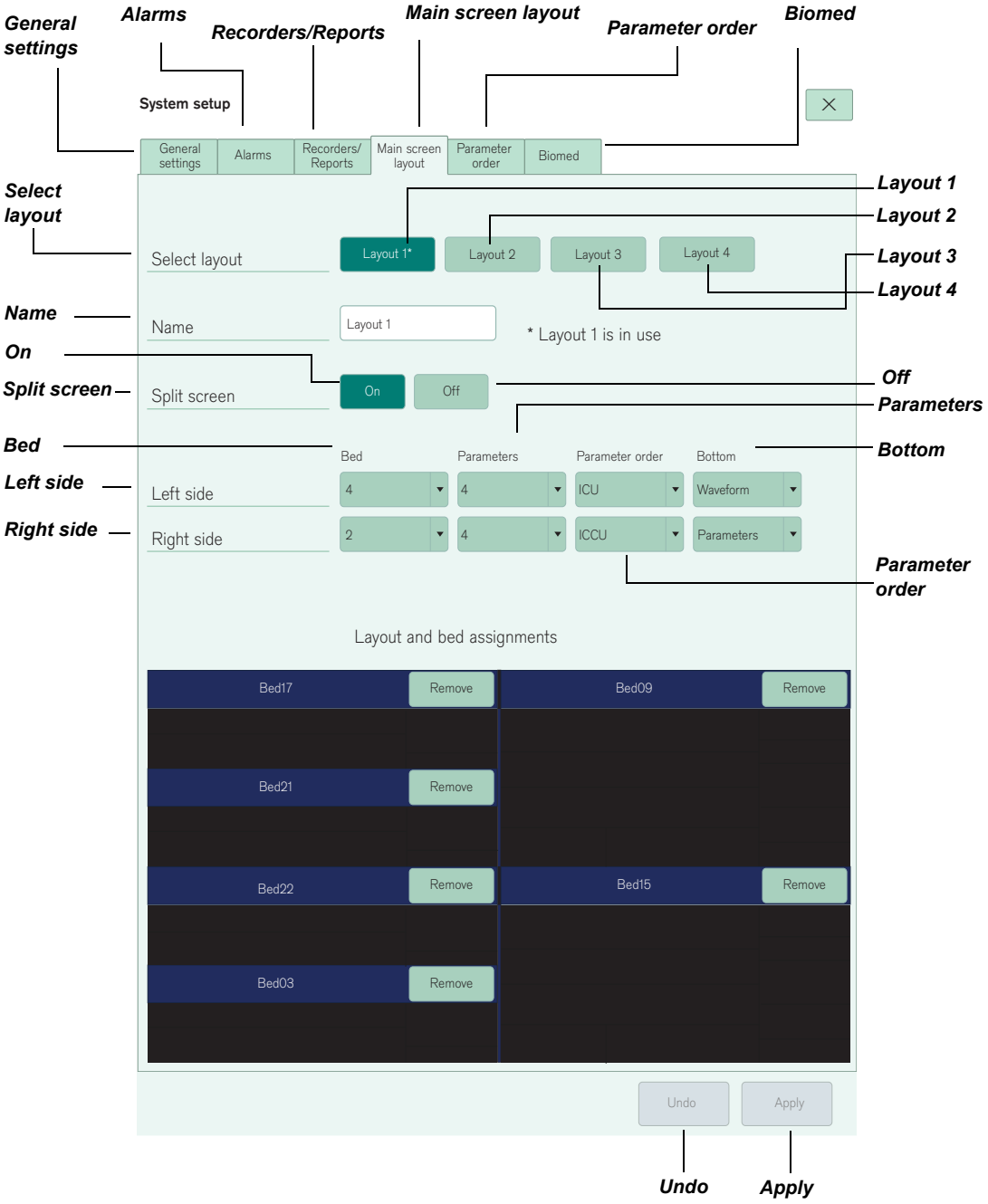
4 In the ***Name*** field, enter a custom name to help you identify the layout.

5 Next to ***Split screen***, select ***On*** to enable a split screen or select ***Off*** to default to a full screen setup.

6 Configure the following options for both ***Left side*** and ***Right side*** when using ***Split screen*** mode, and for ***Full screen*** when ***Split screen*** is ***Off***.

