

FUNDAÇÃO HOSPITALAR DR JOSÉ ATHANÁZIO

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AT.: Sr. Pregoeiro.

À

 REF.:
 Pregão Eletrônico SRP:
 20/2023 - FHJA

 Processo Administrativo:
 173/2023

 Data:
 15/02/2024 às 14h30

 Objeto:
 AQUISIÇÃO DE EQUIPAMENTOS PERMANENTES – MONITOR

 MULTIPARAMÉTRICO, VENTILADOR PULMONAR E CARRO DE

 EMERGÊNCIA PARA SUPRIR AS NECESSIDADES DA FUNDAÇÃO

 HOSPITALAR DR. JOSÉ ATHANÁZIO, CONFORME ESPECIFICAÇÕES DO

 EDITAL E SEUS ANEXOS.

RECURSO ADMINISTRATIVO

Prezados Senhores,

A empresa **Intermed Equipamento Médico Hospitalar Ltda**., inscrita no CNPJ sob o n.º 49.520.521/0001-69 estabelecida na Rua Santa Mônica, n.º 980, Parque Industrial San José, Jardim Belizário, Cotia, São Paulo. CEP: 06.715-865, e-mail: <u>cesar.augusto@crlicitar.com.br</u>, telefone: (11) 9 9956-3552, Inscrição Estadual: 278.082.665.115, Inscrição Municipal: 6002338, por meio de seu procurador abaixo identificado, vem, respeitosamente, perante V.S.as, recorrer da decisão que desclassificou a nossa proposta da empresa para o **ITEM 04** o que faz pelas razões que passa a expor.

Nos parece que foi equivocada a análise técnica que julgou o equipamento ofertado em discordância com as exigências do edital, como podemos ver a seguir:

ITEM 4 QUANTIDADE: 1 DESCRIÇÃO: VENTILADOR PULMONAR - UTI

MARCA / MODELO: VYAIRE MEDICAL / BELLAVISTA 1000

No dia 22 de fevereiro de 2024, fomos comunicados que o modelo BELLAVISTA 1000 foi desclassificado por não atender o seguinte requisito do edital:

EXIGÊNCIAS: • O equipamento deve ser totalmente compatível com a central de monitorização BeneVision CMS, central utilizado no hospital.

No entanto, como pode ser observado no manual de operação do produto, o BELLAVISTA 1000 possui disponível os seguintes protocolos de comunicação:

Protocolos de comunicação	Philips VueLink/IntelliVue
	 HL7 (V2.3, IHE PCD Harmonized Rosetta
	protocol)

Ť.



O protocolo utilizado para realizar a comunicação entre o ventilador pulmonar e a central de comunicação BeneVision CMS é o HL7 como pode ser observado nas instruções do Anexo I.

Monitor connection partners: Mindray

Instructions for Mindray BeneLink

BeneLink can connect bedside devices into the monitoring network, allowing caregiver to view patient-centered data from different devices both on patient monitor and central monitoring system. At the same time, through eGateway, the data of all bedside devices can be sent to information system, provide foundation to achieve paperless workflow.

Physical specifications

- Size: 136.5×40×102 mm
- · Weight: 0.35 kg
- Occupied slot number: 1 slot

Data transmission

- Serial port for connection (physical interface is RJ45)
- Support parameters, respiratory waveforms, loops, alarm data

Number of devices

- Up to 4 devices can be connected simultaneously (T series)
- Up to 8 devices can be connected simultaneously (N series)

Supported Monitor

- BeneVision N22/N19/N17/N15/N12
- BeneView T9/T8/T6/T5

Supported devices

Device type	Brand	Model	Parameter & Alarm	Setup data	Waveform(s)	Loop(s)	ID number	Serial port adapting type
ICU Ventilator	imtmedical	bellavista™ 1000 family	•	-	-	-	4256BDAA	bellavista adapter (refer to manual)

Table 1. Supported devices information

*Note: (N) in the table means the device only support integrating through N series.





Connection steps

- (1) Insert the BeneLink module into the module slot on the BeneView/BeneVision patient monitor. Make sure that BeneLink contain the device drivers which match the devices you want to connect. If it doesn't, you could install driver to BeneLink by using PC upgrade program. After upgrade, stick a label on BeneLink module to indicate installed device drives
- (2) Connect the ID adapter to the BeneLink module with a RJ45 connecting cable.
- (3) Connect the ID adapter to external device with a Serial Port Adapting Cable (Type A/B/C/D/E/F/G/ H/I) or directly connect the ID adapter to external device (Which marked "No need" in Table 1). Make sure to use correct Serial Port Adapting Cable. (Refer to Table 1)



(4) Make sure to use correct ID Number. You could modify the ID number of the ID adapter by yourself. Input correct ID number in the [Factory Maintenance]-> [Upgrade ID module] menu of BeneView/BeneVision monitors. (Refer to Table 1).

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BeneLink Module Port	ť –	L.
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BeneView "Upgrade ID module" Menu



BeneVision "Upgrade ID module" Menu

- (5) Stick a label indicating device name to the RJ4S connecting cable at the end nearby the BeneLink module. When the BeneLink module is connected to several external devices, you can tell the devices apart easily with these labels.
- (6) Switch the external device on. Please note that you may need to configure the communication settings of the external device to enable the connection working.

Table 3 External devices settings



Appendix – Software Version Issue History





Diante das justificativas e argumentos devidamente comprovados solicitamos e esperamos a revisão do julgamento que equivocadamente desclassificou a nossa proposta comercial, pois a manutenção desta decisão implicará na transgressão a vários princípios licitatórios como da legalidade, da igualdade e da vinculação ao instrumento convocatório. Sob este aspecto, transcrevemos as palavras do Professor Jessé Torres Pereira Junior em Comentários à Lei das Licitações e Contratações da Administração Pública (página 33 - editora Renovar):

"(a) o da igualdade impõe à Administração elaborar regras claras, que assegurem aos participantes da licitação condições de absoluta equivalência durante a disputa, tanto entre si quanto perante a Administração, intolerável qualquer espécie de favorecimento;

