FRESENIUS KABI
caring for life

Agilia® Connect
Connected Infusion System

Catalog

Contents

Performances and Characteristics

Accessories

Agilia Connect

A complete range of connected infusion pumps

Agilia Connect is the new infusion system giving you control from your Fresenius Kabi Centerium server.

Powered by Vigilant Software Suite, you can securely and remotely configure and update your infusion fleet.

	Volumetric Pumps	Syringe Pumps

General purpose

Infusion Pumps

Agilia VP

Agilia SP

Advanced Infusion Pumps

Agilia VP MC
Agilia VP MC WiFi

Agilia SP MC
Agilia SP MC WiFi

Specialised pumps

Infusion Pumps for Anaesthesia

Agilia SP TIVA
Agilia SP TIVA WiFi

Infusion Pumps for PCA (Patient-Controlled Analgesia)

Agilia SP PCA WiFi

Agilia SP

Syringe infusion pump

Less programming time & Intuitive Settings

As for all devices Agilia range, special attention has been paid to ergonomics and robustness of the pumps in order to make it easy and pleasant to use

As for all devices of the Agilia range, special attention has been paid to the ergonomics of the pump in order to make it easy, robust and pleasant to use.

Intuitive and safe settings

- The infusion setting is guided and each step clearly identified.

- The displayed instructions are simple to follow. Intuitive settings increase user confidence.

- Sensors continuously check the correct administration of drugs in the syringe .

- Every handled part has been painted blue for easy identification by user.

Clear monitoring

- Infusion monitoring is easy thanks to a clear screen with key information at a glance.

- The syringe is always visible and the flow indicator lights enable quick and safe monitoring.

- The DPS functionality enables close pressure monitoring for early occlusion detection.

Robustness

- Push guard ensures arm protection against shocks.

- Glass-fiber material reinforces critical components protection.

Easy handling

- With an integrated handle, Agilia SP is extremely mobile, easy to carry and assemble. Up to 3 devices can be stacked.

- Combined with the Ambulance holder accessory, the pump is transportable anywhere.

Agilia SP MC & Agilia SP MC WiFi

Advanced syringe infusion pumps

Agilia SP MC offers a wide range of programming modes that suit all infusion protocols, from the simplest to the most advanced

On top of SP features and to meet the demand of a changing clinical environment, Agilila SP MC has been developed to be used intuitively and to promote more safety and comfort.
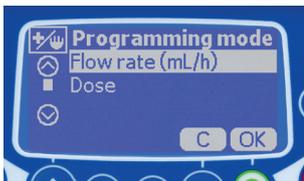
Adaptable to all protocols

- Agilia SP MC offers a wide range of programming modes: loading dose, micro-infusion, manual bolus, programmed bolus.

- The Agilia SP MC can receive up to 19 profiles with 200 drugs each.

Dose rate programmation

- The pump can be programmed in dose rate with direct translation into flow rate in mL/h.

Optimal programming

- The infusion can be programmed from 0.1 up to 1200 mL/h.

- Multiple dose rate units available to mach all clinical practices.

Agilia SP TIVA & Agilia SP TIVA WiFi

Syringe infusion pumps for intravenous anaesthesia

The Agilia SP TIVA provides pharmacokinetic TCI models covering the widest range of patient population, including children

Agilia SP TIVA with the following pharmacokinetic models, all in plasma as well as effect target.

- **Marsh & Schnider** for Propofol administration in adults

- **Kataria & Paedfusor** for Propofol administration on pediatrics

- **Minto, Gepts & Scott for Remifentanil, Sufentanil and Alfentanil** administration in adults
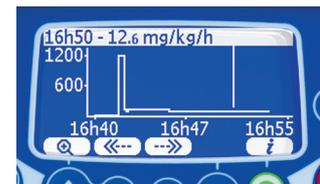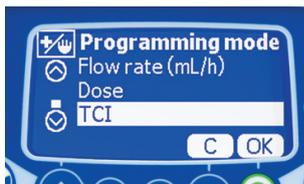
Intuitive setting

- The infusion setting is guided and each step clearly identified. Modes mL/h, Dose and TCI at your disposal.

- The displayed instructions are simple to follow. Intuitive settings increase user confidence.

Clear monitoring

- Monitoring is simple thanks to easily accessible numerical and graphical information.

- The syringe is always visible and the flow indicator lights enable quick and safe monitoring.

Quick history access

The graph key gives direct access to TCI information:

- TCI Infusion history, both in dose and flow rate.

- Key infusion parameters.

- Target and concentration history.

- Wake up time.

Agilia SP PCA WiFi

Patient-Controlled Analgesia (PCA) syringe infusion pump

Take control of the pain with Agilia SP PCA to deliver the prescription
at your patient's pattern

Agilia SP PCA proposes 4 PCA modes to accommodate to every protocol:

· PCA bolus only	· Continuous rate mode	· PCA bolus + Continuous rate mode	· PCA bolus + Variable rates
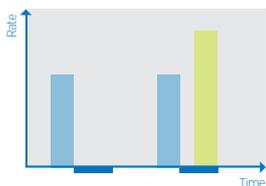
■ PCA bolus
■ Lock out time
■ Clinician bolus
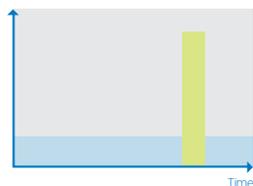
■ Continuous rate
■ Clinician bolus
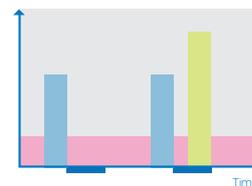
■ PCA bolus
■ Lock out time
■ Clinician bolus
■ Continuous rate
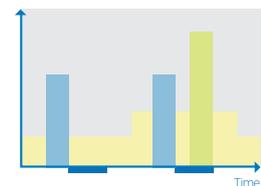
■ PCA Bolus
■ Lock out time
■ Clinician bolus
■ Variable rates

Easy to use

- Intuitive workflow through a simple Menu.
- Easy loading dose and clinician bolus set up.
- A PCA history available to follow your patient's events.
- Monitoring at a glance.

Safe

- Full syringe protection with a key lock to complete a safe self-administration.
- Agilia SP PCA can be used in general infusion mode with a secured hardware and software protection of the pump.
- Keypad protection by password to avoid overdose of medication.

Ergonomic handset

- Comfortable shape and size for your patient.
- Stroke length to get the right feeling.

Agilia VP

Volumetric infusion pump

Less programming time & Intuitive Settings

As for all devices Agilia range, special attention has been paid to ergonomics and robustness of the pumps in order to make it easy and pleasant to use

To meet the demands of a changing clinical environment, Agilia VP has been developed to be used intuitively and to promote more safety and comfort.

Intuitive setting

- The infusion setting is guided and each step clearly identified.
- The displayed instructions are simple to follow. Intuitive settings increase user confidence.

Clear monitoring

- Monitoring is simple thanks to easily accessible numerical and graphical information.
- The syringe is always visible and the flow indicator lights enable quick and safe monitoring.

Ensuring continuous infusion

- With its integrated handle, Agilia VP is extremely mobile, easy to carry and assemble. Up to three devices can be stacked.

Agilia VP MC & Agilia VP MC WiFi

Advanced volumetric infusion pumps

Agilia VP MC offers a wide range of flow rates as well as programming modes that suit all infusion protocols, from the simplest to the most advanced

As for all devices of the Agilia range, special attention has been paid to the ergonomics of the pump in order to make it easy and pleasant to use.

Adaptable to all protocols

- Agilia VP MC offers a wide range of programming modes: loading dose, micro-infusion, manual bolus, programmed bolus, drop /min...

A wide range of flow rates

- The infusion can be programmed from 0.1 up to 1500 mL/h.

- The flow rate range available from the keyboard can be configured.

Dose rate programmation

- The pump can be programmed in dose rate with direct translation into flow rate in mL/h.

Safety in line

- The SafeClip on the Volumat Lines automatically clamps the line to avoid any risk of free-flow when the door is opened.

- The connectors with different shapes and colour codes facilitate the installation and make it impossible to insert the administration set the wrong way.

Vigilant® Software Suite

Intuitive, powerful and secured control

The Agilia Connect sytem seamlessly integrates with hospital IT infrastructures guaranteeing the confidentiality, integrity and availability of your infusion data.

The system supports WiFi connectivity using the latest cybersecurity standards.

Hospital Network

Centerium
The Data Solution management

- Centerium is a software application that enables remote distribution of drug libraries and monitoring a fleet of devices.

Vigilant Bridge
EMR Auto-documentation

- Vigilant Bridge is a software application embedded in Centerium providing interoperability between our pumps and the PDMS/EMR using HL7 standard and IHE profiles.

Vigilant Insight
Quality Improvement

- Vigilant Software is a software embedded in Centerium that collects infusion data and generates reports to analyse and improve drug library utilization and infusion practices.

Vigilant Master Med
Safe administration

- Vigilant Master Med a software that will enable you to create, customise and distribute drug libraries according to the needs of all your clinical care units.

Vigilant Sentinel
Your smart infusion status

- Vigilant Sentinel provides infusion status to organise and prioritise nurse actions at the bedside.

Agilia Partner
Maintenance software

- Agilia Partner is the application that will help you perform upgrade operations on pumps software and hardware.

Centerium

Access Infusion Data, anywhere, anytime

- Easy drug and fleet management
- Simple integration with hospital IT systems
- Latest cybersecurity standards
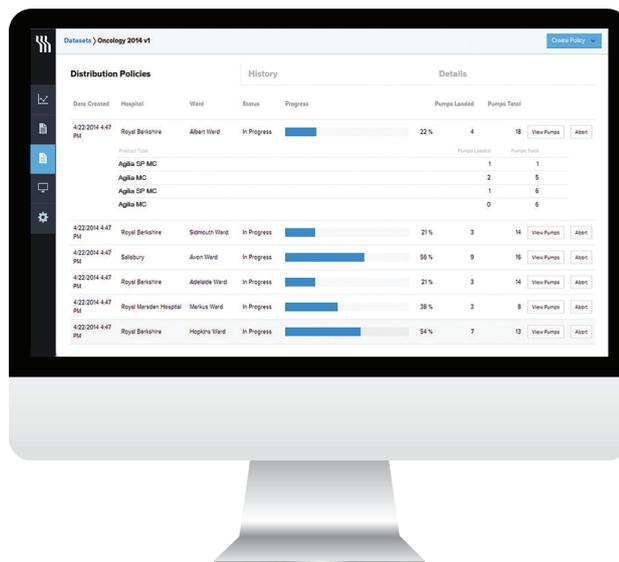
Fleet Monitoring

- Monitor status of installed pumps.
- Designed to support your hospital's topology.
- Save hardware and software costs with a centralized database.