- Under ***Beds***, select the number of beds to monitor in the pull-down box (the number of beds may vary depending on license options).
- Under ***Parameters***, select the number of parameters to display. The number of parameters allowed is based on the number of beds being monitored.

WARNING
Modifying layouts in the *Main screen layout* tab can remove a previously assigned bed.


General settings
Alarms
Recorders/Reports
Main screen layout
Parameter order
Biomed
System setup
General settings
Alarms
Recorders/ Reports
Main screen layout
Parameter order
Biomed
Select layout
Layout 1
Layout 2
Layout 3
Layout 4
Select layout
Layout 1*
Layout 2
Layout 3
Layout 4
Name
Name
Layout 1
* Layout 1 is in use
On
Split screen
Off
Split screen
On
Off
Parameters
Bed
Bottom
Bed
Parameters
Parameter order
Bottom
Left side
Left side
4
4
ICU
Waveform
Right side
Right side
2
4
ICCU
Parameters
Parameter order
Layout and bed assignments
Bed17
Remove
Bed09
Remove
Bed21
Remove
Bed22
Remove
Bed15
Remove
Bed03
Remove
Undo
Apply
Undo
Apply

Beds	Parameters
1-2	Up to 8
3-4	Up to 4
5-6	Up to 3
7-8	Up to 2

– Under ***Parameter order*** select a pre-configured template or select ***Follow bed*** (refers to the order of the waveform and parameters as displayed and sent by the bedside monitor).

– Under ***Bottom***, select ***Waveform*** or ***Parameters***. Selecting ***Parameters*** displays a total of 3 parameter boxes in the lower channel for ***Split screen***, or a total of 4 parameter boxes for ***Full screen***.

7 Select ***Apply*** at the bottom of the screen to save the current configuration, or select ***Undo*** to cancel changes.

8 Repeat steps “3” to “7” to customize ***Layout 2***, ***Layout 3***, and ***Layout 4***.

9 To activate a layout that you created, select ***Layouts...*** from the main menu bar.

10 In the ***Layouts*** dialog, select the desired layout, and click ***Apply***.

Password protection

To allow access to the Main screen layout tab without a password, perform the following steps.