(d) o da vinculação ao instrumento convocatório faz do edital ou do convite a lei interna de cada licitação, impondose a observância de suas regras à Administração Pública e aos licitantes, estes em face dela e em face uns dos outros, nada podendo ser exigido, aceito ou permitido além ou aquém de suas cláusulas e condições ; o artigo 41 da Lei nº 8.666/93 ilustra a extensão do princípio ao declarar que " A Administração não pode descumprir as normas e condições do edital, ao qual se acha estritamente vinculada"

Quanto ao princípio da legalidade, Hely Lopes Meirelles, op. Cit., p. 82, lapidarmente ensina:

"A legalidade, como princípio de Administração (CF, art. 37, caput), significa que o administrador público está, em toda a sua atividade funcional, sujeito aos mandamentos da lei e às exigências do bem comum, e deles não se pode afastar ou desviar, sob pena de praticar ato inválido e expor-se à responsabilidade disciplinar, civil e criminal, conforme o caso. A eficácia de toda atividade administrativa está condicionada ao atendimento da Lei. Na Administração Pública não há liberdade nem vontade pessoal. Enquanto que na Administração Pública é lícito fazer tudo que a Lei não proíbe, na Administração Pública, só é permitido fazer o que a Lei autoriza".

Por todo o exposto, resta incontroverso que o a equipe técnica não possuía todas a as informações necessárias para uma correta avaliação do ventilador bellavista 1000 na proposta para o item 04. Solicitamos a alteração da decisão que nos desclassificou, classificando-nos, por atender à exigência solicitada no edital, e sanando assim os vícios aqui apontados.

Termos em que pede e aguarda deferimento. Respeitosamente, Cotia - SP, 26 de fevereiro de 2024.

Intermed Equipamento Médico Hospitalar Ltda. E-mail: dl-bra10-licitacao@vyaire.com | cesar.augusto@crlicitar.com.br Cesar Augusto Rodrigues da Silva

RG n.°: 25.982.467-7 SSP-SP | CPF n.º: 224.093.448-44 Procurador

49.520.521/0001-69

INTERMED EQUIPAMENTO MÉDICO HOSPITALAR LTDA

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bellavista™ 1000 Family Data Communication Protocols

Training Aide



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bellavista[™] 1000 communication overview

Purpose

This document outlines the capabilities of the bellavista[™] 1000 ventilator family to communicate ventilator values/parameters to hospital information and monitoring systems. It provides details on the data and messages communicated as well as the connection partners Vyaire has worked with to facilitate the sharing of data. Additionally, it touches upon Vyaire's Respiratory Knowledge Portal (RKP) application – which provides an analytics tool to hospital clinicians and administrators focused upon both respiratory and sedation therapy.

bellavista ventilator data communication overview

The bellavista 1000 ventilator family have the capability to output monitored values, settings, alarms, and/or waveforms to external hospital systems or monitors. Typically, this output is desired to support one (or more) of three primary functions: remote alarm surveillance; EMR documentation; and/or Vyaire respiratory analytics.

Data protocol fundamentals

All communication from bellavista is unidirectional and the output is via an RS232 serial communication port using either the ventilator SpO_2/Data communication interface (bellavista 1000, bellavista neo, Fig. 1) or the dedicated data communication interface (bellavista 1000e, Fig. 2).





bellavista supports two different data communication protocols: Health Level 7 (HL7), an international standard for transmitting device data or Philips (Intellibridge & Vuelink Open Interface). The data itself is providing four primary data types:

- Settings/Info
- Monitoring
- Alarms
- Waveforms

For specific protocol details, see each protocols respectively the "Appendix" section at the end of this document.



Figure 1. SpO₂/Data communication interface on bellavista 1000

Connection and data transport

Though bellavista[™] supports two different communication protocols only one communication session via a single protocol can be supported at a time. bellavista is not capable of communicating to multiple systems nor using two different protocols simultaneously.

Use of an RS-232 serial transmission protocol means the ventilators are 'non-networked' and cannot be attached to the hospital WLAN/LAN natively without some type of additional connection system designed to convert the serial data stream into an acceptable network protocol. As a result, vent data can be transmitted to hospital clinical systems. In general, a Medical Device Integration Systems (MDIS) can come in two flavors – wired (802.3b) or wireless (802.11x) – and usually consist of a cable, device adapter, bridge, and server. The components may vary from system to system. In most cases, the connection partner provides the appropriate connection components to establish successful communications between the vent and their system.

bellavista provides the data communication adapter (Fig.3) to connect to those hospital systems.



Figure 3. *bellavista* Data communication adapter (SKU :302.079.000)

It is important to note that data delivery from the ventilator via RS-232 is not guaranteed nor is data queued on the ventilator in the event the connection between the vent and bridge is lost, disrupted, or broken. Any ventilator data generated while the connection is down will be lost. Data can still be retrieved via an export over bellavista trending data directly at the device.

Connection partners

Our connection partners who have developed the capability to connect the ventilators to clinical systems are discussed below in detail. They are divided into two primary categories – direct connections to a monitoring system for the primary purpose of alarms surveillance and connections to an MDIS or Patient data management systems (PDMS) for the primary purpose of EMR documentation. In addition, there is a separate section discussing the bellavista connection to support the Respiratory Knowledge Portal – Vyaire's hosted respiratory analytics application.

It is important to note that any system connected to bellavista may also have the capability to serve multiple purposes, e.g. a monitor connection system may also support EMR documentation or an MDIS may support both EMR documentation and RKP. Check each partners description below to determine each system specific capabilities.

Monitor connection partners

In general, vent connections to monitors are implemented to support ventilator alarms surveillance, primarily through the monitoring systems central monitoring station usually centrally located within the care unit. Most monitoring systems also advertise the capability to provide data output to other hospital clinical systems, e.g. ventilator data for EMR documentation. Though this capability is advertised, actual implementation is often limited. Monitor connections will vary in nomenclature dependent upon the monitoring system but typically entails connecting to either a module or bridge connected with the bedside monitor. From there, the monitor will transmit the data to the central monitoring station and, if necessary, to any servers/interface engines required for transmitting the data to other hospital clinical systems.