Infusion System Deployment

- A single instance of the server software can manage up to 3,000 devices.
- Low network bandwidth consumption: data transfer rate of 3 Mbps.

Cybersecurity

- Secured communication with other applications using digital certificates.
- Proprietary HMAC from Centerium to Fresenius Kabi infusion devices.
- User authentication integrated with MS Active Directory.
- Centerium guarantees confidentiality, integrity and availability of infusion data.

Vigilant Bridge

EMR Auto-documentation Software

- A software to provide you with a smooth interoperability between our pumps and your PDMS/EMR
- A sustainable investment by using a standard language, HL7 and IHE profiles
- An auto-documentation interface for connectivity to reduce nurse charting time

Connectivity with Vigilant Bridge

Vigilant Bridge is a software enabling interoperability with any EMR (Electronical Medical Records) compatible with HL7/IHE standard.

Vigilant Bridge provides auto-documentation workflow by collecting pump's infusion status & events, within a ward through rack Link+, and transmits it to the EMR's flowsheet for nurse review.

Vigilant Bridge is based on Centerium Data Management Solution and therefore compatible with the Agilia Connect Infusion System.

Fresenius Kabi is an active member of IHE (Integrating the Healthcare Enterprise)

IHE is a group of healthcare industry representatives that work to improve the way health care systems share information electronically (https://www.ihe.net).

IHE compliance claims:

- Nurse time saving thanks to auto-documentation interface.
- Reliable and consistent data quality between medical devices and information system.
- Implementation workload/investment economy.

Vigilant Bridge is compatible with the following standard and profiles versions:

- HL7, Standard Version 2.6
- IHE Patient Care Devices (PCD) Technical Framework:
  - Device Enterprise Communication (DEC)
  - Infusion Pump Event Communication (IPEC)

Vigilant Bridge cybersecurity and interface disruption management

In the event of an interface messaging disruption, Vigilant Bridge manages a downtime process to ensure that messages are filed in sequence when the HL7 connection is available.

For cybersecurity reason Vigilant Bridge also secures communication over network with EMR buy using HTTP over TLS authentication.

HL7 standard & IHE profile include mechanisms to prevent loss of data when communication with EMR is broken.

PDMS connectivity

Thanks to Vigilant Bridge and HL7, we have started interoperability with Cerner, Epic, Philips, Copra and more third parties to come.

Vigilant Insight

Vigilant Insight is a software that collects infusion data and generates reports to analyze and improve drug library utilization and infusion practices.
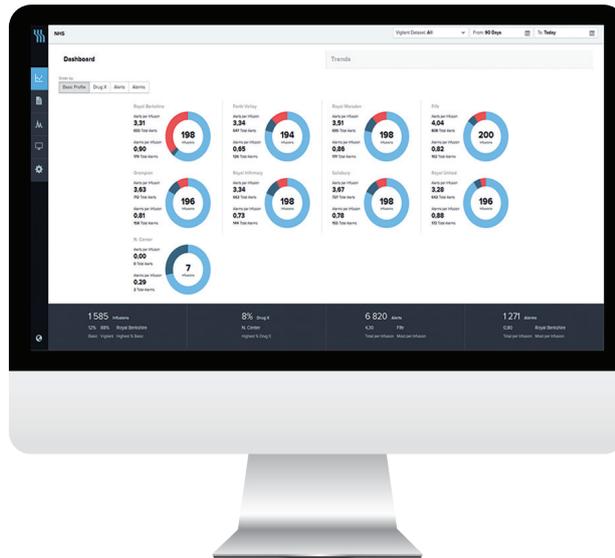
Overview of the infusion practices use in the entire hospital

- Each level of location can be displayed: organization, hospital, ward and profile.
- Get a vision of: Drug Library, Drug X and Basic Profile use ratios, per location.
- Track any drug infusion.

Get automated reports of alerts & alarms in order to help to

- Reduce human errors.
- Prevent alarm fatigue.
- Improve Vigilant Master Med.
- Improve clinical practices.

Powerful and user friendly

- Web based software: access your data seamlessly from any location.
- Powerful data management. From global fleet to unitary pump.
- Exportable analytics reports.
- Visibility to your "Hidden" infusion data.
- Retrospective analysis of infusion pump utilization.
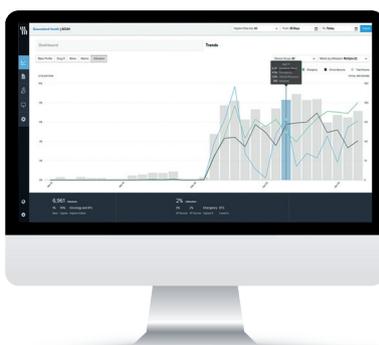
Manage the infusion devices distribution through the dashboard

- Track unused pumps.
- Size your fleet according to your needs.
- Optimize your investment.

Vigilant Master Med

Vigilant Master Med is a software that will enable you to create, customise and distribute drug libraries according to the needs of all your clinical care units.
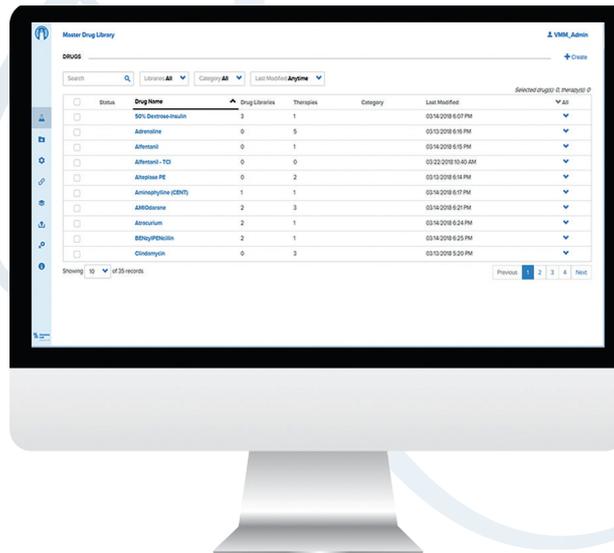
More features and customisation

- Sharing parameters values across devices for a better analysis of outcome.

- Simple decimals management: micro and macro modes.

- All infusion modes are vailable for compatible Agilia Connect pumps, including Ramp and Sequential modes.

- Safety configuration features at the therapy level to reduce risk of errors.

- Advanced clinical features for PCA & TCI infusions.

Latest safety standards

- Reduce adverse drug administration event with hard and soft limits.

- Secured Dataset released process.

- Up-to-date with the latest cyber communication standards.

Leverage your investment

Easy and scalable drug management.

- One DERS for all Agilia Connect Infusion devices.

- Ease large distribution of drug libraries through WiFi connectivity thanks to Centerium.

- Share clinical data with colleagues and hospital within the same organisation.

- Optimise drug and dosage usage in combination with Vigilant Insight.

Vigilant Sentinel

Vigilant Sentinel provides smart infusion status to effectively help nurses to prioritize their actions at the bedside.

Vigilant Sentinel enables to anticipate events thus reducing stress due to infusion pumps and alarm fatigue.
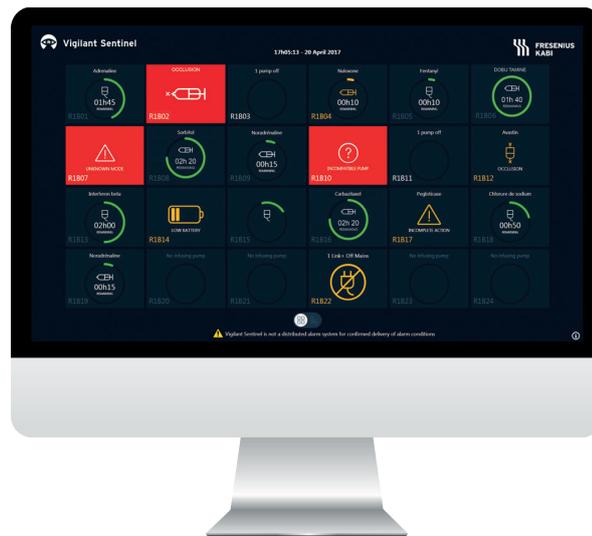
Optimize your workflow

- Closely follow-up all of your patients from a single place.

- Keep constantly informed about any required action at a bedside.

- Use ward and bedside views according to your needs.

Reduce alarm fatigue

- Have a constant view of the infusion status with different levels of details.

- Anticipate end of infusions and help to prevent therapy interruptions.

- Immediately detect pumps on battery before it starts getting discharged.

Manage your time

- Anticipate the preparation of new bags and syringes for a peace of mind.

- Locate easily available pumps.

- Avoid unnecessary visits to isolated patients.

''The touchscreen makes it very easy to operate and delivers very relevant information. The system is very intuitive, and we find the required information very easily and on time. The evolution of the software is very good and well accepted by the user.''

Paulina del Rio, Supervisor Nurse UCIA, Hospital Carlos Van Buren.

Notes

Notes

Performances and Characteristics

Agilia SP

Infusion

Flow rate range
0.1 - 1200 mL/h, depending on the syringe capacity.
0.1 mL/h increment from 0.1 to 99.9 mL/h (optionally 0.01 mL/h from 0.10 to 9.99 mL/h), 1 mL/h from 100 to 1200 mL/h.
Flow rate can be restricted (hard limits) per syringe capacities with Vigilant Master Med, The Dose Error Reduction Software.