1 Select ***System setup...*** on the main menu bar.

2 Select the ***Biomed*** tab.

3 Select the ***Passwords*** tab.

4 Select ***Off*** next to ***Main screen layout password.***

5 Select ***Apply***.

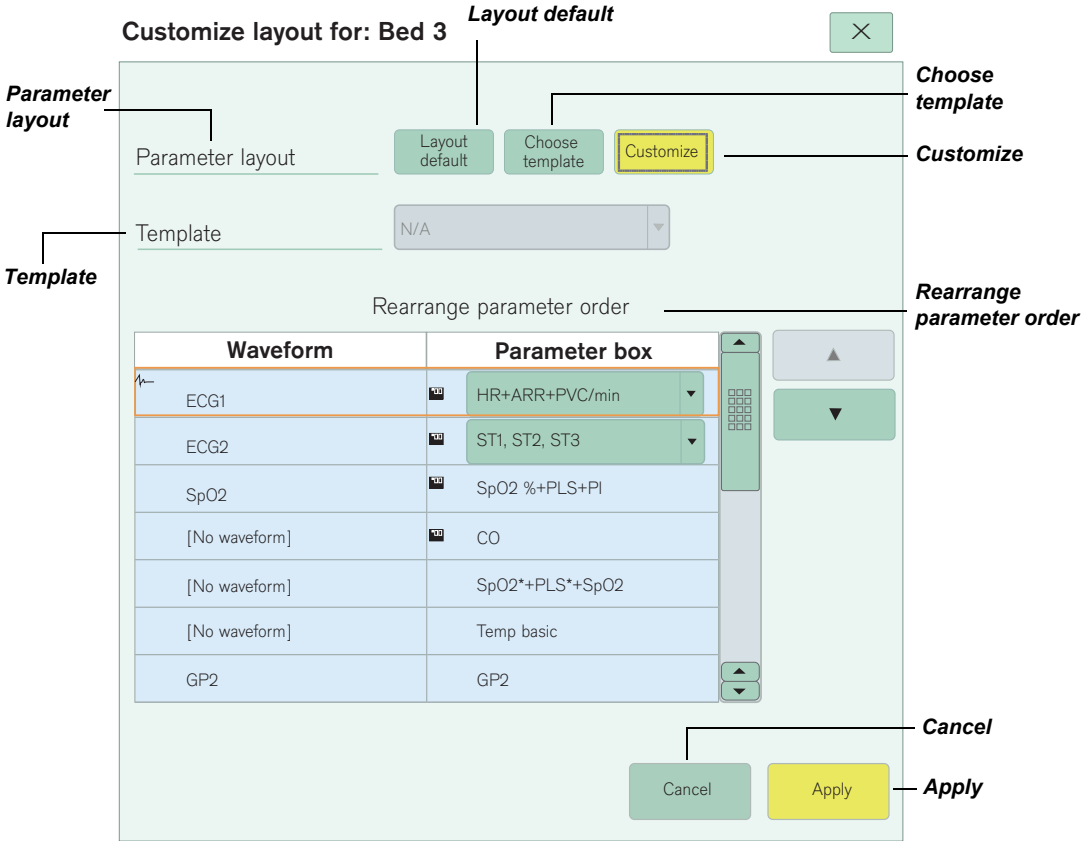
Customized viewport layout

1 Select ***Main screen*** on the main menu bar.

2 Select the  menu icon for the patient bed that you want to customize

NOTE
The triangle  indicates that the patient viewport is customized.

3 Select ***Change patient parameters*** to display the ***Customize layout for:*** dialog for the selected bed.



4 Select ***Customize*** and arrange the desired order of parameter boxes.

5 Select ***Apply***.

NOTE
A change in the parameter order template does not affect the Customized layout.

NOTE
The Customized layout remains until the patient is removed from the Viewport.

Main screen bottom channel access

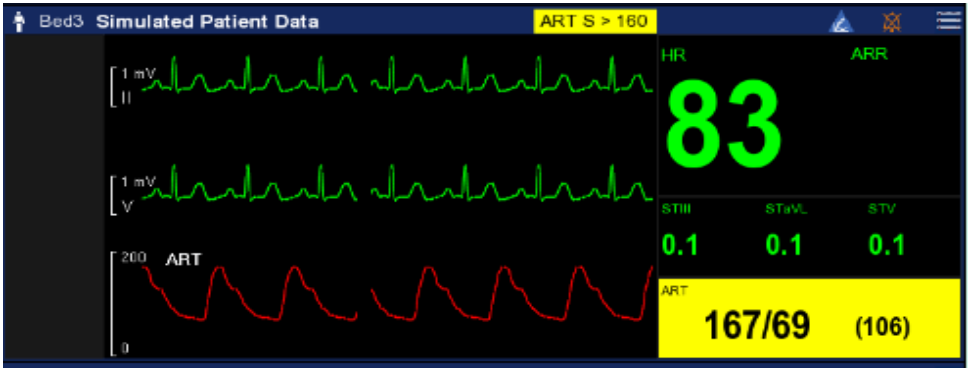
1 Select ***Main screen*** on the main menu bar.

2 Select the menu icon for the patient bed that you want to customize

NOTE
The triangle indicates that the patient viewport is customized

3 When the bottom row is currently set to waveform, and you want to change it to parameters, select ***Parameters***:

or if the bottom row is currently to set to parameters, and you want to change it to waveform, select ***Waveform***:



NOTE
A change in the parameter order template does not affect the customized bottom channel.

Parameter box alarming

In the parameter box (p-box) on the main screen, only the portion of the box that is associated with the alarmed parameter (or parameters) flashes, quickly showing which parameter (or parameters) needs attention.

In addition to the flashing alarm parameters, a yellow alarm message banner flashes for medium alarms and a red alarm message banner flashes for high alarms. A solid cyan appears for low alarms.

Parameters alarm separately in grouped parameter boxes when parameters are from different devices. Multi-parameter boxes which contain parameters from one device cause the entire parameter box to alarm.

NOTE
Only parameters with medium (yellow) and high (red) alarms will flash.

