

Summary

Intesys® Clinical Suite (ICS) is a system that consists of core services, database, data interface applications, and clinical interface applications. The products that follow are all components of ICS.

92810	Smart Disclosure
92842	Admit Discharge Transfer Interface
92843	Vital Signs Interface
92848	Event Notification Interface (ENI)
92876	Custom Trends
92877	12-Lead Electrocardiogram (ECG) Interface
92880	Vital Signs Viewer
92881	Print Manager

Technical Product Requirements

The technical specifications that follow apply to all ICS applications.

Server Requirements	Windows Server 2022 (64 bit) or Windows Server 2019 (64 bit) or Windows Server 2016 (64 bit)
SQL Database	<ul style="list-style-type: none"> • SQL Server 2022 (64 bit) or • SQL Server 2019 (64 bit) or • SQL Server 2017 (64 bit)
Recommended Workstation Requirements	<ul style="list-style-type: none"> • Keyboard and mouse • 17-inch or larger display (recommended screen resolution is 1280 x 1024 pixels) <p><i>Note:</i> <i>Minimum resolution is 1024 x 768</i></p> <ul style="list-style-type: none"> • At a minimum, 10/100 Ethernet network interface card (NIC). For best performance, a 100-Mbps network or higher between workstation and server is recommended. • Windows 11 (64 bit) or Windows 10 (64 bit)
Compatibility	ICS is compatible with Spacelabs Healthcare DM3/DM4, Xprezzon®, Qube® and Qube® Mini bedside monitors, as well as the Xhibit® Central Station, Xhibit® XC4, and Xhibit Telemetry products.
Security	ICS provides centralized user access management for all ICS applications. Each user provides a user name and password to log on to the Clinical Access application. A log is maintained of functions accessed for everyone using the system.

Licensing Requirements

Configurations vary depending on the needs of the institution. Contact your Spacelabs Healthcare representative for details.

Recommended Server Requirements

Server sizing depends on the complete set of ICS applications and the number of monitors from which data is collected.

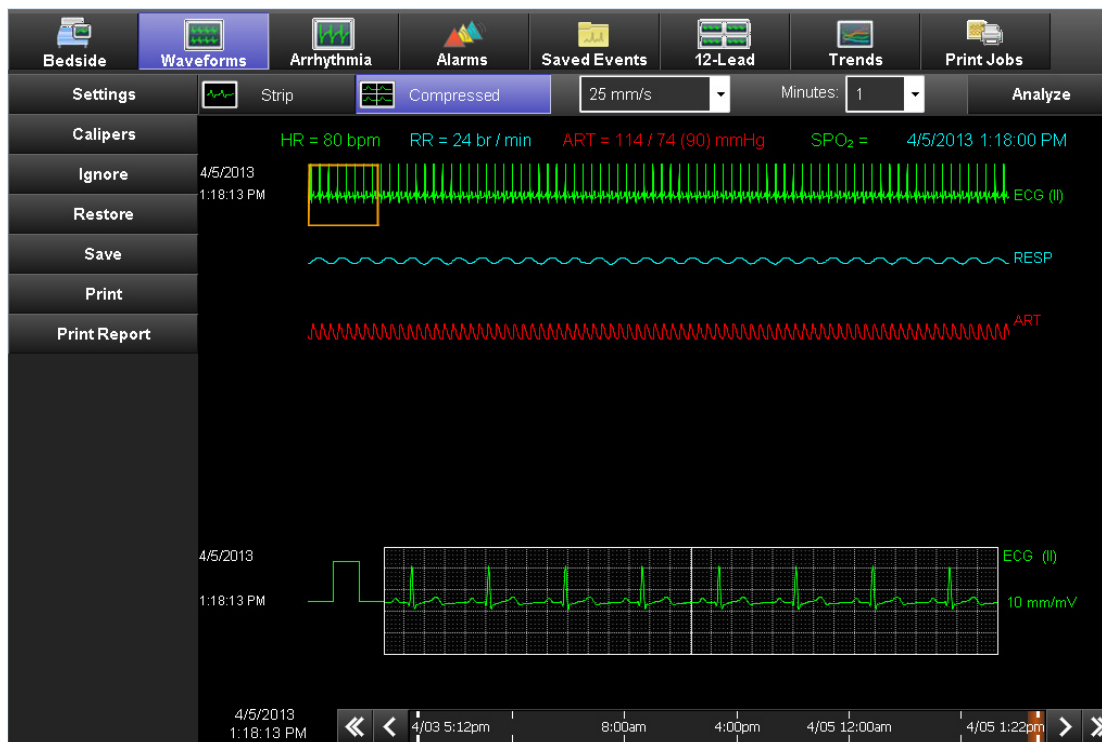
Contact your Spacelabs Healthcare representative for version specifics.