Flow rate accuracy
+/- 1 % on mechanism ; +/- 2 % on syringes.

Syringe capacities
5, 10, 20, 30/35, 50/60 CC.

Types of syringe
Up to 100 types.

Infusion modes
mL/h mode.
Volume / time: 0.1 - 99.9 mL; 00h01 - 96h00.
Volume limit: 0.1 - 999 mL.

Volume infused
0.1 - 999 mL.

Priming
3 modes: Mandatory, not mandatory, or advised / Rate: 1200 mL/h.

Bolus
Direct bolus: Rate: 50 - 1200 mL/h (50 mL/h increment).

End infusion (V/T & VL)
KVO: adjustable from 0.1 to 5 mL/h, continuous infusion or stop.

Fast start
Not mandatory prime set by default resulting in fast start if user does not prime with bolus button ensuring programmed flow rate to be reached faster.

Pause
Programmable from 1 minute to 24 hours, increments from minute to minute.

Data log event
1500 data log events in real time.

Graphical history
Volume / dose infused, pressure, flow rate.

Night mode
The night mode decreases the brightness of the screen and the green lights.
The key beep can optionally be turned off. The night mode can be programmed manually or automatically in a variable time range.

Profiles
Basic Profile: infusion without any display of the drug names.
1 custom profile configurable with Vigilant Master Med.
Drug list with a list of drug names.
Configuration only: custom pump configuration without drug name.

Pressure management

Pressure modes
2 modes available: variable or 3 pre-set levels - Range from 50 to 900 mmHg. (25 mmHg increment from 50 to 250 mmHg / 50 mmHg increment from 250 to 900 mmHg). Can be enables / disabled and adjusted.

DPS
The Dynamic Pressure System - DPS - warns of pressure variations.
A risk of obstruction or a possible leak in the infusion line can thus be anticipated.

Pressure monitoring
Graphic representation of the pressure in the infusion line and of the pressure limit thanks to the pictogram.

Anti-bolus system
Reduces significantly bolus after occlusion release*.
≤ 0.35 mL max for a 50 mL syringe.
* Test condition: Back pressure: 0 mmHg - Syringe: BD Precise.

Alarms / Pre-alarms / Security

Pump status
- GREEN for infusion in progress.
- ORANGE for Low and Medium priority.
- RED for High priority.
Visibility at 4 meters minimum.
All alarms are expressed by means of light indicators, written words, pictograms and sound beeps.

Syringes installation control
Syringe barrel clasp check, plunger head detection, anti-siphon system check, flange detection.

Infusion control
Occlusion pressure pre-alarm, occlusion pressure alarm, end of infusion pre-alarm, end of infusion alarm, volume limit pre-alarm, volume limit alarm, keypad manual locking or keypad autolock, hard and soft flow rate limits, start infusion at pause end.

Device control
Disengaged driving mechanism alarm, low battery pre-alarm, discharged battery alarm, battery capacity display in hours and minutes, unconfirmed programming, technical malfunction alarm (auto-test, rotation), drive system advance check, watchdog check, communication connection failure, plug-head disengagement, auto-lock/lock code (on Keypad).

Maintenance
Preventive maintenance warning.

Technical specifications

Manual pusher
Protection for the ongoing infusion thanks to "Push-Guard".

Display
Blue graphic LCD monochrome, size 66 mm x 33 mm
(256 x 128 pixels).

Swinglock clamp
Versatile clamp that allows the fixation on a rail or on a pole
(Pole: 20-40 mm max. / Rail: 25-35 x 10 mm).

Stackability
Up to 3 devices self-stackable on a pole.

Dimensions (h/w/d) / weight
135 X 345 X 170 mm / ~ 2.1 kg.

Battery
Characteristics: 7.2 V 2.2 Ah - Li-ion Smart battery, remaining battery life and battery charge level available on the display.

Battery Life (when fully charged): > 11 h at 5 mL/h.

Battery recharge:
- Pump OFF: < 6 h
- Pump ON: < 20 h

Waterproofness
IP22

Power supply
100 V - 240 V ~ / 50 / 60 Hz with functional earth.

Compliance

Electromagnetic compatibility EMC
IEC 60601-1-2, IEC 60601-2-24

Medical Device Directive
CE 0123 marking in compliance with the Concil Directive 93/42/EEC

Electrical Compliance
Protection against leakage current: Defibrillation-proof type CF
Protection against electric shocks: class II in accordance with IEC 60601-1

Alarm system
IEC 60601-1-8

Usuability Engineering
IEC 60601-1-6 and IEC 62366

Agilia SP MC & Agilia SP MC WiFi

Infusion

Flow rate range
0.1-1200 mL/h
0.1 mL/h increment from 0.1 to 99.9 mL/h (optionally 0.01 mL/h from 0.10 to 9.99 mL/h), 1 mL/h from 100 to 1200 mL/h.
Flow rate can be restricted for each drug (soft and hard limits) with Vigilant Master Med, The Dose Error Reduction Software.

Flow rate accuracy
+/- 1 % on mechanism : +/- 2 % on syringes.

Syringes capacities
5, 10, 20, 30/35, 50/60 CC.

Type of syringe
Up to 100 types.

Infusion Modes
- mL/h mode.
- Dose rate mode: ng/h, ng/kg/min, ng/kg/h, microg/min, microg/h, microg/kg/min, microg/kg/h, mg/min, mg/h, mg/24h, mg/kg/min, mg/kg/h, mg/kg/24h, mg/m²/h, mg/m²/24h, g/h, g/kg/min, g/kg/h, g/kg/24h, mmol/h, mmol/kg/h, mmol/kg/24h, mU/min, mU/kg/min, mU/kg/h, U/min, U/h, U/kg/min, U/kg/h, kcal/h, kcal/24h, kcal/kg/h, mEq/min, mEq/h, mEq/kg/min, mEq/kg/h.
- Dilution setting: -- units / mL or -- units / -- mL. With or without loading dose.
- Volume or dose / time: 0.1 - 99.9 mL; 00 h 01 - 96 h 00.
- Volume limit: 0.1 - 999 mL.

Volume/Dose infused
Volume: 0.1 - 999 mL / Dose: 0.1 - 9999 units

Priming
3 modes: mandatory, not mandatory, or advised / Rate: 1200 mL/h.

Bolus
- Direct bolus: Rate: 50 - 1200 mL/h (50 mL/h increment).
- Programmed bolus (dose or volume / time): 0.1 - 99.9 mL 0.01 - 9999 units / 1 second - 24 h.

Loading dose
Dose / time: 0.01 - 9999 units / 1 second - 24 h.
Rate auto-calculation.

End infusion (V/T & VL)
KVO: adjustable from 0.1 to 5 mL/h, continuous infusion or stop.

Fast start
Not mandatory prime set by default resulting in fast start if user does not prime with bolus button ensuring programmed flow rate to be reached faster.

Pause
Programmation from 1 minute to 24 hours, increments from minute to minute.

Data log event
1500 data log events in real time.

Graphical history
Volume / dose infused, pressure, flow rate.

Night mode
The night mode decreases the brightness of the screen and the green lights. The key beep can optionally be turned off. The night mode can be programmed manually or automatically in a variable time range.

Profiles
Basic Profile: infusion without any display of the drug names.
19 Custom profiles configurable with Vigilant Master Med: Drug library to be created with up to 200 drugs.
Drug list with a list of drug names.
Configuration only: Custom pump configuration without Drug Name.

Pressure management

Pressure modes
2 modes available: variable or 3 pre-set levels - Range from 50 to 900 mmHg. (25 mmHg increment from 50 to 250 mmHg / 50 mmHg increment from 250 to 900 mmHg). Can be enabled / disabled and adjusted.

DPS
The Dynamic Pressure System - DPS - warns of pressure variations.
A risk of obstruction or a possible leak in the infusion line can thus be anticipated.

Pressure monitoring
Graphic representation of the pressure in the infusion line and of the pressure limit thanks to the pictogram.

Anti-bolus system
Reduces significantly bolus after occlusion release*.
≤ 0.35 mL max for a 50 mL syringe.
* Test condition: Back pressure: 0 mmHg - Syringe: BD Precise.

Alarms / Pre-alarms / Security

Pump status
- GREEN for infusion in progress.
- ORANGE for Low and Medium priority.
- RED for High priority.
Visibility at 4 meters minimum.
All alarms are expressed by means of light indicators, written words, pictograms and sound beeps.

Syringes installation control
Syringe barrel clasp check, plunger head detection, anti-siphon system check, flange detection.

Infusion control
Occlusion pressure pre-alarm, occlusion pressure alarm, end of infusion pre-alarm, end of infusion alarm, volume limit pre-alarm, volume limit alarm, hard and soft flow rate limits, start infusion at pause end.

Device control
Disengaged driving mechanism alarm, low battery pre-alarm, discharged battery alarm, battery capacity display in hours and minutes, unconfirmed programming, technical malfunction alarm (auto-test, rotation), drive system advance check, watchdog check, communication connection failure, plug-head disengagement, auto-lock/lock code (on Keypad).

Maintenance
Preventive maintenance warning.

Technical specifications

Manual pusher
Protection for the ongoing infusion thanks to "Push-Guard".

Display
Blue graphic LCD monochrome, size 66 mm x 33 mm
(256 x 128 pixels).

Swinglock clamp
Versatile clamp that allows the fixation on a rail or on a pole
(Pole: 20-40 mm max. / Rail: 25-35 x 10 mm).

Stackability
Up to 3 devices self-stackable on a pole.

Dimensions (h/w/d) / weight
135 X 345 X 170 mm / ~ 2.1 kg.

Battery
Characteristics: 7.2 V 2.2 Ah - Li-ion Smart battery, remaining battery life and battery charge level available on the display.

Battery Life (when fully charged):
- Agilia SP MC and Agilia SP MC WiFi (WiFi disabled / not used): > 11 h at 5 mL/h
- Agilia SP MC WiFi (WiFi enabled): > 6 h at 5 mL/h

Battery recharge:
- Pump OFF: < 6 h
- Pump ON: < 20 h

Waterproofness
IP22

Power supply
100 V - 240 V ~ / 50 / 60 Hz with functional earth.