Moving an M300/M300+ patient from one room (viewport) to a different room (viewport)

A new ***Question*** dialog displays when an M300/M300+ patient is moved to a new room (viewport). For viewports on the same ICS, the dialog contains the following buttons:

- ***Cancel***
- ***Move*** – moves the M300/M300+ patient to the new viewport, and then discharges the patient from the original viewport.
- ***Admit*** – discharges the M300/M300+ patient from the original viewport and admits them as a new patient to the new viewport.

NOTE
For patients on different ICS systems, the ***Question*** dialog contains only a ***Cancel*** button and a ***Move*** button.

VentCentral Setup screen

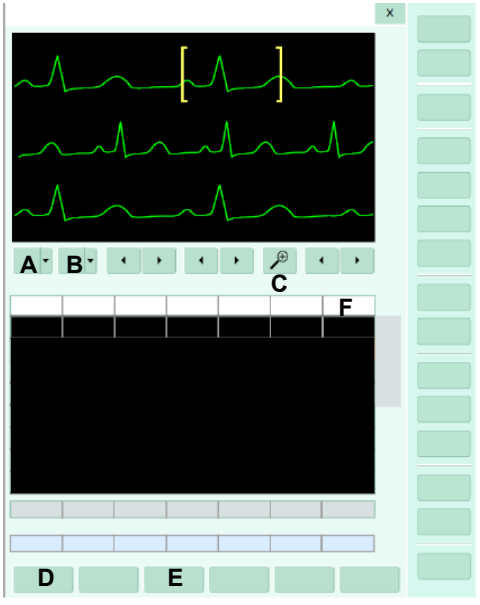
The default settings on the ***VentCentral*** Setup screen are the current settings on the corresponding bed. Users can save up to 12 trend ventilator parameters on the VentCentral screen. The default is up to 3 ventilator parameters active at the bedside.

ECG Calipers tool

The ECG Calipers tool enables users to measure, store, calculate, review, and document time-based interval measurements and averages using stored ECG waveform data.

Calipers - Measure page

The following Caliper measurement features are available on the ***Calipers*** page:



A ***Lead*** button – Selects the lead to provide measurements.

B ***Size*** button – Selects the size of the waveform.

C – Zooms in or out of a particular waveform.

D ***Add row*** button – Creates a new row to contain a new set of measurements. Only one lead can be measured at a time (in one row).

E ***Delete row*** button – Deletes the current measurement row.

F ***HR*** (***RR***) column – Displays the heart rate in bpm. The calculation is: HR (RR) = (60*1000)/RR with RR interval in milliseconds.

Hardware

ICS speakers

The ICS supports external USB speakers. Dräger-approved external USB speakers include the Edifier R19U speaker (which includes AUX/USB input).

NOTE

For an analog speaker, the user must connect to the analog port for sound, and the USB port for power. For a USB speaker, the user connects to the USB port.

If a connected USB speaker becomes disconnected, the following alarm message and symbol appear in the ICS main screen and remain until the speaker is reconnected:

USB speakers disconnected! ***Audio off***

The Warning under “ICS CPU precautions” in *Instructions for use Infinity CentralStation Wide SW VG1.n and Infinity M300,* reads as follows:

WARNING

The Infinity CentralStation (ICS) CPU and its display(s) must always remain on and functional, and the external speakers must always remain connected and powered on. Never press any of the On/Off buttons to turn the CPU or the display(s) off. Contact your technical personnel for assistance in properly shutting down the ICS.

The two tables titled “ICS alarm tones” and “M300 speaker alarm tones” in the Alarms chapter in the *Instructions for use Infinity CentralStation Wide SW VG1.n and Infinity M300* provide specifications for external speakers to implement audible alarm notification, including periodic checks.

ICS battery indicator icon

Following are additional indications of the ICS battery indicator icon for the M300/M300+:

– The battery icon turns red when the battery runtime indicator shows only a single bar.

– The battery icon is framed in red when the battery runtime indicator shows no bars.

– The battery icon turns white when the battery runtime indicator shows more than a single bar or the device is charging. This applies only to the M300.

Canvys touchscreen and widescreen displays

ICS supports the following displays:

– Canvys 21.5 inch touchscreen display. See “Canvys 21.5-inch touchscreen display” for specification information.