Two monitor connection partners are discussed in detail below:

- Philips
- Mindray

Monitor connection partners: Philips Healthcare

Instructions for Intellibridge and Vuelink

• Purpose

- Alarms Surveillance*
- EMR Documentation
- Trending/Patient Context Overview
- Ventilators
 - bellavistaTM 1000
 - bellavistaTM 1000 neo
 - bellavistaTM 1000e
- Software Option bellavista
 - 302.124.000 Data communication software
- Hardware bellavista
 - 302.079.000 External device interface adapter
- Ventilator Data Protocol/Comm Settings
 - Vuelink/Intellibridge (IVOI)
- Type/Connection Components
 - Wired
 - Bridge
 - Monitors
 - Intellibridge EC10 Module
 - Vuelink Module
 - Adapters/Cables Intellibridge
 - Intellibridge
 - EC10 Module (Ref# 865115/#A01/#101)
 - 865115 # 101 Open Interface Driver
 - 865115 # A01 EC10-Modul RS232/LAN
 - 865114 IntelliBridge EC5 ID-Module
 - 865114 # 104 OI DSUB9f crossed IDM
 - 865114 # L02 Connection Cable RJ45 3m
 - Vuelink
 - Vuelink Module (Ref#M1032A/#A02)
 - M1032-61699 Open Interface cable (D-Sub 9, 4 m) Option K6C
 - M1032-TU1AA Driver for VL Open Interface (normally already installed

- Compatible Clinical Systems
 - Philips Monitors
 - IntelliVue MP40-MP90 Rev H.15 (and higher)
 - MX400-MX800 (all versions)
 - CMS install base
- For connecting a different monitor type than the above, please contact the monitor manufacturer
- RKP Connection Partner: No
- Contact
 - Victoria Tower (victoria.tower@philips.com)
 - www.usa.philips.com/healthcare
 - www.philips.com/healthcare
- *not available in the US

Connection diagrams Philips Intellibridge and Vuelink

Philips Intellibridge





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30

17

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Philips MP/MX monitor

Figure 4. *bellavistaTM* connection to Philips Intellibridge

Philips Vuelink



Figure 5. bellavista connection to Philips Vuelink

Setting up the connection to Philips monitoring with bellavistaTM

bellavista[™] 1000

Enter the main menu and swipe to the next screen. Open the configuration assist and scroll down to section periphery. Select under port usage, "Intellibridge/Vuelink" and apply. When connecting the device interface adapter with the Philips Intellibridge/ Vuelink setup, the ventilator data will be transmitted as soon as ventilation is starting. The selected setting is persistent and does not need to be confirmed again once the ventilator is restarted.



Figure 6. Port usage setting to Intellibridge/Vuelink in the *bellavista* 1000 configuration assist.

bellavista[™] 1000e

Enter the main menu and swipe to the next screen. Open the configuration assist and scroll down to section periphery. Under port usage, "Intellibridge/ Vuelink" is the default selection. When connecting the device interface adapter with the Philips Intellibridge/ Vuelink setup, the data will be transmitted as soon as ventilation is starting. The selected setting is persistent and does not need to be confirmed again once the ventilator is restarted.



Figure 7. Port usage setting to Intellibridge/Vuelink in the *bellavista* 1000 configuration assist.

Comments: The used protocol connecting directly to a Philips monitor is the proprietary (Philips) IVOI protocol which bellavistaTM supports with the data communication option. The physical connection to Philips monitors can be accomplished via one of two Philips modules – the older Vuelink module and the more recently released EC10. Each has different cabling requirements – see above for specifics. The Vuelink module was discontinued in 2012 only EC10s can be purchased now. We do not provide any Philips accessories, they have to be supplied from Philips directly.

Philips is not an RKP connection partner.

Warning*

To prevent potential patient harm when connecting bellavista to a patient monitor, always check the ventilator when the monitor reports a ventilator alarm. Detailed information and the alarm ID are not displayed on the monitor.

As part of configuring the communication interface, transmitted data from bellavista (parameters, settings and alarms) is configured to specific display characteristics on connected patient monitors.

As a consequence the monitor is not recognizing and reporting all parameters and alarms. We strongly recommend to always read the alarm and corresponding messages directly from the bellavista device when at bedside.

Suspending the monitor's audible alarm is not automatically suspending the alarm at bellavista. The data supplied via the network / data sharing system is provided for reference purposes only. Decisions on patient treatment should be made by the clinician on the basis of patient observation. In the event of an alarm, check the patient and bellavista on the spot immediately because not all alarms are displayed in detail in the network/data sharing system. Only use the recommended connecting cables. The devices connected must be approved medical devices conforming to EN 60601-1.

Connecting bellavista to a network / data sharing system that contains other devices can lead to previously unknown risks for the patient, user or third parties.

The following changes to the network/data sharing system can lead to risks and thus require additional analyses. Changes to the network / data sharing system particularly include the following:

- Changes in configuration
- Connection of additional elements
- Updates or upgrades of other devices

Monitor connection partners: Mindray

Instructions for Mindray BeneLink

BeneLink can connect bedside devices into the monitoring network, allowing caregiver to view patient-centered data from different devices both on patient monitor and central monitoring system. At the same time, through eGateway, the data of all bedside devices can be sent to information system, provide foundation to achieve paperless workflow.

Physical specifications

- Size: 136.5×40×102 mm
- Weight: 0.35 kg
- Occupied slot number: 1 slot

Data transmission

- Serial port for connection (physical interface is RJ45)
- Support parameters, respiratory waveforms, loops, alarm data

Number of devices

- Up to 4 devices can be connected simultaneously (T series)
- Up to 8 devices can be connected simultaneously (N series)

Supported Monitor

- BeneVision N22/N19/N17/N15/N12
- BeneView T9/T8/T6/T5

Supported devices

Device type	Brand	Model	Parameter & Alarm	Setup data	Waveform(s)	Loop(s)	ID number	Serial port adapting type
ICU Ventilator	imtmedical	bellavista™ 1000 family	•	_	-	_	4256BDAA	bellavista adapter (refer to manual)

 Table 1. Supported devices information

*Note: (N) in the table means the device only support integrating through N series.