Compliance

Electromagnetic compatibility EMC
IEC 60601-1-2, IEC 60601-2-24

Medical Device Directive
CE 0123 marking in compliance with the Concil Directive 93/42/EEC

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Alarm system
IEC 60601-1-8

Usuability Engineering
IEC 60601-1-6 and IEC 62366

Wireless LAN

Technology
IEEE 802.11 a/b/g/n. Frequency Band: 2.400 -> 2.500 GHz (2.4 GHz is ISM band) / 4.900 -> 5.850 GHz (High Band).

Modulation
OFDM with BPSK, QPSK, 16-QAM, and 64-QAM 802.11b with CCK and DSSS.

Wireless Security
WPA/WPA2-Entreprise, WPA/WPA2-PSK.

Network Protocols
TCP, IPv4, DHCP, HTTP.
CE, FCC and IC compliant.

Agilia SP TIVA & Agilia SP TIVA WiFi

Infusion

Flow rate range
0.1-1200 mL/h
0.1 mL/h increment from 0.1 to 99.9 mL/h (optionally 0.01 mL/h from 0.10 to 9.99 mL/h), 1 mL/h from 100 to 1200 mL/h.
Flow rate can be restricted for each drug (soft and hard limits) with Vigilant Master Med, The Dose Error Reduction Software.

Flow rate accuracy
+/- 1 % on mechanism : +/- 2 % on syringes.

Syringes capacities
5, 10, 20, 30/35, 50/60 CC.

Type of syringe
Up to 100 types.

Infusion Modes
· mL/h mode.
· Dose rate modes: ng/h, ng/kg/min, ng/kg/h, micro g/min, microg/h, microg/kg/min, microg/kg/h, mg/min, mg/h, mg/24h, mg/kg/min, mg/kg/h, mg/kg/24h, mg/m²/h, mg/m²/24h, g/h, g/kg/min, g/kg/h, g/kg/24h, mol/h, mmol/kg/h, mmol/kg/24h, mU/min, mU/kg/min, mU/kg/h, U/min, U/h, U/kg/min, U/kg/h, kcal/h, kcal/24h, kcal/kg/h, mEq/min, mEq/h, mEq/kg/min, mEq/kg/h.
· TCI infusion mode.
· Dilution setting: -- units / mL or -- units / -- mL.
· With or without loading dose.
· Volume or dose / time: 0.1 - 99.9 mL; 00 h 01 - 96 h 00.
· Volume limit: 0.1 - 999 mL.

TCI Mode
Pharmacokinetic Models:
· Marsh & Schnider for Propofol administration on adults.
· Kataria & Paedfusor for Propofol administration on pediatrics.
· Minto, Gepts & Scott for Remifentanil, Sufentanil and Alfentanil.
Administration in adults.
Targets: TCI Effect or Plasma control Modes.

Volume/Dose infused
Volume: 0.1 - 999 mL / Dose: 0.1 - 9999 units.

Priming
3 modes: mandatory, not mandatory, or advised / Rate: 1200 mL/h.

Bolus
· Direct bolus: Rate: 50 - 1200 mL/h (50 mL/h increment).
· Programmed bolus (dose or volume / time): 0.1 - 99.9 mL
  0.01 - 9999 units / 1 second - 24 h.

Induction dose
Dose / time: 0.01 - 9999 units / 1 second - 24 h.
Rate auto-calculation.

End infusion (V/T & VL)
KVO: adjustable from 0.1 to 5 mL/h, continuous infusion or stop.

Fast start
Not mandatory prime set by default resulting in fast start if user does not prime with bolus button ensuring programmed flow rate to be reached faster.

Pause
Programmation from 1 minute to 24 hours, increments from minute to minute.

Data log event
1500 data log events in real time.

Graphical history
Volume / dose infused, pressure, flow rate.

Night mode
The night mode decreases the brightness of the screen and the green lights. The key beep can optionally be turned off. The night mode can be programmed manually or automatically in a variable time range.

Profiles
Basic Profile: infusion without any display of the drug names and with TCI modes.
19 Custom profiles configurable with Vigilant Master Med: Drug library to be created with up to 200 drugs.
Drug list with a list of drug names.
Configuration only: Custom pump configuration without Drug Name.

Pressure management

Pressure modes
2 modes available: variable or 3 pre-set levels - Range from 50 to 900 mmHg. (25 mmHg increment from 50 to 250 mmHg / 50 mmHg increment from 250 to 900 mmHg). Can be enables / disabled and adjusted.

DPS
The Dynamic Pressure System - DPS - warns of pressure variations.
A risk of obstruction or a possible leak in the infusion line can thus be anticipated.

Pressure monitoring
Graphic representation of the pressure in the infusion line and of the pressure limit thanks to the pictogram.

Anti-bolus system
Reduces significantly bolus after occlusion release*.
≤ 0.35 mL max for a 50 mL syringe.
* Test condition: Back pressure: 0 mmHg - Syringe: BD Precise.

Alarms / Pre-alarms / Security

Pump status
· GREEN for infusion in progress.
· ORANGE for Low and Medium priority.
· RED for High priority.
Visibility at 4 meters minimum.
All alarms are expressed by means of light indicators, written words, pictograms and sound beeps.

Syringes installation control
Syringe barrel clasp check, plunger head detection, anti-siphon system check, flange detection.

Infusion control
Occlusion pressure pre-alarm, occlusion pressure alarm, end of infusion pre-alarm, end of infusion alarm, volume limit pre-alarm, volume limit alarm, hard and soft flow rate limits, start infusion at pause end.

Device control
Disengaged driving mechanism alarm, low battery pre-alarm, discharged battery alarm, battery capacity display in hours and minutes, unconfirmed programming, technical malfunction alarm (auto-test, rotation), drive system advance check, watchdog check, communication connection failure, plug-head disengagement, auto-lock/lock code (on Keypad).

Maintenance
Preventive maintenance warning.

Technical specifications

Manual pusher
Protection for the ongoing infusion thanks to "Push-Guard".

Display
Blue graphic LCD monochrome, size 66 mm x 33 mm
(256 x 128 pixels).

Swinglock clamp
Versatile clamp that allows the fixation on a rail or on a pole
(Pole: 20-40 mm max. / Rail: 25-35 x 10 mm).

Stackability
Up to 3 devices self-stackable on a pole.

Dimensions (h/w/d) / weight
135 X 345 X 170 mm / ~ 2.1 kg.

Battery
Characteristics: 7.2 V 2.2 Ah - Li-ion Smart battery, remaining battery life and battery charge level available on the display.

Battery Life (when fully charged):
· Agilia SP TIVA and Agilia SP TIVA WiFi (WiFi disabled / not used): > 11 h at 5 mL/h
· Agilia SP TIVA WiFi (WiFi enabled): > 6 h at 5 mL/h

Battery recharge:
· Pump OFF: < 6 h
· Pump ON: < 20 h

Waterproofness
IP22

Power supply
100 V - 240 V ~ / 50 / 60 Hz with functional earth.

Compliance

Electromagnetic compatibility EMC
IEC 60601-1-2, IEC 60601-2-24

Medical Device Directive
CE 0123 marking in compliance with the Concil Directive 93/42/EEC

Electrical Compliance
Protection against leakage current: Defibrillation-proof type CF Protection against electric shocks: class II in accordance with IEC 60601-1

Alarm system
IEC 60601-1-8

Usuability Engineering
IEC 60601-1-6 and IEC 62366

Wireless LAN (For Agilia SP TIVA WiFi only)

Technology
IEEE 802.11 a/b/g/n. Frequency Band: 2.400 -> 2.500 GHz (2.4 GHz is ISM band) / 4.900 -> 5.850 GHz (High Band).

Modulation
OFDM with BPSK, QPSK, 16-QAM, and 64-QAM 802.11b with CCK and DSSS.

Wireless Security
WPA/WPA2-Entreprise, WPA/WPA2-PSK.

Network Protocols
TCP, IPv4, DHCP, HTTP.
CE, FCC and IC compliant.

Agilia SP PCA WiFi

Infusion

Flow rate range
0.1 - 1200 mL/h, depending on the syringe capacity (0.1 mL/h increment).
Flow rate can be restricted for each drug (soft and hard limits) with Vigilant Master Med, The Dose Error Reduction Software.

Flow rate accuracy
+/- 1 % on mechanism : +/- 2 % on syringes.

Syringes capacities
5, 10, 20, 30/35, 50/60 CC.

Type of syringe
Up to 100 different types.

PCA Infusion modes

- PCA bolus mode
- Continuous rate mode
- PCA bolus + continuous mode
- PCA bolus + variable rates mode
- All programmable in dosing units (mcg, mg, mcg/kg, mg/kg) or in volume (mL).

PCA bolus
0 to 10 mL, 0 to 100 mg, 0 to 1000 mcg, 0 to 100 mcg/kg, 0 to 10 mg/kg.
rate from 40 to 1200 mL/h.

Lock out time
1 to 120 minutes.

Patient Handset
Ergonomic design, waterproof, with light, with handstrap, beep emission.

Clinician bolus
Available at start-up as a loading dose, available during the PCA cycle with a password.

Hardware & Software protection
Optional syringe protective cover with key lock, password required.

Cumulated limits
- Adjustable in 1, 2, 4, 12 or 24 h.
- In total dose given (in mL, or mg, or mg/kg, mcg, mcg/kg).
  and/or
- In number of PCA boluses given.

PCA history
- Follow-up from 1h to 24h.
- Total dose given.
- Number of PCA boluses attempted.
- Number of PCA boluses given.
- Number of clinician boluses.
- Background dose.