– Canvys 21.5 inch widescreen display. See “Canvys 21.5-inch widescreen display” for specification information.

NOTE
This display is capable of operating from an HDMI input from the ICS.

WARNING
All changes or modifications to the device hardware or software must only be done by Dräger authorized service personnel, otherwise patient safety may be negatively impacted. Any unauthorized change could decrease patient safety, could void the user's authority to operate the equipment, and will void the warranty.

Canvys 21.5-inch touchscreen display

Touchscreen display	
Type	54.7 cm (21.5 in) diagonal LCD TFT active matrix LCD, Anti-glare
Touch technology	Projected Capacitive
Active display area (h x w)	476.64 x 268.11 mm (18.77 x 10.56 in)
Native resolution	1680 x 1050 or 1920 x 1080
Response time	16 ms
Viewing angle (H x V)	178° / 178°
Trolley	Tilt base
Electrical specifications	
Power consumption	22 watts (max.)
Power input	100 to 240 VAC, 50/60 Hz
Environmental specifications	
Temperature range	Operating: 5 °C to 40 °C (41 °F to 104 °F) Storage: -10 °C to 60 °C (14 °F to 140 °F)
Relative Humidity (non-condensing)	Operating: 90 % at max. +50 °C (122 °F) Storage: 90 % at max. +50 °C (122 °F)
Physical specifications	
Size (H x W x D)	378 x 525.3 x 180 mm (14.88 x 20.68 x 7.08 in)
Weight	7.2 kg (15.87 lbs)
Chassis color	White

Canvys 21.5-inch widescreen display

Widescreen display	
Type	54.7 cm (21.5 in) diagonal LCD TFT active matrix LCD, Anti-glare
Active display area (h x w)	476.64 x 268.11 mm (18.77 x 10.56 in)
Native resolution	1680 x 1050 or 1920 x 1080
Response time	16 ms
Viewing angle (H x V)	178° / 178°
Trolley	Tilt base
Electrical specifications	
Power consumption	23.6 watts (max.)
Power input	100 to 240 VAC, 50/60 Hz
Environmental specifications	

Widescreen display	
Temperature range	Operating: 5 °C to 40 °C (41 °F to 104 °F) Storage: -10 °C to 60 °C (14 °F to 140 °F)
Relative Humidity (non-condensing)	Operating: 90 % at max. +50 °C (122 °F) Storage: 90 % at max. +50 °C (122 °F)
Physical specifications	
Size (H x W x D)	378 x 525.3 x 180 mm (14.88 x 20.68 x 7.09 in)
Weight	7.2 kg (15.87 lbs)
Chassis color	White

Mouse movement with dual-display configurations

In dual-display configurations, users can position a second display relative to the primary display with the following position options: Right of, Left of, Above, or Below. Users can move the mouse horizontally or vertically between the displays, based on their relative position.

ICS supports the use of a universal Black Box KVM box Extender that includes:

Part Number	Quantity	Description
ACR1020A-T	1	Agility Dual Head Sender
RMK2004	1	Transmitter Rack Mount Kit
ACR1020A-R	1	Agility Dual Head Receiver
ACR1X-VESA	2	Mount Bracket for Single/Dual Head Receivers
LGB1110A	1	Black Box L2+ Ethernet Switch
EJG9300L	1	3.5mm Audio Y-Cable
AVSP-DVI1X2	2	1 x 2 DVI-D Splitter with Audio & HDCP
EVNDVI02-0003	2	DVI-D Cable 0.9m
EVNDVI02-0006	2	DVI-D Cable 1.8m

Gen 4 Central Processing Unit (CPU) Upgrade

The ICS includes a Gen 4 CPU (MS32504).