Connection steps

- Insert the BeneLink module into the module slot on the BeneView/BeneVision patient monitor. Make sure that BeneLink contain the device drivers which match the devices you want to connect. If it doesn't, you could install driver to BeneLink by using PC upgrade program. After upgrade, stick a label on BeneLink module to indicate installed device drives
- (2) Connect the ID adapter to the BeneLink module with a RJ45 connecting cable.
- (3) Connect the ID adapter to external device with a Serial Port Adapting Cable (Type A/B/C/D/E/F/G/ H/I) or directly connect the ID adapter to external device (Which marked "No need" in Table 1). Make sure to use correct Serial Port Adapting Cable. (Refer to Table 1)



(4) Make sure to use correct ID Number. You could modify the ID number of the ID adapter by yourself. Input correct ID number in the [Factory Maintenance]-> [Upgrade ID module] menu of BeneView/BeneVision monitors. (Refer to Table 1).

Upgrade ID module			×
BeneLink Module Port	1		
ID	0		
Con	firm		
_	_	_	

BeneView "Upgrade ID module" Menu

	Update ID module
BeneLink Module Port	1 >
ID	0
Cont	irm

BeneVision "Upgrade ID module" Menu

- (5) Stick a label indicating device name to the RJ45 connecting cable at the end nearby the BeneLink module. When the BeneLink module is connected to several external devices, you can tell the devices apart easily with these labels.
- (6) Switch the external device on. Please note that you may need to configure the communication settings of the external device to enable the connection working.

Table 3 External devices settings

imtmedical	bellavista 1000 family	HL7	/	/	/	/	Use port HL7 HL7 Message Send Interval:
							15s

Appendix – Software Version Issue History

2.15.00	BeneVision N: imtmedical	• Support forwarding alarms for PMD200.
	bellavista 1000 family	 BeneVision N series support uploading the following data through BeneLink module:
		 Support Mindray ventilator/anaesthesia machine setting parameters
		 Uploading equipment management information
		 Mindray anesthesia shutdown without alarm

Warning*

To prevent potential patient harm when connecting bellavistaTM to a patient monitor, always check the ventilator when the monitor reports a ventilator alarm. Detailed information and the alarm ID are not displayed on the monitor.

As part of configuring the communication interface, transmitted data from bellavista (parameters, settings and alarms) is configured to specific display characteristics on connected patient monitors.

As a consequence the monitor is not recognizing and reporting all parameters and alarms. We strongly recommend to always read the alarm and corresponding messages directly from the bellavista device when at bedside.

Suspending the monitor's audible alarm is not automatically suspending the alarm at bellavista. The data supplied via the network / data sharing system is provided for reference purposes only. Decisions on patient treatment should be made by the clinician on the basis of patient observation. In the event of an alarm, check the patient and bellavista on the spot immediately because not all alarms are displayed in detail in the network/data sharing system. Only use the recommended connecting cables. The devices connected must be approved medical devices conforming to EN 60601-1.

Connecting bellavista to a network/data sharing system that contains other devices can lead to previously unknown risks for the patient, user or third parties.

The following changes to the network/data sharing system can lead to risks and thus require additional analyses. Changes to the network / data sharing system particularly include the following:

- Changes in configuration
- Connection of additional elements
- Updates or upgrades of other devices

Medical Device Integration Systems (MDIS) connection partners

An MDIS is designed to support the capture of medical device data – typically via serial connection – for transport across the hospital network to clinical systems, e.g. the EMR. Like monitors, MDIS connections vary in nomenclature depending upon the specific MDIS. The amount/specificity of the ventilator data available to the EMR, etc. will vary, however, dependent upon the ventilator serial protocol as well as the specific MDIS capabilities.

Also HIS systems will have specific requirements regarding data processing (usually around a patient identifier component) and not every MDIS can support every HIS. Connection partners such as Capsule, have developed this dual capability to allow the hospital to leverage their MDIS investment for use with both the HIS EMR and RKP.

An MDIS has two primary components – a bridge (wired or wireless) to connect the vent to the network and a server (installed in the data center) that renders the vent data into an HL7 format for communication to hospital information systems. The two bridge connection methods differ in the following manner:

Wired

- Physically installed in the room where ventilators are used
- Requires electrical power
- Requires an active, physical network connection (802.3b) for bridge to connect to
- Association to patient will typically be automatic with no manual process required by the clinician

Wireless

- Physically attached to the ventilator
- Hospital WLAN used for communications (802.11x)
- Manual device -> patient association by clinician required. Association can be done via several methods (varies from system to system):
 - Barcode scanning of patient and device via HIS or MDIS
 - Manual association via the HIS or MDIS

MDIS connection partners discussed in detail below are:

Capsule

MDIS connection partners Capsule

• Purpose

- EMR documentation
- Ventilators
 - bellavistaTM 1000
 - bellavistaTM 1000 neo
 - bellavistaTM 1000e
- Software Option bellavista
 - 302.124.000 Data communication software
- Hardware bellavista
 - 302.079.000 External device interface adapter
- Ventilator Data Communication Protocol
 - o HL7
- Bridge Type/Connection Components
 - Wired
 - DataCaptor Terminal Server 400/800 Series
 - Four to eight device connection ports
 - Physically attached to wall in critical care room and uses a wired connection to the hospital LAN/WAN
 - Patient association done automatically based upon physical room location of terminal server
 - Wireless (and/or Wired)
 - Smartlinx Neuron 2
 - Multiple connection ports
 - Installation options:
 - Neuron physically attached to wall in critical care room and uses a wired connection to the hospital LAN/WAN (802.3b – 10/100/1000mbps)
 - Neuron physically attached to the ventilator and uses a wireless or wired connection to the hospital WLAN (802.11a/b/g/n) or LAN/WAN.
 - RFID proximity card reader
 - User interface available for patient association
 - Done via Capsule Secure Association Application (barcode scanning capability) or within certain HIS applications (EPIC and Cerner)
 - Battery pack for mobile use
 - SmartLinx Axon 410-810 (wired and/or wireless)
 - Replacing the DataCaptor Terminal Server
 - Eight ports/device connections

- SmartLinx Axon 110 (wired and/or wireless)
 - Single port/device connection
 - Low cost
 - No patient association (done through location mapping or HIS)
- SmartLinx Client
 - Software only installed on PC
 - Device connects to PC serial ports
- Capsule adapters/cables
 - B1-CFP (RJ45m<->DB9m)/DB9f<->RJ45m)

For connecting a different device type than the above, please contact Capsuletech for advice.