Documentation

This product ships with a complete set of comprehensive documentation.

For a full list of available supplies and accessories, go to <https://www.spacelabshealthcare.com/products/supplies>.

Smart Disclosure (92810)



The Smart Disclosure product collects patient waveforms, alarms, vital signs, and 12-lead reports. A 24-hour waveform acquisition is standard, with an upgrade option to 72 hours. The product provides basic trends in both tabular and graphical format, along with a retrospective ECG analysis. The analysis may be defined by patient, and the data may be presented in multiple formats, including a rhythm, a histogram, and a summary view. Standard reports are available from Smart Disclosure, including saved events, disclosure, trends, histogram, and summary. Smart Disclosure is an integrated component of the Intesys Clinical Suite (ICS).

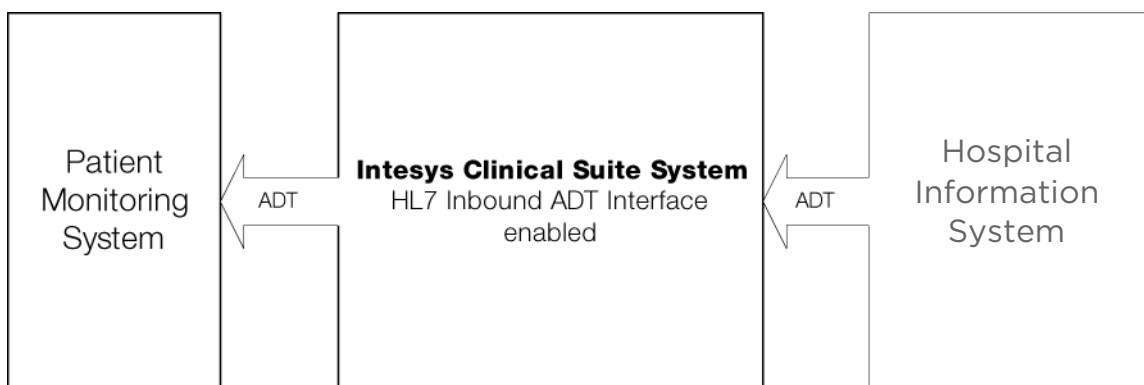
Capabilities

Patient Census

The patient list provides access to all monitored patients. A menu allows the user to easily view all departments in a hospital collecting patient data and reports.

Alarms	Review all patient bedside alarms by type, parameter, or priority in two different views: thumbnail or strip view.
Trends	Review patient vital signs, including flexports and peripheral devices, in tabular or graphical format. Vital signs may be logically organized into groups. Groups may be individually expanded or collapsed.
Analysis	Smart Disclosure provides retrospective analysis of acquired ECG waveforms and identifies ventricular rhythms based on an initial dominant rhythm.
Arrhythmia Review	Use a summary, histogram, or thumbnail view to review events. Calipers measure ECG events. Waveforms from other patient parameters are also recorded.
Data Acquisition	Standard 24-hour recording (72-hour option) captures alarm events, waveforms, and 12-lead reports from monitors.
Architecture	Client/Server. Using Smart Disclosure, data from all hospital beds is collected on a single enterprise server and accessed from any network personal computer.
Reports	All Smart Disclosure data and graphs may be printed or saved in PDF format to any location on the network. Reports are user-configurable as to data intervals, time ranges, and inclusion of graphs. <ul style="list-style-type: none"> • Waveform report • Saved event report • 12-lead report • Histogram report • Summary report • Tabular trend report