Gen 4 CPU specifications

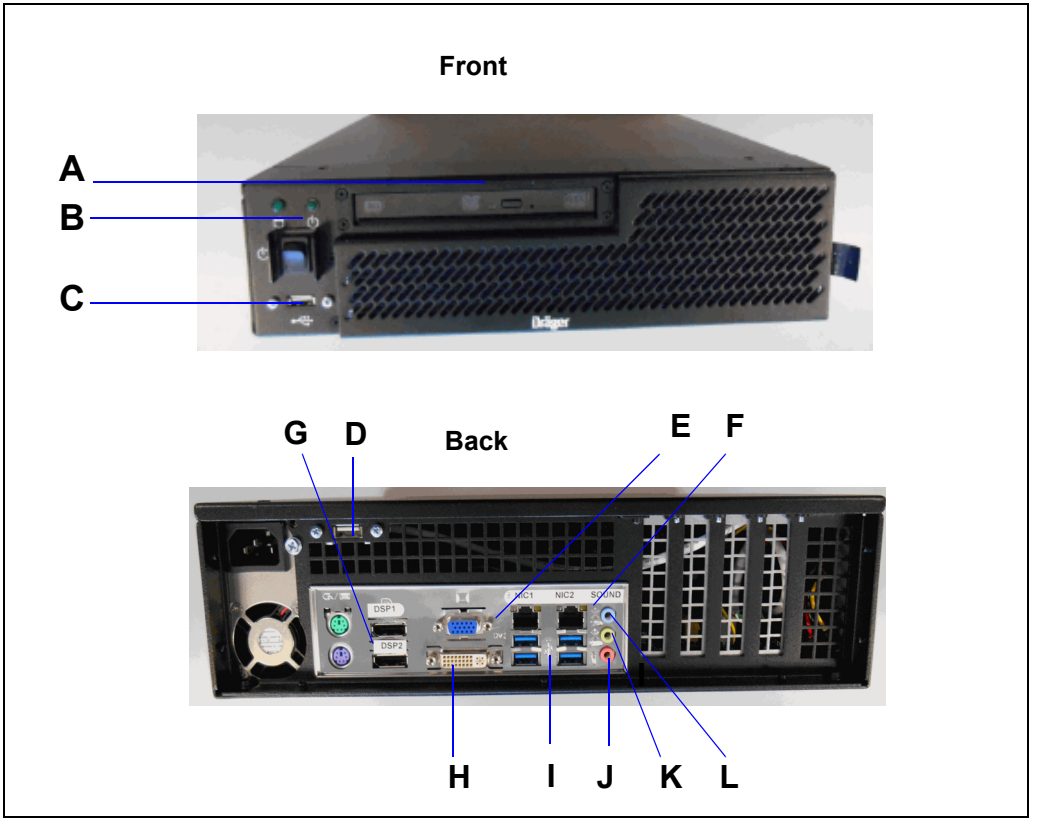
The following table describes the Gen 4 CPU specifications.

Infinity CentralStation	
Display specifications	
Display size	54.7 cm (21.5 in) diagonal or larger wide screen
Resolution	1680 x 1050 or 1920 x 1080 (native resolution)
User controls	
Input device controls	USB/PS/2-compatible keyboard and USB/PS/2-compatible optical mouse included in country-specific kit. Optional Dräger supplied touchscreen is also supported.
Central Processing Unit (Gen 4 CPU: MS32504)	
Processor	Intel® Processor
Storage	– 8 GB RAM, DVD-RW/CD-RW – 1x 1TB HD (standard) – 1x 1TB HD (optional for RAID DB) – 1x 128GB SSD (standard) – 1x 128GB SSD (optional for RAID OS)
Disk array	SATA with optional RAID1 mirror
Software updates	DVD-ROM (optical drive)
Connections	– 6 USB ports (1 in front, 5 in rear) – 2 RJ45 LAN connections – 1 DVI graphics connection – 2 DisplayPort connectors – 1 VGA DB 15 – 2 PS/2 ports for keyboard/mouse – IEC C14 power input connector – 1x3 audio jack connectors (line-in, line-out, microphone)
Network connectivity	– *Infinity Network*
Video output	Dual DisplayPort graphics output 1680 x 1050 (minimum) at 60 Hz
Audio output	Dräger-supplied external speakers (analog or USB) plus an internal speaker as backup.
Input current rating	4.5A (RMS) FOR 115 VAC/2.0A (RMS) FOR 230 VAC