- Compatible Clinical Systems
 - See comprehensive list under: https://capsuletech. com/brochures
- RKP Connection Partner: Yes*
- Contact
 - Darshil Modi (dmodi@capsuletech.com)
 - www.capsuletech.com

Setting up the connection to Capsule in the bellavistaTM Configuration Assist

bellavista[™] 1000

Enter the main menu and swipe to the next screen. Open the configuration assist and scroll down to section periphery. Select under port usage "HL7" and apply. Please make sure the protocol version is 1.6 or higher. Otherwise a bellavista software update must be executed first.



Figure 8. Port usage setting to HL7 with protocol version 1.6 in the *bellavista* 1000 configuration assist.

When HL7 is selected the message interval has to be determined by the hospital or the software companies field service. The message interval setting is adjustable from 15-90 seconds



Figure 9. Message interval settings flyout in the HL7 menu.

When connecting the device interface adapter with the Capsule setup, the ventilator data will be transmitted as soon as ventilation is starting. The selected setting is persistent and does not need to be confirmed again once the ventilator is restarted.

bellavista[™] 1000e

Enter the main menu and swipe to the next screen. Open the configuration assist and scroll down to section periphery. Under port usage choose "HL7" and apply. Please make sure the protocol version is 1.6 or higher. Otherwise a bellavista software update must be executed first.



Figure 10. Port usage setting to HL7 with protocol version 1.6 in the *bellavista* 1000e configuration assist.

When HL7 is selected the message interval has to be determined by the hospital or the software companies field service. The message interval setting is adjustable from 15-90 seconds



Figure 11. Message interval settings flyout in the HL7 menu.

When connecting the device interface adapter with the Capsule setup, the ventilator data will be transmitted as soon as ventilation is starting. The selected setting is persistent and does not need to be confirmed again once the ventilator is restarted.

Comments: Capsule has extensive experience integrating medical devices to hospital HIS systems and is believed to have the largest install base of any of the MDIS vendors/connection partners.

Capsule is an RKP connection partner.

Connection partners Patient Data Management Systems (PDMS)

About HL7 (Health Level 7)

HL7 was founded in 1987 to compile a standard for clinical information systems. HL7 Inc. is accredited by the American National Standards Institute (ANSI) since 1994.

The focus of HL7 is data processing for medical and administrative data.

HL7 is widely used for system integration within hospitals, to communicate patient and performance data, as well as performance requirements and findings. The necessary application areas in the hospital are:

- Patient data administration
- Findings communication
- Performance request and transmission
- Document and master data exchange
- Employee and logistics data
- Material management
- Resource planning

The exchange format for HL7 is text-based. HL7 provides interoperability between hospital information systems (HIS), practice management systems (PVS), laboratory information systems (LIMS), systems for billing, and systems that act as electronic patient records.

This enables bellavista[™] to directly connect to PDMS/ EMR systems. The software application company usually needs to develop a driver before connecting bellavista[™] to their system.

Some systems offer an open HL7 interface to directly connect without driver, but these interfaces often offer a limited transmission of data. Therefore, a dedicated driver development is preferable. Since HL7 is a standardized protocol, all data management software today should be able to get connected with bellavista.



iMDsoft MetaVision

• Purpose

• EMR documentation

Ventilators

- bellavistaTM 1000
- bellavista™ 1000 neo
- bellavista™ 1000e
- Software Option bellavista
 - 302.124.000 Data communication software
- Hardware bellavista
 - 302.079.000 External device interface adapter
- Ventilator Data Communication Protocol
 - HL7
- Bridge Type/Connection Components
 - Wired
 - Multi-Port Bridge (MPB)
 - Terminal server is physically attached to wall in critical care room and uses a wired connection to the hospital LAN/WAN
 - Patient association done automatically based upon physical room location of terminal server
- Adapters/cables
- Compatible Clinical Systems
 - iMDsoft Metavision
- RKP Connection Partner: No
- Contact
 - Ofir Avni (ofir.avni@imd-soft.com)
 - Jonathan.de Lieme (jonathan.delieme@imd-soft. com)
 - www.imd-soft.com

HIM QCare

- Purpose
 - EMR documentation
- Ventilators
 - bellavistaTM 1000
 - bellavista[™]1000 neo
 - bellavista™ 1000e
- Software Option bellavista
 - 302.124.000 Data communication software
- Hardware bellavista
 - 302.079.000 External device interface adapter
- Ventilator Data Communication Protocol
 - HL7
- Bridge Type/Connection Components
 - Wired
 - Multi-Port Bridge or Digibox
 - Terminal server is physically attached to wall in critical care room and uses a wired connection to the hospital LAN/WAN
 - Patient association done automatically based upon physical room location of terminal server
- Adapters/cables
- Compatible Clinical Systems
 - HIM QCare
- RKP Connection Partner: No
- Contact
 - Jens Dörr (jens.doerr@him-info.com)
 - Stephan Letschert (stephan.letschert@him-info. com)
 - www.him-info.com

GE Centricity

• Supports

- EMR documentation
- Ventilators
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 - bellavista[™] 1000 neo
 - bellavista™ 1000e
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- Adapters/cables
- Compatible Clinical Systems
 - GE Centricity EMR Version 8.1SP4 and higher
- RKP Connection Partner: No
- Contact
 - Christian Wagner (christianwagner@ge.com)
 - www.gehealthcare.com

Epic EpicCare

• Supports

- EMR documentation
- Ventilators
 - bellavistaTM 1000
 - bellavista[™]1000 neo
 - bellavista™ 1000e
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- Hardware bellavista
 - 302.079.000 External device interface adapter
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- Adapters/cables
- Compatible Clinical Systems
 - EpicCare
- RKP Connection Partner: No
- Contact
 - Leela Vaughn (leela@epic.com)
 - www.epic.com

Picis 10c

- Supports
 - EMR documentation
- Ventilators
 - bellavistaTM 1000
 - bellavista[™] 1000 neo
 - bellavista™1000e
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- Adapters/cables
- Clinical System
 - Picis 10c
- RKP Connection Partner: No
- Contact
 - Victor Rubio Cosials (vrubio@picis.com) www.picis.com

Setting up the connection to Patient Data Management Systems (PDMS) in the bellavistaTM software

bellavista[™]1000

Enter the main menu and swipe to the next screen. Open the configuration assist and scroll down to section periphery. Select under port usage "HL7" and apply. Please make sure the protocol version is 1.6 or higher. Otherwise a bellavista software update must be performed first.