Admit Discharge Transfer Interface (92842)



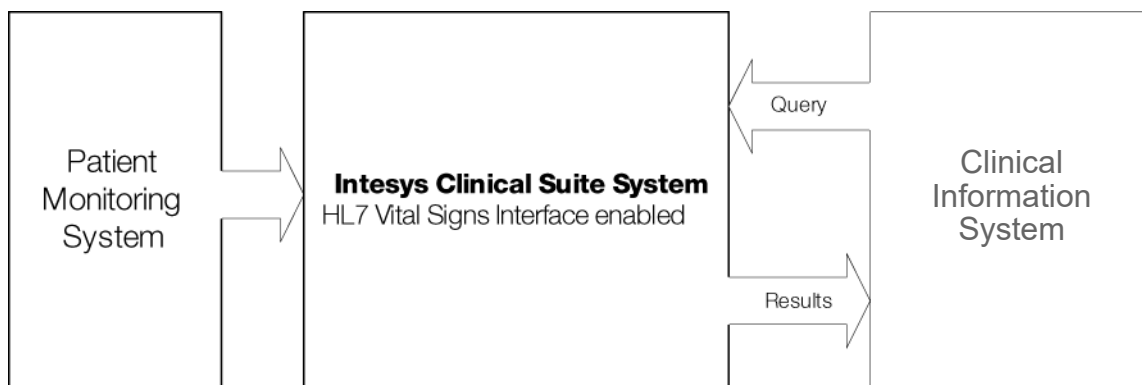
The Admit Discharge Transfer (ADT) interface facilitates the process of loading patient identity and demographic information into the Intesys Clinical Suite (ICS). The interface functions by receiving Health Level Seven (HL7) messages from the Hospital Information System (HIS). This information is made available to applications in the suite and is used to update Spacelabs Healthcare patient monitors. ADT is an integrated component of the Intesys Clinical Suite (ICS).

Capabilities

Automation	ADT facilitates the entry of patient information into ICS applications and patient monitors.
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Message Filtering	
Standard Configuration	No filtering is provided; all supported messages are processed. Filtering may be performed prior to message delivery by the HL7 Interface Adapter (P/N 999-1900-00) by request.
Message Standard	HL7 version 2.3.1
Messages Supported	A01, A02, A03, A04, A05, A06, A07, A08, A31.
Monitor Update	ADT messages update patient information in Spacelabs Healthcare monitors when the patient ID in the monitor matches the patient identification number in the message.
System Administration	System administration is performed through the ICS Administration Tool, and an HL7 message log.

Vital Signs Interface (92843)

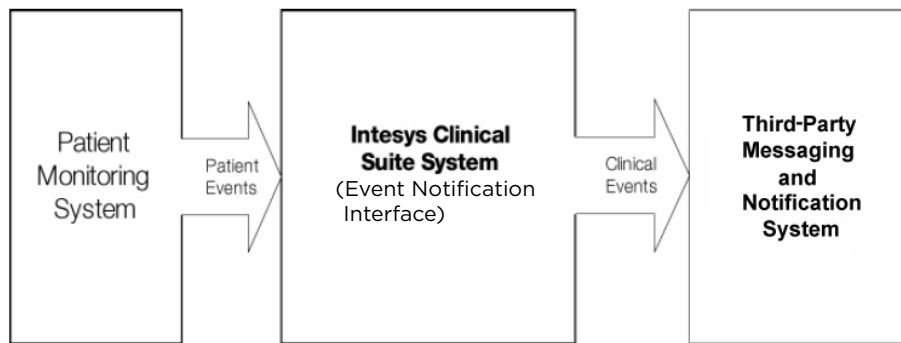


The Vital Signs Interface transfers vital signs data from Spacelabs Healthcare monitors and attached peripheral devices to a hospital clinical information system (CIS). The interface provides solicited and unsolicited Health Level Seven (HL7) result messages to the destination system at a rate that is configurable by clinical unit. The Vital Signs Interface is an integrated component of the Intesys Clinical Suite (ICS).