Infinity CentralStation	
Electrical specifications	
Power consumption (typical)	30 watts
BTU output	116 BTU/hour
External sound level/fan noise	< 46 dB(A) at a 1 meter radius
Maximum patients per CPU	Up to 64 beds total: – 32 patients on the main screen – up to 32 patients in Surveillance mode (not including M300)
Environmental specifications	
Temperature range	Operating: 5 °C to 40 °C (41 °F to 104 °F) Storage: -20 °C to 60 °C (-4 °F to 140 °F)
Altitude/Atmospheric pressure	Operating: 700 to 1100 hPa Storage: 500 to 1100 hPa
Humidity (non-condensing)	Operating: 10 % to 95 % Storage: 10 % to 95 %
Mode of operation	Continuous
Acoustic noise	< 46 dB(A) at 1 meter
Physical specifications	
Size (H x W x D)	90 x 325 x 330 mm (3.54 x 12.8 x 12.99 in)
Weight	4.6 kg (10.1 lbs)
Chassis color	Black

Gen 4 CPU figure

The following figure shows the front and back of the Gen 4 CPU.



Front		Back	
A	DVD drive	D	USB port
B	On/Off	E	VGA Display port
C	USB	F	Two LAN Connectors
		G	Two Display ports
		H	DVI Display port
		I	Four USBs ports
		J	Microphone port
		K	Sound Out
		L	Sound In

RAID disk error message (CPU Gen 4 only)

For an ICS with an optional RAID, when a disk error or failure occurs in one of the drives in a mirrored set, one of the following messages displays in the ICS Main Screen status message area.

RAID failure on DB drive
RAID failure on OS drive

When there are dual screens, the warning message displays on both screens.

Additional language support

The Language settings on the ***Biomed*** > ***Configure central*** > ***Country*** tab include the following additional languages:

– Finnish (missing from the IFU)

– Lithuanian (newly supported)

– Serbian (newly supported)

Corrections to the IFU

In the *Instructions for use Infinity CentralStation Wide SW VG1.n and Infinity M300:*

– The section “Selected events” is corrected as follows:

  Depending on the number of events selected, the ***Selected event report*** section may consist of up to six pages, with four waveform strips per page. For an event to appear in the Shift report, the symbol corresponding to that event must be selected so that a check mark appears.

– The following alarm settings information is added to the section “Latching and non-latching alarm”:

  Certain special modes on the bedside monitor (such as ***OR mode***, ***ECMO mode***, ***Pressures paused***, and ***Pressures off***) might affect alarm settings. See the Instructions for use for the specific device.

– The following note is added to the section “Rest ECG report”:

  NOTE
  The Rest ECG report displays leads in sequential format.

– The following information is added to the section “Selecting different waveforms (manual waveform configuration)”:

  If the user docks a different monitor or discharges the patient and admits a different patient, that viewport changes back to Auto mode. For a new patient, the user can manually change waveforms again.

– The description of ***External device alarm audio*** in the ***System setup*** > ***Alarms*** page is updated. See “System setup > Alarms page” for more information.

Limitations

Alternate speed feature

The R-50 “Alternate speed” feature is not supported for IACS or M300/M300+ monitors.

Changing layouts

NOTE
When changing layouts, all recordings are canceled (even if the bed is assigned in both layouts).

Reprocessing

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Observe before disassembly 54

Information on reprocessing 54
Safety information. 54

Classifications for reprocessing 55
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Classification of device-specific components . . 56

Reprocessing list 57

Reprocessing procedures 57
Validated reprocessing procedures 57
Disinfectants 57
Surface disinfection with cleaning 58

Disassembly

Observe before disassembly

1 Switch off the device and all devices connected to it.

2 Disconnect the mains plugs.

Information on reprocessing

Instructions for reprocessing are based on internationally accepted guidelines, e.g., standard ISO 17664.

Safety information

WARNING

Risk due to inappropriately reprocessed products.

Reusable products must be reprocessed, otherwise there is an increased risk of infection.

- **Observe the hygiene regulations and reprocessing regulations of the healthcare facility.**
- **Observe national hygiene regulations and reprocessing regulations.**
- **Use validated procedures for reprocessing.**
- **Reprocess reusable products after every use.**
- **Observe the manufacturer's instructions for cleaning agents, disinfectants, and reprocessing devices.**

CAUTION

Risk due to faulty products

Signs of wear, e.g., cracks, deformation, discoloration, or peeling, may occur with reprocessed products.