Figure 13. Port usage setting to HL7 with protocol version 1.6 in the *bellavista* 1000 configuration assist.

When HL7 is selected, the message interval has to be determined by the hospital or the software companies field service. The message interval setting is adjustable from 15-90 seconds



Figure 14. Message interval settings flyout in the HL7 menu

When connecting the device interface adapter with the PDMS company setup, the ventilator data will be transmitted as soon as ventilation is starting. The selected setting is persistent and does not need to be confirmed again once the ventilator is restarted.

bellavista[™] 1000e

Enter the main menu and swipe to the next screen. Open the configuration assist and scroll down to section periphery. Under port usage choose "HL7" and apply. Please make sure the protocol version is 1.6 or higher. Otherwise a bellavista software update must be performed first.

Periphery			
Port usage		Pro	HL7 tocol version 1.6
	Port usage		
HL7 Message Send Interval	IntelliBridge / VueLink		
	HL7	×	
			Cancel
			Apply
			J.L

Figure 15. Port usage setting to HL7 with protocol version 1.6 in the *bellavista* 1000e configuration assist.

When HL7 is selected, the message interval has to be determined by the hospital or the software companies field service. The message interval setting is adjustable from 15-90 seconds



Figure 16. Message interval settings flyout in the HL7 menu

When connecting the device interface adapter with the PDMS company setup, the ventilator data will be transmitted as soon as ventilation is starting. The selected setting is persistent and does not need to be confirmed again once the ventilator is restarted.

Respiratory & sedation analytics

The Respiratory Knowledge Portal (RKP) is a cloudbased application that provides clinicians and administrators retrospective analytics on clinical and process variability related to ventilator therapy. This information is then used in combination with hospital care protocols (such as weaning, operational alarms, and lung protective strategies) to help improve patient outcomes and lower the cost of care. In addition to respiratory analytics, RKP also has a Ventilator Associated Events (VAE) tracking and surveillance component to assist with compliance around CDC reporting guidelines. Last, if the hospital is using the BD Alaris or ICU Medical systems for infusion delivery, RKP can track compliance with hospital sedation awakening trial (SAT) protocols. It then pairs this infusion data with ventilation data to provide a unique combination of analytics that can improve patient outcomes. RKP is specifically designed for use with Vyaire ventilators (manual entry data entry for VAE reporting only, can be used to support non-Vyaire ventilators).

Mobile applications

Messenger is a mobile application for viewing RKP ventilation and sedation information along with VAE status and other analytics. Users receive notifications for tracked events. Once the app is downloaded from Apple App Store or Google Play, it is ready to use with an RKP installation and subscription.

Concerto is a mobile application for associating patients to ventilators using the mobile device camera for greater convenience. Once the app is downloaded from the Apple App Store or Google Play, the URL to the locally installed VVS/PAA server is entered manually or pushed via the hospital IT MDM.

See below Diagram #4: Messenger & Concerto Mobile Applications – Installation and Connections.

Connecting to the respiratory knowledge portal

Vyaire has an affordable MDIS specifically designed to capture/process bellavista[™] ventilator data to support RKP. It consists of two components – a ventilator wireless bridge (Lantronix) and a Vyaire Ventilation Server (VVS). See the section above for how to enable HL7 output required for transmitting vent data. RKP system architecture within the hospital is outlined in Diagrams #1 and #2 (below) and is discussed extensively in the Respiratory Knowledge Portal Technical Overview (August 2014).

In addition to Vyaire's connection solution, several MDIS vendors have become RKP connection partners by developing/validating their HL7 interface to support RKP (in addition to providing ventilator documentation into the HIS EMR). Current RKP connection partners are:

- Capsule
- Bridgetech

Diagram #3 (below) outlines RKP system architecture using an MDIS connection partner.

If the hospital's MDIS vendor is not a Vyaire RKP connection partner, Vyaire will work with the MDIS vendor to develop/validate the capability to support RKP.

Diagram #1: RKP – Vyaire Wireless/ VVS/ EMR



Diagram #2: RKP & Sedation Analytics – Vyaire Wireless VVS/Patient Association Application



ICU Medical Plum 360



Diagram #4: Messenger & Concerto mobile applications – installation and connections



Appendix A: bellavistaTM HL7 data communications specification summary

HL7 (V2.3, IHE PCD Harmonized Rosetta protocol)

- bellavista Firmware:
 - Generation 3 and higher:
 - Software 4.3 and higher
 - HL7 protocol version 1.6 and higher
- Data
 - Settings/Info (27 values)
 - Monitors (54 values)
 - Alarms (n/a)
 - Waveforms (n/a)
- Communication Mode
 - Active (event driven)
- RS232 Details
 - 19200 Baud
 - 8 Data Bits
 - 1 Start Bit
 - 1 Stop Bit
 - Parity: None
 - Flow Control: None
- Required to support Vyaire Respiratory Knowledge Portal (RKP)

Monitoring					
HL7: Observ-Id	HL7: Unit-Id	HL7: ValueType	HL7: Decimal Places	bellavistaTM: Monitoring value	Remark
AUTO_PEEP	cm[H2O]	NM	1	AutoPEEP	
C_RATIO	N/A	NM	0	C ₂₀ /C _{Dyn}	
C_DYN	mL/cm[H2O]	NM	1	C _{Dyn}	
C_STAT	mL/cm[H2O]	NM	1	C _{Stat}	
DP_AW	cm[H2O]	NM	1	ΔP _{aw}	new since protocol version 1.6
DP_ES	cm[H2O]	NM	1	ΔP _{es}	new since protocol version 1.6
DP_TP	cm[H2O]	NM	1	ΔΡ _{ΤΡ}	new since protocol version 1.6
DP_TA_STAT	cm[H2O]	NM	1	ΔP _{TAStat}	new since protocol version 1.6
ETCO2	mmHg	NM	0	etCO ₂	
FIO2	%	NM	0	FiO ₂	
FLOW	L/min	NM	1	Flow for HFOT mode FlowMean for nCPAP(flow) mode	new since protocol version 1.6
FLOW_EXP_MAX	L/min	NM	1	Flow _{Exp Peak}	
FLOW_INSP_MAX	L/min	NM	1	Flow _{Insp Peak}	
I:E	N/A	ТХ	N/A	I:E	
INCO2	mmHg	NM	0	inCO ₂	
LEAK	%	NM	0	Leak %	
LEAK_FLOW	L/min	NM	0	Leak Flow	
MV_CO2	mL/min	NM	0	MVCO ₂	new since protocol version 1.6