General Infusion Modes

- mL/h mode.
- Dose rate mode: ng/h, ng/kg/min, ng/kg/h, microg/min, microg/h, microg/kg/min, microg/kg/h, mg/min, mg/h, mg/24h, mg/kg/min, mg/kg/h, mg/kg/24h, g/m²/h, mg/m²/24h, g/h, g/kg/min, g/kg/h, g/kg/24h, mmol/h, mmol/kg/h, mmol/kg/24h, mU/min, mU/kg/min, mU/kg/h, U/min, U/h, U/kg/min, U/kg/h, kcal/h, kcal/24h, kcal/kg/h, mEq/min, mEq/kg/min, mEq/kg/h.
- Dilution setting: -- units / mL or -- units / -- mL.
  With or without loading dose.
- Volume or dose / time: 0.1 - 99.9 mL; 00 h 01 - 96 h 00.
- Volume limit: 0.1 - 999 mL.

Volume/Dose infused
Volume : 0.1 - 999 mL / Dose: 0.1 - 9999 units.

Priming
3 modes: mandatory, not mandatory, or advised / Rate: 1200 mL/h.

Bolus
Direct bolus: Rate: 50 - 1200 mL/h (50 mL/h increment)
Programmed bolus (dose or volume / time): 0.1 - 99.9 mL ; 0.1 - 9999 units / 1 min - 24 h.

Pause
Program from 1 minute to 24 hours with 1 minute increment.

Data log event
1500 data log events in real time.

Night mode
The night mode decreases the brightness of the screen and the green lights.
The key beep can eventually be turned off. The night mode can be programmed manually or automatically in a variable time range.

Profiles
Basic Profile: infusion without any display of the drug names and with PCA infusion modes. 19 Custom profiles configurable with Vigilant Master Med: Drug library to be created with up to 200 drugs.Drug list with a list of drug names.
Configuration only: Custom pump configuration without Drug Name.

Pressure management

Pressure modes
2 modes available: variable or 3 pre-set levels - Range from 50 to 900 mmHg (25 mmHg increment from 50 to 250 mmHg / 50 mmHg increment from 250 to 900 mmHg). Can be enabled / disabled and adjusted. Availability of PCA bolus.

DPS
The Dynamic Pressure System - DPS - warns of pressure variations.
A risk of obstruction or a possible leak in the infusion line can thus be anticipated.

Pressure monitoring
Graphic representation of the pressure in the infusion line and of the pressure limit thanks to the pictogram.

Anti-bolus system
Reduces significantly bolus after occlusion release : +/- 1 mL max for a 50 mL syringe.

Alarms / Pre-alarms / Security

Pump status
- GREEN for infusion in progress.
- ORANGE for Low and Medium priority.
- RED for High priority.
Visibility at 4 meters minimum. All alarms are expressed by means of light indicators, written words, pictograms and sound beeps.

Patient Handset status
When the pump is on (connected handset), a BLUE LED placed above the Bolus button lights up - Blinking light for PCA bolus request.

Syringes installation control
Protective cover check, syringe barrel clasp check, plunger head detection, anti-siphon system check, flange detection.

Infusion control
Occlusion pressure pre-alarm, occlusion pressure alarm, end of infusion pre-alarm, end of infusion alarm, volume limit pre-alarm, volume limit alarm, hard and soft flow rate limits, start infusion at pause end.

Device control
Disengaged driving mechanism alarm, low battery pre-alarm, discharged battery alarm, battery capacity display in hours and minutes, unconfirmed programming, technical malfunction alarm (auto-test, rotation), drive system advance check, watchdog check, communication connection failure, plug-head disengagement, auto-lock/lock code (on Keypad).

Patient Handset control
Patient handset not connected. Patient handset button continuously pressed. Patient bolus refused.

Maintenance
Preventive maintenance warning.

Technical specifications

Manual pusher
Protection for the ongoing infusion thanks to "Push-Guard" and the protective cover.

Display
Blue graphic LCD monochrome, size 66 mm x 33 mm(256 x 128 pixels).

Swinglock clamp
Versatile clamp that allows the fixation on a rail or on a pole, with locking mechanism allowing the pump to be permanently locked to the pole (Pole: 20-40 mm max. / Rail: 25-35 x 10 mm).

Stackability
Up to 3 devices self-stackable on a pole.

Pump dimensions (h/w/d) / weight
Without protective cover: 155 X 360 X 195 mm / ~ 2.5 kg
With protective cover: 155 X 360 X 210 mm / ~ 2.7 kg.

Patient Handset dimensions (h/w/d) / weight
Without cable: 20 X 35 X 115 mm / ~ 65 g /With cable: 20 X 35 X 1860 mm / ~ 65 g.

Battery
Characteristics: 7.2 V 2.2 Ah - Li-ion Smart battery, remaining battery life and battery charge level available on the display.
Battery Life (when fully charged):
WiFi disabled / not used: > 11 h at 5 mL/h - WiFi enabled: > 6 h at 5 mL/h
Battery recharge: Pump OFF: < 6 h - Pump ON: < 20 h

Waterproofness
Pump: IP22. ; Patient handset: IP67

Power supply
100 V - 240 V ~ / 50-60 Hz with functional earth.

Compliance

Electromagnetic compatibility EMC
IEC 60601-1-2, IEC 60601-2-24

Medical Device Directive
CE 0123 marking in compliance with the Concil Directive 93/42/EEC

Electrical Compliance
Protection against leakage current: Defibrillation-proof type CF Protection against electric shocks: class II in accordance with IEC 60601-1

Alarm system
IEC 60601-1-8

Usuability Engineering
IEC 60601-1-6 and IEC 62366

Wireless LAN

Technology
IEEE 802.11 a/b/g/n. Frequency Band: 2.400 -> 2.500 GHz (2.4 GHz is ISM band) / 4.900 -> 5.850 GHz (High Band).

Modulation
OFDM with BPSK, QPSK, 16-QAM, and 64-QAM 802.11b with CCK and DSSS.

Wireless Security
WPA/WPA2-Entreprise, WPA/WPA2-PSK.

Network Protocols
TCP, IPv4, DHCP, HTTP.
CE, FCC and IC compliant.

Agilia VP

Infusion

Flow rate range
0.1 - 1200 mL/h.
0.1 mL/h increment from 0.1 to 99.9 mL/h, 1 mL/h from 100 to 1200 mL/h.
Flow rate can be restricted (hard limits) with Vigilant Master Med, The Dose Error Reduction Software.

Flow rate accuracy
+/- 5 % and even better in most clinical situations.

Volume to infuse
0.1 - 9999 mL.

Infusion Modes
mL/h modes: Volume + Flow rate, Volume + Time, Flow rate + Time, Volume + Time + Rate.

Times of infusion
0 h 01 min - 168 h 00 min.
Warning function: a warning message can be activated and adjusted from 0 h 01 min to 96h00min.

Priming
Manual or by using the purge/prime function of the pump.

Bolus
Direct bolus: adjustable.
50 - 1200 mL/h (50 mL/h increment).

KVO
Automatic Keep Vein Open rate of 1 mL/h (adjustable from 1 to 20 mL/h) when volume limit is reached.

Pause
Programmable from 1 minute to 24 hours, increments 1 minute.

Data log event
Up to 1500 data log events in real time.

Graphical history
flow rates, pressure.

Night mode
The night mode decreases the brightness of the screen and the green lights.
The key beep can be optionally turned off.
The night mode can be programmed manually or automatically in a variable time range.

Profiles
Basic Profile: infusion without any display of the drug names.
1 custom profile configurable with Vigilant Master Med.
Drug list with a list of drug names.
Configuration only: custom pump configuration without drug name.

Volumat lines administration sets

Free-flow protection
All sets integrate the SafeClip* that automatically clamps the line to avoid any risk of free-flow when the door is opened and when the set is disengaged.

Auto-test function: The patented** OCS (Occlusivity Check System) checks the correct working order of the pump in association with its tubing set, thus preventing any risk of free-flow.

* French Patent FR2908176 / ** European Patent EP1031358

Pumping segment
The silicone pumping segment allows a tight flow rate accuracy as well as long term performances.

Material
All Volumat Lines infusion sets are DEHP-free & Latex-free.
PVC-free and opaque materials are available.

Needle-free access
Some sets integrate a needle-free Y injection site to protect the medical staff against the risk of needle-stick injuries.

Pressure management

Pressure modes
2 modes available: variable or 3 pre-set levels - Range from 50 to 750 mmHg.
(25 mmHg increment from 50 to 250 mmHg / 50 mmHg increment from 250 to 750 mmHg).

DPS
The Dynamic Pressure System - DPS - warns of pressure variations.
A risk of obstruction or a possible leak in the infusion line can thus be anticipated.

Pressure monitoring
Graphic representation of the pressure in the infusion line and of the pressure limit thanks to the pictogram.

Anti-bolus system
Reduces significantly bolus after occlusion release (0.35 mL max.).

Alarms / Pre-alarms / Security

Pump status
- GREEN for infusion in progress.
- ORANGE for Low and Medium priority.
- RED for High priority
Visibility at 4 meters minimum.
All alarms are expressed by means of light indicators, written words, pictograms and sound beeps.

Set installation control
Door's closing, set positioning, SafeClip control, OCS test.

Infusion control
End of infusion, imminent end of infusion, downstream occlusion, upstream occlusion, line disconnection, air in line, under flow rate, over flow rate, empty container, unconfirmed setting, end of pause, unauthorised flow rate (hard or soft), auto restart if false occlusion detected, start infusion at pause end.

Device control
Motor rotation check, power source indication, mains power disconnection, low battery, discharged battery, technical fault, watchdog check, communication connection failure, auto-lock/lock code (on Keypad).

Maintenance
Preventive maintenance warning.

Technical specifications

Pumping mechanism
2nd generation linear peristaltic pumping system with software adjustments and compensations.

Display
Blue graphic LCD monochrome, size 66 mm x 33 mm.
(256 x 128 pixels).

Swinglock clamp
Versatile clamp that allows the fixation on a rail or a pole.
(Pole: 20-40 mm max. / Rail: 25-35 x 10 mm)

Stackability
Up to 3 devices self-stackable on a pole.

Dimensions (H/W/D) / Weight
135 x 190 x 170 mm / Approximately 2kg.

Battery
Characteristics: 7.2 V 2.2 Ah - Li-ion Smart battery, remaining battery life and battery charge level available on the display.