Capabilities

Vital Signs Interface	The interface sends solicited and unsolicited vital signs collected from patient monitors and telemetry devices to the CIS. Solicited HL7 messages result from queries sent by the CIS to the ICS.
Enterprise Solution	ICS HL7 aggregates all vital signs into a single interface to the CIS.
Data Frequency	Data frequency is configurable from 30- to 36000-second intervals.
Message Standard	HL7 version 2.3.1
Messages Supported	ORU R01, QRY R02, ORF R04
Peripheral Devices	The product supports Flexport® system interface data from devices such as ventilators and infusion pumps.
System Administration	System administration is performed through the ICS Administration Tool, and an HL7 message log.

Event Notification Interface (ENI) (92848)



The ENI product provides historical information regarding past patient alarm events. The information is not provided in real time and is not intended as a basis for diagnosis, clinical decisions, or active patient monitoring. ENI is intended to transfer data to other vendors' information systems using an industry standard data exchange protocol, such as XML or HL7. ENI is intended for use only when the patient is otherwise actively monitored. ENI is an integrated component of the Intesys Clinical Suite (ICS).

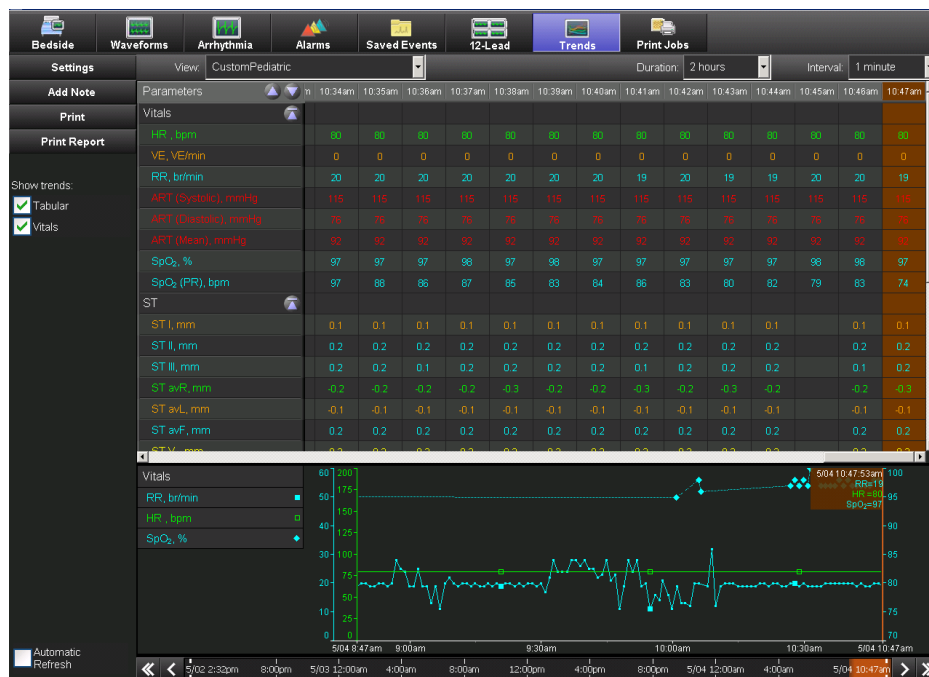
Capabilities

Messaging Standard	The ENI messaging standard is an XML format.
Network Connection	The ENI communicates using TCP/IP protocol.
System Administration	ENI system administration is performed through the ICS Administration Tool, and various configuration files.

Messages

Alarm Information	The historical alarm information may be configured as text-only messages or text with waveform images.
Message Content	The ENI messages includes the Bed Name, Patient Name, Event Data, Event Time, Waveform Images, Patient ID(s), Node ID, Unit Name, Message ID, Sequence Number, Type, and Priority.