Monitoring								
HL7: Observ-Id	HL7: Unit-Id	HL7: ValueType	HL7: Decimal Places	Bellavista: Monitoring value	Remark			
MV_EXP	L/min	NM	2	MV _{Exp}				
MV_EXP_SPONT	L/min	NM	2	MV _{Exp Spont}				
MV_INSP	L/min	NM	2	MV _{Insp}				
MV_INSP_SPONT	L/min	NM	2	MV _{Insp Spont}				
P_ES_INSP	cm[H2O]	NM	1	Pesinsp	new since protocol version 1.6			
P_ES_EXP	cm[H2O]	NM	1	P _{esExp}	new since protocol version 1.6			
P01	cm[H2O]	NM	1	P01				
PEEP	cm[H2O]	NM	1	PEEP				
P_MEAN	cm[H2O]	NM	1	P _{Mean}				
P_PEAK	cm[H2O]	NM	1	P _{Peak}				
P_PLATEAU	cm[H2O]	NM	1	P _{lateau}				
P_TA_INSP	cm[H2O]	NM	1	PTAInsp	new since protocol version 1.6			
P_TA_EXP	cm[H2O]	NM	1	P _{TAExp}	new since protocol version 1.6			
P_TP_INSP	cm[H2O]	NM	1	P _{TPInsp}	new since protocol version 1.6			
P_TP_EXP	cm[H2O]	NM	1	P _{TPExp}	new since protocol version 1.6			
PULSE	beats/min	NM	0	Pulse				
RATE	bpm	NM	0	Rate				
RATE_SPONT	bpm	NM	0	Ratespont				
R_EXP	cm[H2O]/L/s	NM	0	R _{Exp}				
R_INSP	cm[H2O]/L/s	NM	0	R _{Insp}				
RC_EXP	S	NM	2	RC _{Exp}				
RSBI	bpm/L	NM	0	RSBI				
SPO2	%	NM	0	SpO ₂				
T_EXP	S	NM	2	T _{Exp}				
T_INSP	S	NM	2	T _{Insp}				
INSP_RATIO	%	NM	0	T _{Insp} /T _{Tot}				
VD_AW	mL	NM	1	Vd _{aw}	new since protocol version 1.6			
VD_KG	mL/kg	NM	2	Vd/kg	new since protocol version 1.6			
VT_ALV	mL	NM	1	Vt _{Alv}	new since protocol version 1.6			
VT_CO2	mL	NM	0	VtCO2	new since protocol version 1.6			
VT_EXP	mL	NM	1	Vt _{Exp}				
VT_EXP_KG	mL/kg	NM	2	Vt _{Exp} /kg	new since protocol version 1.6			
VT_INSP	mL	NM	1	Vt _{Insp}				
VD_VT_EXP_RATIO	%	NM	0	Vd/Vt _{Exp}	new since protocol version 1.6			
%SPONT	%	NM	0	%Spont				
WOB	J/L	NM	3	WOB _{Imp}				

Settings					
HL7: Observ-Id	HL7: Unit-Id	HL7: ValueType	HL7: Decimal Places	bellavistaTM: Monitoring value	Remark
sEXH_SENS_MODE	N/A	ТХ	N/A	ExpTriggerType	
sEXH_SENS_VALUE	%	NM	0	Exh Sens	
sFIO2	%	NM	0	FiO ₂	
sFLOW_TGR	L/min	NM	1	Flow Trigger	
sFLOW	L/min	NM	1	Flow	new since protocol version 1.6
sNEBULIZER	N/A	ТХ	N/A	Nebulizer	
sNEBULIZER_MODE	N/A	ТХ	N/A	NebulizerMode	
sPEEP	cm[H2O]	NM	1	PEEP; CPAP	
sP_HIGH	cm[H2O]	NM	1	P _{High}	
sP_INSP	cm[H2O]	NM	1	P _{Insp}	
sPLATEAU	ms	NM	0	Plateau	
sP_LOW	cm[H2O]	NM	1	P _{Low}	
sPRESS_TGR	cm[H2O]	NM	1	Pressure Trigger	
sP_SUPP	cm[H2O]	NM	1	P _{support} , P _{Support High}	
sRISE_MODE	N/A	ТХ	N/A	Enable AutoRamp	
sRISE_VALUE	ms	NM	0	Rise Time	
sRATE	bpm	NM	0	Rate, Rate _{Backup}	
sT_HIGH	S	NM	2	T _{High}	
sT_INSP	S	NM	2	T _{Insp}	
sT_INSP_MAX	S	NM	2	T _{insp Max}	
sT_LOW	S	NM	2	T _{Low}	
sVT_INSP	mL	NM	1	Vt _{Insp} , Vt _{Target}	
sMODE*	N/A	ТХ	N/A	Mode, ApneaMode	
sPATTERN	N/A	ТХ	N/A	Pattern	
sATC	mm	NM	1	ATC	

Appendix B: Philips VueLink & Intellibridge data communications specifications for bellavistaTM

The Philips proprietary Intellibridge & Vuelink Open Interface (IVOI) protocol is used for connecting directly to Philips monitors for the purpose of ventilation monitoring and alarms surveillance.

Either the Philips EC10 module or the older Philips Vuelink Open Interface module can be used to connect the bellavistaTM to the monitor.