Battery Life (when fully charged):
> 8 h at 25 mL/h
> 5 h at 1200 mL/h

Battery recharge:
- Pump OFF: < 6 h
- Pump ON: < 20 h

Waterproofness
IP22

Power supply
100 V - 240 V ~ / 50 / 60 Hz with functional earth.

Compliance

Electromagnetic compatibility EMC
IEC 60601-1-2, IEC 60601-2-24

Medical Device Directive
CE 0123 marking in compliance with the Concil Directive 93/42/EEC

Electrical Compliance
Protection against leakage current: Defibrillation-proof type CF Protection against electric shocks: class II in accordance with IEC 60601-1

Alarm system
IEC 60601-1-8

Home healthcare Environment
IEC 60601-1-11

Usuability Engineering
IEC 60601-1-6 and 62366

Agilia VP MC & Agilia VP MC WiFi

Infusion

Flow rate range
0.1 - 1500 mL/h.
0.1 mL/h increment from 0.1 to 99.9 mL/h (optionally 0.01 mL/h from 0.1 to 9.99mL/h), 1 mL/h from 100 to 1500 mL/h.
Flow rate can be restricted for each drug (soft and hard limits) with Vigilant Master Med, The Dose Error Reduction Software.

Flow rate accuracy
+/- 5 % and even better in most clinical situations.

Volume to infuse
0.1 - 9999 mL.

Infusion Modes
- mL/h modes: Volume + Flow rate, Volume + Time, Flow rate + Time, Volume + Time + Rate, Ramp-up / Ramp down, Sequential / Intermittent, Secondary / Piggyback, Drop/min.
- Dose rate modes: ng/h, ng/kg/min, ng/kg/h, microg/min, microg/h, microg/kg/min, microg/kg/h, mg/min, mg/h, mg/24h, mg/kg/min, mg/kg/h, mg/kg/24h, mg/m²/h, mg/m²/24h, g/h, g/kg/min, g/kg/h, g/kg/24h, mmol/h, mmol/kg/h, mmol/kg/24h, mU/min, mU/kg/min, mU/kg/h, U/min, U/h, U/kg/min, U/kg/h, kcal/h, kcal/min, kcal/24h, kcal/kg/h, mEq/min, mEq/h, mEq/kg/min, mEq/kg/h.
- Dilution setting: -- units / mL or -- units / -- mL. With or without loading dose.

Times of infusion
0h01min - 168h00min.
Warning function: a warning message can be activated and adjusted from 0h01min to 96h00min.

Priming
Manual or by using the purge/prime function of the pump.

Loading Dose
0.1 - 1500 mL/h.
0.10 - 9.99 mL/h: 0.01 mL/h increment.
10.0 - 99.9 mL/h: 0.1 mL/h increment.
100 - 1500 mL/h: 1 mL/h increment.

Bolus
- Direct bolus: Rate : 50 - 1500 mL/h (50 mL/h increment).
- Programmed bolus (Dose or volume / time): 0.1 - 1000 mL 0,01 - 9999 unit / 1 second - 24 h.

KVO
Automatic Keep Vein Open rate of 1 mL/h (adjustable from 1 to 20 mL/h) when volume limit is reached.

Pause
Programmable from 1 minute to 24 hours, increments 1 minute.

Data logo event
Up to 1500 data log events in real time.

Graphical history
Flow rates, pressure.

Night mode
The night mode decreases the brightness of the screen and the green lights. The key beep can optionally be turned off.
The night mode can be programmed manually or automatically in a variable time range.

Profiles
Basic Profile: infusion without any display of the drug names.
19 Custom profiles configurable with Vigilant Master Med: Drug library to be created with up to 200 drugs.
Drug list with a list of drug names.
Configuration only: Custom pump configuration without Drug Name.

Volumat lines administration sets

Free-flow protection
All sets integrate the SafeClip* that automatically clamps the line to avoid any risk of free-flow when the door is opened and when the set is disengaged.
Auto-test function: The patented** OCS (Occlusivity Check System) checks the correct working order of the pump in association with its tubing set, thus preventing any risk of free-flow.
* French Patent FR2908176 / ** European Patent EP1031358

Pumping segment
The silicone pumping segment allows a tight flow rate accuracy as well as long term performances.

Material
All Volumat Lines infusion sets are DEHP-free & Latex-free.
PVC-free and opaque materials are available.

Needle-free access
Some sets integrate a needle-free Y injection site to protect the medical staff against the risk of needle-stick injuries.

Pressure management

Pressure modes
2 modes available: variable or 3 pre-set levels - Range from 50 to 750 mmHg. (25 mmHg increment from 50 to 250 mmHg / 50 mmHg increment from 250 to 750 mmHg).

DPS
The Dynamic Pressure System - DPS - warns of pressure variations.
A risk of obstruction or a possible leak in the infusion line can thus be anticipated.

Pressure monitoring
Graphic representation of the pressure in the infusion line and of the pressure limit thanks to the pictogram.

Anti-bolus system
Reduces significantly bolus after occlusion release (0.35 mL max.).

Alarms / Pre-alarms / Security

Pump status
- GREEN for infusion in progress.
- ORANGE for Low and Medium priority,
- RED for High priority
Visibility at 4 meters minimum.
All alarms are expressed by means of light indicators, written words, pictograms and sound beeps.

Set installation control
Door's closing, set positioning, SafeClip control, OCS test.

Infusion control
End of infusion, imminent end of infusion, downstream occlusion, upstream occlusion, line disconnection, air in line, under flow rate, over flow rate, empty container, unconfirmed setting, end of pause, unauthorised flow rate (hard or soft), keypad manual locking or keypad autolock, autorestart if false occlusion detected, start infusion at pause end.

Device control
Motor rotation check, power source indication, mains power disconnection, low battery, discharged battery, technical fault, watchdog check, communication connection failure, auto-lock/lock code (on Keypad).

Maintenance
Preventive maintenance warning.

Technical specifications

Pumping mechanism
2nd generation linear peristaltic pumping system with software adjustments and compensations.

Display
Blue graphic LCD monochrome, size 66 mm x 33 mm (256 x 128 pixels).

Swinglock clamp
Versatile clamp that allows the fixation on a rail or a pole (Pole: 20-40 mm max. / Rail: 25-35 x 10 mm)

Stackability
Up to 3 devices self-stackable on a pole.

Dimensions (H/W/D) / Weight
135 x 190 x 170 mm / Approximately 2kg.

Battery
Characteristics: 7.2 V 2.2 Ah - Li-ion Smart battery, remaining battery life and battery charge level available on the display.

Battery Life (when fully charged):
- Agilia VP MC and Agilia VP MC WiFi (WiFi disabled / not used): > 8 h at 25 mL/h. > 5 h at 1500 mL/h
- Agilia VP MC WiFi (WiFi enabled): > 5 h at 25 mL/h. > 4 h at 1500 mL/h

Battery recharge: Pump OFF: < 6 h . Pump ON: < 20 h

Waterproofness
IP22

Power supply
100 V - 240 V ~ / 50 / 60 Hz with functional earth.

Compliance

Electromagnetic compatibility EMC
IEC 60601-1-2, IEC 60601-2-24

Medical Device Directive
CE 0123 marking in compliance with the Concil Directive 93/42/EEC

Electrical Compliance
Protection against leakage current: Defibrillation-proof type CF Protection against electric shocks: class II in accordance with IEC 60601-1

Alarm system
IEC 60601-1-8

Home healthcare Environment
IEC 60601-1-11

Usuability Engineering
IEC 60601-1-6 and IEC 62366

Wireless LAN (For Agilia VP MC WiFi only)

Technology
IEEE 802.11 a/b/g/n.
Frequency Band: 2.400 -> 2.500 GHz (2.4 GHz is ISM band) / 4.900 -> 5.850 GHz (High Band).

Modulation
OFDM with BPSK, QPSK, 16-QAM, and 64-QAM 802.11b with CCK and DSSS.

Wireless Security
WPA/WPA2-Entreprise, WPA/WPA2-PSK.

Network Protocol
TCP, IPv4, DHCP, HTTP.
CE, FCC and IC compliant.

Agilia Link 4, 6, 8

Dimensions - Weight

Agilia Link 4
Dimensions (H/W/D): 718 mm (28.27 in) x 203 mm (7.99 in) x 121 mm (4.76 in)
Weight: 4 kg (8.82 lb).

Agilia Link 6
Dimensions (H/W/D): 1004 mm (39.53 in) x 203 mm (7.99 in) x 121 mm (4.76 in)
Weight: 5.2 kg (11.46 lb).

Agilia Link 8
Dimensions (H/W/D): 1290 mm (50.79 in) x 203 mm (7.99 in) x 121 mm (4.76 in)
Weight: 6.09 kg (15.21 lb).

Mains power input specifications

Function
Primary power source for Agilia power outlets.

Connector
Standard line outlet IEC type C14 - male - 3 poles.

Power supply
100 V to 240 V AC / 50 / 60 Hz.

Maximum power (with pumps)
Agilia Link 4: 60 VA.
Agilia Link 6: 90 VA.
Agilia Link 8: 120 VA.

Protective fuses
2 fuses, 2 A timed with high breaking capacity - T 2A H 250 V Fuseholder is externally accessible on AC power inlet connector.

Electric protection
Class I with protective earth, with 3-wire power cord.

Agilia pump power output specifications

Function
Power source output for Agilia infusion pumps.

Connector
Standard line outlet IEC type C13 - female - 3 poles.

Power supply
100 V to 240 V AC / 50 / 60 Hz.

Maximum Power
15 VA per outlet.

Protective fuses
Report to AC power input fuses.

ON/OFF power
No power on empty position - Earth pole is functional earth only.

Mechanical Specifications for locking clamps

Pole
Diameter: from 16 to 42 mm.

Rail
Height: from 16 to 42 mm / Depth: 10 mm max.

Compliance With Standards

CE
Complies with the 93/42/CEE Medical directive.

Safety of electromedical equipments:
• Complies with EN/IEC 60601-1.
• IP22 protection against dust and splashing liquid.
• Protection against leakage current; type B applied part.
• Class I with protective earth.
Agilia power outlets are wired on internal functional earth which is connected to the functional earth terminal. In order to reduce residual current that may disturb ECG or EEG device, this terminal shall be connected to the hospital infrastructure using the specific cable accessory.