Custom Trends (92876)

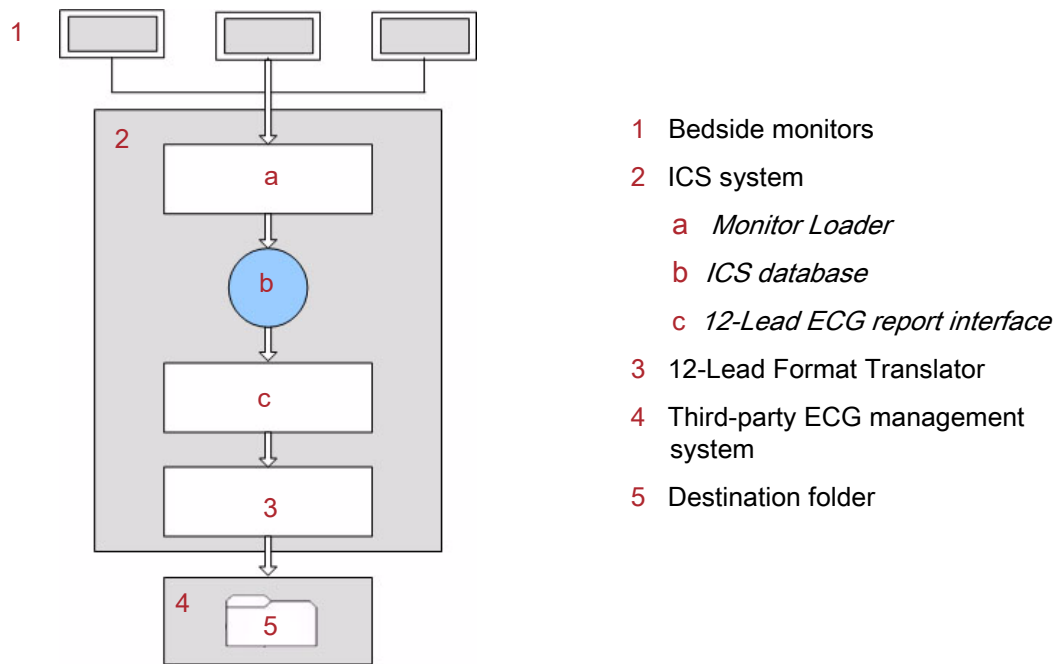


Custom Trends enables you to save custom views for vital signs data from Spacelabs Healthcare monitors and attached peripheral devices. Data may be viewed in user-configurable flowsheets or graphs. Comments and notes may be added to trends to document specific items. Reports may be printed or saved in PDF format. Custom Trends is an integrated component of the Intesys Clinical Suite (ICS).

Capabilities

Trends Review	The trends flowsheet is an automated collection of numeric vital signs from Spacelabs Healthcare monitors. Graphical trends are optional and may or may not be displayed, depending on user preference.
Views	Create custom views for departments or individual clinicians. Save and reuse default flowsheet formats or specific flowsheet protocols.
Reports	All flowsheet data and graphs may be printed or saved in PDF format. Reports are user-configurable as to data intervals, time ranges, and inclusion of graphs.
Comments	Add comments. Changes are tracked via audit logs.
User Interface	Create and modify trend templates in ICS Administration Tool. Numerous flowsheets may be created for care areas, patient types, or user preferences.
Flowsheet Groups	Vital signs may be logically organized into groups. Groups may be individually expanded or collapsed.
Data Collection Interval	Intervals are configured, per department, from once per minute to once per day. Collection rates may be changed at any time via the ICS Administration Tool. Default automatic collection rates may be set by clinical units. System default collection rate upon installation is one minute.
Peripheral Devices	The product supports Flexport system interface data from devices such as ventilators.

12-Lead ECG Interface (92877)



The 12-Lead Electrocardiogram (ECG) Interface is a product in the Intesys Clinical Suite (ICS). This interface enables Spacelabs Healthcare patient monitors, with 12-Lead capability, to send 12-Lead reports to an ECG management system.

A 12-Lead ECG Format Translator is available for ECG management systems not capable of reading the Spacelabs Healthcare 12-Lead ECG report format. The 12-Lead Interface and Format Translator run as background applications, with no user interface. 12-Lead ECG Interface is an integrated component of the Intesys Clinical Suite (ICS).