• Philips Intellibridge & Vuelink Open Interface Protocol-IVOI Specifications

- bellavista Generation 3 and higher:
 - Software 4.1 and higher
 - HL7 protocol version 1.6 and higher
- Data
 - Settings/Info (33 values)
 - Monitors (26 values)
 - Alarms (20 values)
 - Waveforms (4 waveforms)
- Communication Mode
 - Active (event driven)

Specification	Detail
bellavista software option	302.124.000 Data Communication Option
Connection	RS232 External device interface Enable in Configuration Assist
Protocol	Philips VueLink "Ventilator" Open InterfacePhilips Intellibridge Open Interface
Languages	DE, EN
Adapter	302.079.000 External Device Interface Adapter blue (D-Sub 9M)
VueLink components	 M1032A VueLink module with option A02 (ventilator) M1032-61699 Open Interface cable (D-Sub 9, 4 m) option K6C M1032-TU1AA Driver for VL Open Interface (normally already installed)
Intellibridge components	 865115 *A01 101 Intellibridge EC10 Module M8081-61002 Intellibridge connecting cable 865114 #104 Intellibridge EC5 adapter (D-Sub 9)
RS232 Details	19,200 baud 8 data bits 1 stop bit No parity No handshake

List of transmitted bellavista[™] parameters to Philips Monitoring

Waveforms			
Parameter	Label	Unit	Range
Pressure	"AWP"	"cmH_2O"	- 52 130
Flow	"AWF"	"L/min"	- 300 300
Volume	"AWV"	"mL"	0 2500
CO ₂	CUSTOM "CO ₂ aw"	"mmHg"	0 190

Monitoring Numeric			
Parameter	Label	Unit	Range
Vt _{Exp} ; Vt _{Insp} *	CUSTOM "Vt"	"mL"	0 2500
Rate	"AWRR"	"1/min"	0 200
P _{Peak}	"Ppeak"	"cmH_2O"	- 52 130
PEEP	"PEEP"	"cmH_2O"	- 52 130
MV _{Exp} ; MV _{Insp} *	"MV"	"L/min"	0 250
FiO2	"FIO_2"	"%"	0 100
etCO ₂	"ETCO_2"	"mmHg"	0 190
inCO ₂	"IMCO_2"	"mmHg"	0 190
Flow _{Exp Peak}	"exPkFl"	"L/min"	0 600
Flow _{Insp Peak}	"inPkFl"	"L/min"	0 600
I:E	"I:E 1:"		0.1 99
Leak Flow	"Leak"	"L/min"	0 200
MV _{Exp Spont} , MV _{Insp Spont} *	"SpMV"	"L/min"	0 250
Parameter	Label	Unit	Range
PMean	"Pmean"	"cmH_2O"	- 52 130
PPlateau	"Pplat"	"cmH_2O"	- 52 130
ТЕхр	"ExpTi"	"sec"	0 60
TInsp	"InsTi"	"sec"	0 60
% Spont	CUSTOM "%Spont"	"%"	0 100
AutoPEEP	"iPEEP"	"cmH_2O"	- 52 130
CDyn	"Cdyn"	"mL/cmH_20"	0 1000
CStat	"Cstat"	"mL/cmH_2O"	0 1000
RateSpont	"SpRR"	"1/min"	0 200
RExp	"Rexp"	"cmH_2O/_l/s"	0 300
RInsp	"Rinsp"	"cmH_2O/_l/s"	0 300
RSBI	"RSBI"	"1/(min*l)"	01

Setting Numeric, Alarm Limits, Modes			
Parameters/Alarms	Label	Unit	Range
FiO2	"sFIO_2"	"%"	21 100
PEEP; CPAP	"sPEEP"	"cmH_20"	0 999
P _{Insp}	"sPin"	"cmH_2O"	0 999
Plateau	"sPltTi"	"msec"	0 999
P _{Insp Max}	"sPmax"	"cmH_2O"	0 999
P _{Support} ; P _{Support} High	"sPSV"	"cmH_2O"	0 999
Ramp	"sPincR"	"msec"	0 999
Rate; Rate _{Backup}	"sRRaw"	"1/min"	0 150
T _{Insp}	"sInsTi"	"sec"	0 99
Pressure Trigger	"sTrig"	"cmH_2O"	0 99
Flow Trigger	"sTrgFl"	"L/min"	0 99
Vt _{Insp} ; Vt _{Target}	"sTV"	"mL"	0 9999
Sigh ampl.	"sSghTV"	"%"	0 999
Sigh interv.	"sSghR"		0 999
Sigh no.	"sSghNr"		0 999
etCO2 High/Low	"ETCO_2"		
inCO2 High	"IMCO_2"		
FiO2 High	"FIO_2"		
MV High/Low	"MV"		
PPeak High/Low	"Ppeak"		
Rate High/Low	"AWRR"		
Vt High/Low	"TV"		
СРАР	СРАР		
PCV or T	PCV		
P-A/C	P-A/C		
PC-SIMV	P-SIMV		
PSV or S or S/T	PSV		
beLevel	beLevel		
APRV	APRV		
V-A/C	V-A/C		
VC-SIMV	V-SIMV		

Alarms*		
bellavista alarm ID	High priority Alarm	Medium Priority Alarm
260, 262	Occlusion	
251, 256, 258	Disconnection	
254, 255, 257, 259, 266, 274, 275	Breathing circuit	
131, 132	Apnoea	
111	Pressure high	
101	Volume high	
121	Volume low	
150, 151, 220, 221, 222, 224, 270, 271,		
272, 273	O ₂ alarm	
All other patient alarms with high priority	Patient alarm	
All other technical alarms with high priority	Ventilator	
130		Breathing circuit
104		Volume low
113, 115		Pressure low
141		Rate low
140		Rate high
120		Volume high
114		Pressure high
170, 171, 172, 244, 245, 246, 281, 391		Capnography
All other patient alarms with medium priority		Patient alarm
All other technical alarms with medium priority		Ventilator

* Alarms are not available in the US

Appendix C: bellavista[™] RS232 pin out

The RS 232 connection interface for data communication. The port is an ODU Medi-Snap connector and accommodates a single cable connection.

- Transmit (Tx) 3
- Receive (Rx) 2
- Ground (GND) 5

Specification	Detail		
Specification	Detail		
Connection	RS232 interface		
Port on Device	Blue Connection on the right side of bellavista Device		
Cable	bellavista Adapter External Device Interface		
	(302.079.000) ODU Connector 4p, Male D-Sub Connector 9p, Male		
D-Sub Connector Pins	1 n/c		
	2 RX 3 TX		
	$ \begin{array}{c c} 4 & n/c \\ \hline & & \\ \hline \\ \hline$		
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	7 n/c		
	8 n/c 9 n/c		

As mentioned previously, the vents can only communicate to one device using a single protocol at any given time.

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