EMC (electromagnetic compatibility)
Complies with EN/IEC 60601-1-2.

Link+ Agilia 4, 6, 8

Data communication connector

1. Infrared (IR) connector specifications
Function: Data communication with the Agilia IV infusion pumps.
Mode: Wireless optical communication using infrared light.
Compatibility: Asynchronous Serial Infrared (SIR) physical layer irPHY 1.0, baseband no carrier.
Transport protocol: Proprietary.
Speed: 115.2 kb/s max.
Wavelength: 880 nm to 900 nm infrared band with 45 nm spectral bandwidth.
Eyes safety: < 500 mW/sr maximum intensity for class 1 of IEC/EN 60625-1 - January 2001.

2. USB PC connector specifications
Function: External PC connection for maintenance and configuration.
Connector: External standard Mini B slave connector.
Indicator: External standard Mini B slave connector.
Output power: No power output available and remote host power not used.
Compatibility: USB 2.0 OTG Slave role only.
Insulation: Not insulated from USB external device, but provides double insulation (4 kV) from mains.
Speed: 480 Mb/s max. (theoretical).

3. RS232 serial communication connector specifications
Function: System management, PC, PDMS, or maintenance connection.
Connector: ADAM TECH shielded circular female connector, 3 pins.
Indicator: Blue LED.
Compatibility: RS232 levels, serial asynchronous, half duplex.
Insulation: 1.5 kV insulation from external system + provides double insulation (4 kV) from mains.
Speed: 115.2 kb/s max. (theoretical).

4. Wired network connector specifications
Function: System management, PC, or maintenance connection.
Connector: RJ45 8 pins.
Indicator: Blue LED.
Compatibility: IEEE 802.3 Ethernet 10baseT or fast Ethernet 100baseT, twisted pairs, Full duplex.
Insulation: 1.5 kV insulation from external system + provides double insulation (4 kV) from mains.
Speed: Automatic speed selection 10 Mb/s or 100 Mb/s (theoretical).

5. Nurse call connector specifications
Function: Data processing and communications.
Processor: 32 bits, 400 MHz.
Central memory: 64 Mbytes, high speed RAM 266 MHz.
Flash memory: Non volatile 256 Mbytes.
Operating system: Safety and flexible multitasking / multithreading operating system with GPL license.

User interface specifications

Pump centralization display
Function: displays infusion pump alarms and pre-alarms.
Size: 70 mm x 30 mm - Type: LED
Viewing angle: 360° @ 4 meters.
Color: RED (pump alarms - high priority) / YELLOW (pump pre-alarms - Medium and low priority) / RED and YELLOW (maintenance mode).

Main status indicator
Function: displays main connected status - Type: LED - Color: GREEN.

Battery status indicator
Function: displays Link+ Agilia battery status and alarm
Type: LED - Color: GREEN / YELLOW / RED.

Reset button
Function: reboots Link+ Agilia internal software
Type: protected push button.

Battery specifications

Function
Backup battery for mains power failures and transport of the rack.

Access
Internal battery holder accessible with specific tools by qualified engineer.

Characteristics
7.2 V / 2.2 Ah - Lithium Ion rechargeable battery.

Battery autonomy
1 H min.

Self protections
Over-current, over-discharge, over-voltage and overtemperature.

Battery life
Preventive replacement after 3 years.

Mains power input specifications

Function
Primary power source for Agilia power outlets and for internal electronics Link+ Agilia.

Connector
Standard appliance inlet IEC type C14 - male - 3 poles.

Power supply
100 V to 240 V AC / 50 - 60 Hz.

Maximum power (with pumps)
· Link+ Agilia 4: 75 VA.
· Link+ Agilia 6: 105 VA.
· Link+ Agilia 8: 135 VA.

Protective fuses
2 fuses, 2 A timed with high breaking capacity - T 2A H 250 V. Fuseholder is externally accessible on mains power inlet connector.

Electric protection
Class I with protective earth, with 3-wire power cord.

Agilia pump power output specifications

Function
Power source output for Agilia infusion pumps.

Connector
Standard line outlet IEC type C13 - female - 3 poles.

Power supply
100 V to 240 V AC / 50 - 60 Hz.

Maximum power
15 VA per outlet.

Protective fuses
Report to mains power input fuses.

On/Off power
No power on empty position - Earth pole is functional earth only.

Dimensions - Weight

Link+ Agilia 4
Dimensions (H/W/D): 720 mm (28.35 in) x 195 mm (7.68 in) x 163 mm (6.42 in)
Weight 4.1 kg (9.04 lb).

Link+ Agilia 6
Dimensions (H/W/D): 1010 mm (39.76 in) x 195 mm (7.68 in) x 163 mm (6.42 in)
Weight 5.2 kg (11.46 lb).

Link+ Agilia 8
Dimensions (H/W/D): 1290 mm (50.79 in) x 195 mm (7.68 in) x 163 mm (6.42 in)
Weight 6.4 kg (14.11 lb).

Mechanical Specifications for locking clamps

Pole
Diameter: from 16 to 42 mm.

Rail
Height: from 16 to 42 mm / Depth: 10 mm max.

Compliance

CE
Complies with the 93/42/CEE Medical directive

Safety of electromedical equipments
· Complies with EN/IEC 60601-1.
· IP22 protection against dust and splashing liquid.
· Protection against leakage current; type B applied part.
· Class I with protective earth.
Agilia power outlets are wired on internal functional earth which is connected to the functional earth terminal. In order to reduce residual current that may disturb ECG or EEG device, this terminal shall be connected to the hospital infrastructure using the validated Fresenius cable accessory.

EMC (electromagnetic compatibility)
Complies with EN/IEC 60601-1-2.

Centerium
Vigilant Insight & Vigilant Bridge

Vigilant Insight and Vigilant Bridge are applications hosted in Centerium version 2.0

Hardware Requirements

The 1 hardware requirements for Centerium are dependent on the number of pumps used, as more powerful hardware is needed when Centerium is used with a large number of pumps. Centerium was validated against the following host computer requirements:

Number of devices	Up to 250 pumps	Up to 500 pumps	Up to 1000 pumps	Up to 3000 pumps	Up to 4500 pumps
Configuration	1-tier*	2-tier**	2-tier**	2-tier**	2-tier***

Centerium Application Server

Number of devices	Up to 250 pumps	Up to 500 pumps	Up to 1000 pumps	Up to 3000 pumps	Up to 4500 pumps
Processor/Nb of cores@Min. Freq.	Xeon E5/4@2,1GHz	Xeon E5/4@2,1GHz	Xeon E5/8@2,1GHz	Xeon E5/8@2,1GHz	Xeon E5/8@2,1GHz
Total Physical Memory	8	8	16	32	32
Disk Size (GB)	1000	200	200	200	200
NIC	IEEE 802.3 10/100/1000 Mbps card				

Centerium DataBase Server

Number of devices	Up to 250 pumps	Up to 500 pumps	Up to 1000 pumps	Up to 3000 pumps	Up to 4500 pumps
Processor/Nb of cores@Min. Freq.		Xeon E5/4@2,1GHz	Xeon E5/8@2,1GHz	Xeon E5/8@2,1GHz	Xeon E5/16@2,1GHz
Total Physical Memory	na	8	32	64	64
Disk Size (GB)		1000	1000	1000	1000
NIC	IEEE 802.3 10/100/1000 Mbps card				

Supported Operating Systems:
- Microsoft Windows Server 2012 Standard
- Microsoft Windows Server 2012 R2
- Microsoft Windows Server 2016 Standard

Supported SQL Server versions:
- SQL Server 2012 Standard or Business Intelligence or Enterprise Edition.
- SQL Server 2016 Standard or Enterprise Edition.

*   1 physical or virtual server supports both Centerium application & database.
** 2 physical or virtual servers are needed, at minimum: 1 dedicated server for Centerium application & 1 dedicated server for Centerium database.
*** 3 physical or virtual servers are needed, at minimum: 2 dedicated servers for 2 distinct Centerium application instances
    (max. pumps supported is 3000 on one Centerium application) and 1 dedicated server for Centerium Database (max. pumps supported is 4500 on one Centerium database).

	Windows Server 2016	Windows Server 2012	Windows Server 2012 R2	Windows Versions other than specified
SQL Server 2016 Standard	Validated	Validated	Not Validated*	Not Supported**
SQL Server 2012	Not Validated*	Validated	Validated	Not Supported**
SQL Server (Releases other than 2016 and 2012)	Not Supported**	Not Supported**	Not Supported**	Not Supported**

*   The installer will display a message stating that the version has not been validated. Use with other versions must be validated prior to use.
** The Centerium Installer enforces usage for specified versions; use with other versions will be prevented by the installer.

Security requirements

Centerium software must be protected with an up-to-date virus scanner.

Vigilant Bridge

Product characteristics

Features: allows auto-documentation with PDMS/EMR using:
- HL7 V2: 6 messages
- IHE Patient Care Device (PCD) Technical Framework
- With Device Enterprise Communication (DEC) profile
- With Infusion Pump Event Communication (IPEC) profile

Link+ Agilia rack communicates with Centerium over the hospital 802.3 based intranet.

Language: English.

Hardware requirements

Vigilant Bridge software must be installed on the same server as Centerium Data Management Solution.

Please refer to Centerium data sheet for Software requirements, adding for Vigilant Bridge:

Software requirements

Vigilant Bridge software must be installed on the same server as Centerium Data Management Solution.

- OpenVPN server version 2.3.6
- Visual C++ Redistribuable package for Visual Studio 2012 Update 4, 64 bit
- Python programming language version 2.6.5

All these software: Redistributable Package are installed automatically during software installation.