Capabilities

Architecture	The 12-Lead ECG Interface functions as a Windows service on an ICS server. All 12-Lead reports are stored in the ICS Database for use of applications or interfaces.
Data Acquisition	The 12-Lead ECG Interface captures monitor-initiated 12-Lead ECG reports and places them in a network shared directory for access by an ECG management system.
Data Translation	The format translator translates captured ECG reports from Spacelabs Healthcare format to formats of other ECG management systems.
Export Frequency	The export frequency for the 12-Lead ECG Interface is user-configurable. The default setting is every 60 seconds.
Monitor Setup	The monitor may be configured to send all 12-Lead ECG reports, or to send only user-selected 12-Lead ECG reports.
Monitor Configuration	Monitors must be equipped with an ECG parameter module capable of producing 12-Lead ECG reports.

12-Lead ECG Format Translator

ECG Management System Compatibility

The 12-Lead ECG Format Translator is required to interface to most ECG management systems, such as GE Muse, Epiphany, or Philips Tracemaster. Spacelabs Healthcare uses the DataMedFT solution to translate to external systems. We recommend that you check the ECG management system compatibility list shown in the *12-Lead ECG Format Translator System Administration Manual* (P/N 070-1302-xx).

Note:

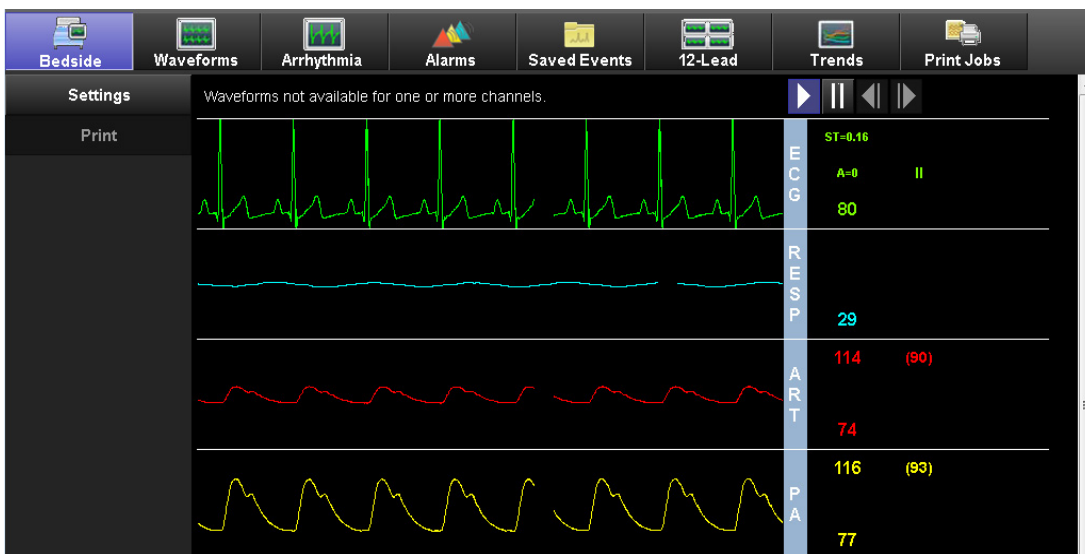
The ECG management system compatibility list is based on information provided by DataMed Solutions.

Server Specification

The 12-Lead ECG Format Translator may be installed on an ICS server. Network access to the hospital Local Access Network (LAN) is required. Network access to an ECG management system is required. No additional hardware is required.

Contact your Spacelabs Healthcare representative for version specifics.

Vital Signs Viewer (92880)



Vital Signs Viewer enables you to remotely view near real-time waveforms generated by Spacelabs Healthcare monitors. This application also allows you to view up to six waveforms with associated numerics. They may be paused, scrolled backwards up to 30 seconds, and printed. Vital Signs Viewer is an integrated component of the Intesys Clinical Suite (ICS).

Capabilities

Display	Up to six waveforms may be selected by the user.
Print	Paused screen waveforms may be printed to the default printer.
Sweep Speed Control	Sweep speeds are adjusted independently for each parameter.
User Interface	Clinical Access hosts the application, displaying patient waveforms and associated numerics; the application is controlled by a mouse or other pointing device.
Waveform Color	Color is selected independently for each parameter. The same color is used by all components of Clinical Access. These defaults are established in ICS Administration.