Check the products for signs of wear and replace them if necessary.

Classifications for reprocessing

Classification of medical devices

Medical devices and their components are classified according to the way they are used and the resulting risk.

Classification	Explanation
Non-critical	Components that come only into contact with skin that is intact
Semi-critical (A, B)	Components that carry breathing gas or come into contact with mucous membranes or pathologically altered skin
Critical (A, B, C)	Components that penetrate skin or mucous membranes or come into contact with blood

Classification of device-specific components

Observe the instructions for use for the components.

The following classification is a recommendation from Dräger.

Non-critical

– Infinity CentralStation Wide

Semi-critical A

– None

Semi-critical B

– None

Critical

– None

Reprocessing list

Components	Surface disinfection with cleaning	Manual cleaning followed by disinfection by immersion	Machine cleaning with thermal disinfection	Steam sterilization	Special reprocessing measures
Infinity CentralStation Wide	Yes	N/A	N/A	N/A	N/A

Reprocessing procedures

Validated reprocessing procedures

At the time of product-specific validation, the following reprocessing procedures showed good material compatibility and effectiveness:

Procedure	Agent	Manufacturer	Concentration	Contact time	Temperature
Surface disinfection with cleaning	Dismozon pur	Bode Chemie	1.5 %	15 min	N/A
	Dismozon plus	Bode Chemie	1.6 %	15 min	N/A

The effectiveness of the listed reprocessing procedures has been validated by independent laboratories that are certified to the standard ISO 17025.

Disinfectants

Use disinfectants that are nationally approved and are suitable for the particular reprocessing procedure.

Surface disinfectant

At the time of the test, the surface disinfectants listed in the following table showed good material compatibility. They can be used in addition to the surface disinfectants listed in the section *Validated reprocessing procedures.*

The manufacturers of the surface disinfectants have verified at least the following spectra of activity:
– Bactericidal
– Yeasticidal
– Virucidal or virucidal against enveloped viruses

Observe the specifications of the surface disinfectant manufacturers.

Other surface disinfectants are used at one's own risk.

Class of active ingredient	Surface disinfectant	Manufacturer
Chlorine-releasing agents	Actichlor plus	Ecolab
	BruTab 6S	Brulin
	Clorox Professional Disinfecting Bleach Cleaner	Clorox
	Dispatch Hospital Cleaner Disinfectant Towels with Bleach	
	Klorsept 17	Medentech
Oxygen-releasing agents	Descogen Liquid	Antiseptica
	Descogen Liquid r.f.u.	
	Dismozon plus	Bode Chemie
	Dismozon pur	
	Oxycide	Ecolab USA
	Perform	Schülke & Mayr
	Virkon	DuPont
Quaternary ammonium compounds	Mikrozid sensitive liquid[1)]	Schülke & Mayr
	Mikrozid sensitive wipes[1)]	
	Mikrozid alcohol free liquid[1)]	
	Mikrozid alcohol free wipes[1)]	
	acryl-des[1)]	
Aldehydes	Buraton 10 F	Schülke & Mayr

1) Virucidal against enveloped viruses

Dräger states that oxygen-releasing agents and chlorine-releasing agents may cause color change in some materials. Color change does not indicate that the product is not functioning correctly.

Surface disinfection with cleaning

WARNING
Risk due to penetrating liquid

Penetrating liquid may cause the following:
- **Damage to the device**
- **Electric shock**
- **Device malfunctions**

Ensure that no liquid penetrates the device.

1. Remove soiling immediately. Use a cloth dampened with disinfectant to remove soiling.
2. Perform surface disinfection.
3. After the product has been exposed to the disinfectant for the specified contact time, remove residual disinfectant.
4. Wipe with a cloth dampened with water (at least drinking-water quality). Allow the product to dry.
5. Check the product for visible soiling. Repeat steps 1 to 5 if necessary.
6. Check the product for visible damage and replace if necessary.

This page has been left blank intentionally.

This supplement only applies to
Infinity CentralStation Wide VG3.0
with the Serial No.:
If no Serial No. has been filled in by Dräger, these Instructions for Use are provided for general information only and are not intended for use with any specific machine or unit.
This document is provided for customer information only, and will not be updated or exchanged without customer request.

CE 0123

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