Waveform Control Keys	Keys operate like those found on cell phones and media players
Play	Restarts the waveforms after being paused
Pause	Stops the movement of the waveforms for review
Rewind	Rapidly scrolls the waveforms back 30 seconds in time
Fast Forward	Rapidly scrolls the waveforms forward in time up to the present
<i>Note:</i> <i>This product is not intended for use as a diagnostic tool.</i>	

Print Manager (92881)



Preview	Description	Date/Time	Pages
Close	MANUAL RECORDING 13:27 18APR2012 (400)	4/18/2012 1:28:00 PM	1
Print	4/18/2012 1:25:00 PM (400)	4/18/2012 1:27:55 PM	1
	4/18/2012 1:25:00 PM (400)	4/18/2012 1:26:14 PM	1
	4/18/2012 1:25:00 PM (400)	4/18/2012 1:26:02 PM	1
	ALARM RECORDING 13:25 18APR2012 (400)	4/18/2012 1:25:22 PM	2
	MANUAL RECORDING 13:25 18APR2012 (400)	4/18/2012 1:25:07 PM	1
	ALARM RECORDING 13:25 18APR2012 (400)	4/18/2012 1:25:06 PM	2

Print Manager enables you to print waveforms and associated annotation values and reports from a monitor to a network printer, instead of using the strip chart printer. Print Manager also retains the print jobs so that you can reprint them at a later time. Print Manager is an integrated component of the Intesys Clinical Suite (ICS).

Capabilities

Centralized Management	All printer assignments are performed in ICS Administration
Configuration	Standard Windows print spooler
Chart Speeds	12.5, 25, or 50 mm/sec; dependent on the waveform sweep speed shown on the monitor. With Xhibit Telemetry, a sweep speed of only 25 mm/sec is used for printed alarms.
Paper	Letter or A4-size plain paper
Printer	Standard Windows network printer. Print Manager is not compatible with parallel port printers.
Print Log	Maintains a log of all print jobs for later review and reprinting from Clinical Access
Print Request Output	Requested waveforms with patient name or ID, parameter ID and values, alarm message and limits (when in alarm), time, and date; arrhythmia class printout; ST printout; non-waveform graphics
Resolution	Dependent on the printer
System Recordings	All recordings are initiated from Spacelabs Healthcare DM3/DM4, Xprezzon and Qube or Qube Mini bedside monitors, as well as the Xhibit Central Station, Xhibit XC4, and Xhibit Telemetry products.

Unit Assignment	Supports both a default and an alarm printer for each unit
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Classifications

Intesys Clinical Suite (ICS) is a Class IIa software as medical device (SaMD) and is compliant with the following standards:

ISO 13485	Medical devices – Quality management systems – Requirements for regulatory purposes, 3rd Ed, 1 Mar 2016
ISO 14971	Medical devices – Application of risk management to medical devices, Ed 3.0, 1 Dec 2019
ISO 15223-1	ISO 15223-1:2021, Medical devices – Symbols to be used with information to be supplied by the manufacturer - Part 1, 4 th Ed, 1 Jul 2021
ISO 20417	ISO 20417:2021, Medical devices – Information to be supplied by the manufacturer, 1 st Ed, 1 Apr 2021
IEC 62366-1	Medical devices – Part 1: Application of usability engineering to medical devices, Ed 1.1, 1 Jun 2020
IEC 62304	Medical device software – Software life cycle processes – Consolidated Text; Ed. 1.1, 1 Jun 2015
IEC 82304-1	Health software – Part 1: General requirements for product safety, Ed 1.0, 1 Oct 2016
IEC 80001-1	Application of risk management for IT-networks incorporating medical devices – Part 1: Roles, responsibilities and activities; Ed. 2.0, 1 Sep 2021
ISO 11240	Health informatics – Identification of medicinal products – Data elements and structures for the unique identification and exchange of units of measurement; 1st Ed, 1 Nov 2012

Regulatory Approvals

Smart
Disclosure
(92810)



CE marked in accordance with the Medical Device Directive, 93/42/EEC2022-08

We are continuously improving our products. Specifications are subject to change without notice. Product images are provided for general reference. This product may not be available for sale in all countries.

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