Connected devices requirements

Vigilant Bridge software is compatible with the following devices:
- Link 4+ Agilia (4 pump slots) with firmware version 3.0
- Link 6+ Agilia (6 pump slots) with firmware version 3.0
- Link 8+ Agilia (8 pump slots) with firmware version 3.0
  And
- All Agilia Connect VP pumps with firmware version 1.4 and 2.2.c
- All Agilia Connect SP pumps with firmware version 1.6, 1.6a and 2.2

Pumps must be connected through a Link+ Agilia.
A maximum of 100 Link+ can be connected simultaneously.

- Centerium 1.0b and 1.0c.

Cable requirements

- Ethernet RJ45 cable. Category 5e minimum.

Security requirements

Vigilant Bridge software must be installed on the same server as Centerium Data Management Solution.

Please refer to Centerium Administrator's Guide for Security requirements.

Storage area requirements

Vigilant Bridge software must be installed on the same server as Centerium Data Management Solution.

Please refer to Centerium for Hardware and Software requirements.

Vigilant Master Med

Supports two types of deployment models

Deployment model	Description
Single tier	Both Vigilant Master Med and the application database management system (DBMS) are installed on the same host computer.
Multi-tier	Vigilant Master Med and its DBMS are installed on separate host computers.

Hardware Requirements

			2-Tier	
			Database Server	
	1-Tier	Application server	Microsoft SQL Server Standard Edition	Microsoft SQL Server Express Edition
Core	4	4	4	4
Processor	3 GHz	3 GHz	3 GHz	3 GHz
Memory	16 GB	16 GB	16 GB	8 GB
Disk size	1 tb	100 GB	1 tb	500 GB
Network Interface Card	IEEE 802.3 10/ 100 /1000 Mbps card	IEEE 802.3 10/ 100/ 1000 Mbps card	IEEE 802.3 10/ 100/ 1000 Mbps card	IEEE 802.3 10/ 100/ 1000 Mbps card

Microsoft® Visual C++ 2012 Redistributable Package (x86 or x64): 25 MB[1].
Microsoft® .Net Framework 4.5: 850 MB[1].
Vigilant Master Med software: < 80 MB.
- Display with minimum resolution 1280x720.
- USB port to communicate with the pump.
- Ethernet port to communicate with the Centerium server.
- DVD-Rom drive.

[1] Microsoft® .Net framework version 4.5 and Microsoft® Visual C++ 2012 Redistributable Package are installed automatically during software installation. Please refer to "Administrator's Guide" document for additional information.

Cable Requirements

Agilia USB cable.

Computer Software Requirements

Operating system	SQL server platform
• Windows 7 Entreprise SP1 (64-bit) • Windows 10 Entreprise (64-bit) • Windows Server 2012 R2 Standard (64-bit) • Windows Server 2016 Standard (64-bit)	• Microsoft SQL Server 2012 Service Pack 4 (SP4) • Microsoft SQL Server 2012 (SP4) Express • Microsoft SQL Server 2016 Service Pack 1 (SP1) • Microsoft SQL Server 2016 (SP1) Express

Adobe® Acrobat reader version 11 or above.

Internet Information Services (IIS)

Vigilant Master Med requires one of the following version of IIS, dependent on the operating system:

Operating system	IIS version
Windows 7	7.5
Windows 10	10.0
Windows Server 2012	8.5
Windows Server 2016	10.0

Connected Devices Requirements

Vigilant Master Med software is compatible with the following devices:
- Agilia VP, Agilia VP MC and Agilia VP MC WiFi Volumetric Infusion Pumps with software version 2.2 or above.
- Agilia SP, Agilia SP MC and Agilia SP MC WiFi Syringe Infusion Pumps with software version 2.2 or above.
- Agilia SP TIVA and Agilia SP TIVA WiFi Syringe Infusion Pumps with software version 2.2 or above.
- Agilia SP PCA WiFi Syringe Infusion Pump with software version 3.1 or above.
- Centerium 2.0 or above.

NET framework

Vigilant Master Med requires the following framework to be installed on the system:
- Microsoft .NET 3.5 Framework
- Microsoft .NET 4.5 Framework (or higher)

Security Requirements

Vigilant Master Med software must be protected with an up-to-date virus scanner and firewall.

Vigilant Master Med software should be configured to support user authentification as described in the "Administrator's Guide" document.

Web browsers

Vigilant Master Med is compatible with the following web browsers:
- Internet Explorer 11
- Google Chrome

Vigilant Sentinel

Product characteristics

Features: Aggregated view at the ward level, detailed views at the bedside level and empty container view.

Scalability: 24 beds, 2 links per bed, 384 pumps.

Languages: English, Spanish, German, French, Dutch, Italian, Czech, Slovak, Brazilian Portuguese, Bahasa, Polish, Hungarian, European Portuguese.

Hardware requirements

Computer requirements: Desktop PC mandatory, no laptop allowed.

Display requirements: Display with resolution 1920 x 1080.
Minimum recommended size 24 inches.
Possibility to use touchscreen or mouse.

Cable requirements: Ethernet RJ45 cable: category 5e minimum.

Computer software requirements

Microsoft Windows 8.1, 64 bits.
Microsoft Windows 10, 64 bits.
.Net framework version 4.6.2 and Microsoft® Visual C++ 2015
Redistributable Package are installed automatically during software installation.
Adobe Acrobat Reader.
Please refer to software Installation Instructions for additional information.

Connected devices requirements

Vigilant Sentinel software is compatible with the following devices:
- Volumat standard with firmware version equal to 1.2e
- Volumat MC with firmware version equal to 2.3f
- Injectomat standard with firmware version equal to 2.5g
- Injectomat MC and TIVA with firmware version equal to 4.3h
- All VP pumps with firmware version 1.4 and later versions up to and including 2.2.x
- All SP pumps with firmware version 1.6a and later versions up to and including 2.2.x
- Link+ 4 (4 pump slots) with firmware version 3.0
- Link+ 6 (6 pump slots) with firmware version 3.0
- Link+ 8 (8 pump slots) with firmware version 3.0

Security requirements

Vigilant Sentinel software must be protected with an up-to-date virus scanner.
Vigilant Sentinel software must be configured to support user authentication as described in the software Installation Instructions.

Storage area requirements

A storage area must be available and allocated with the following specifications:
Data volume: 50 MB.

Delivery Media

CD-ROM including software and product documentation in electronic and printed form.
Key 2 download site at https://key2.fresenius-kabi.com

Agilia Partner

Hardware Requirements

Processor Core i3 2GHz or above.
Memory of 4 GB RAM.
5 GB free space on the hard drive to install:
Microsoft® Visual C++ 2012 Package (x86 or x64): 25 MB.
Microsoft® .Net Framework 4.5: 850 MB.
- Agilia Parner software: < 200 MB.Display with minimum resolution 1280x720.
- USB port to communicate with the pump or on the Link+.
- Network connecteur to communicate with the Centerium server.
- CD-Rom drive.

Microsoft® .Net framework version 4.5 and Microsoft® Visual C++ 2012 Redistributable Package are installed automatically during software installation. Please refer to "Software installation instructions" document for additional information.

Cable Requirements

- Agilia USB cable.
- With Link+, mini USB cable.

Computer Software Requirements

Microsoft® Windows 7, 32 and 64 bit version with Service Pack 1 or above.Adobe® Acrobat reader version 11 or above.

Connected Devices Requirements

Agilia Partner software 3.0 is compatible with the following:
- Agilia VP Volumetric Infusion Pump with software version 1.3 or above.
- Agilia SP Syringe Infusion Pump with software version 1.5 or above.
- Agilia SP PCA Advanced Syringe Infusion Pumps for Patient Controlled Analgesia (PCA) with software version 3.1 or above.
- Link+ 3.0 (a.k.a. D14) or above.
- Centerium 1.0 or above.

Security Requirements

Agilia Partner software must be protected with an up-to-date virus scanner and firewall.
Agilia Partner software should be configured to support user authentification as described in the "Software installation instructions" document.

Storage Area Requirements

A storage area must be available and allocated according to the following specifications: Database volume: 100 MB per pump.

Notes

Accessories

Rolling Stand

The Infusion Pump Rolling Stand is designed to accommodate from 1 up to 3 Agilia pumps. to a maximum weight load of 6.8 kg.

It benefits from a telescopic bar with four robust plastic hooks on top, on which the infusion bags can be hanged (up to 4 bags, 2 kg each).

It is mounted on 5 wheels, all of them have brakes, and there is an adjustable handle on the central bar.

Medical device classification: class I

Multi-Channel Rolling Stand

The Multi-Channel Rolling Stand is designed to attach a Link Agilia rack.

Its central bar is situated at the back and allows positioning the pumps so that the centre of gravity of the system is in the middle of the rolling stand.

There are 6 hooks (3 different heights) available on the top of the telescopic bar allowing to hang up to 6 infusion bags (6kg maximum in total).

Medical device classification: class I

Twin Link Rolling Stand

The Twin Link Rolling Stand is a big robust accessory with two poles designed to attach two Link Agilia Racks with their respective Agilia pumps. Each pole can support a set of IV pumps, including Agilia Link 8 with 8 Agilia pumps.

The rolling stand is mounted on a telescopic bar with 6 hooks on top, each one can support up to 2 kg.

Medical device classification: class I

Foldable handle

The Handle is an optional accessory to the Multi-Channel Rolling Stand that helps transporting it from one place to another.

Medical device classification: class I

Tray

The Tray is an optional accessory to the Multi-Channel Rolling Stand that allows laying small items (syringe, bag, line...) needed for handling or preparing the infusion. It is not designed to carry any pump.

Medical device classification: class I

U-support

The U-support is an accessory to the Multi-Channel Rolling Stand that can be attached to it thanks to a screwable handle. It can be used to attach small lightweight medical devices (4 kg maximum on each side) like an enteral feeding pump (Amika) or a CVP device (Central Venous Pressure).

Medical device classification: class I

Duo Agilia

The Agilia Duo is a device to be attached to two Agilia pumps connected in tandem, allowing to power them by using only one single power cable.

GMDN classification: 42498

Medical device classification: I

Holder for Ambulance

The Agilia Holder for Ambulance is a medical device intended to be used in road ambulances equipped with AC power source and a horizontal rail in order to fix one Agilia IV pump.

Agilia Holder for Ambulance is designed to be used only on ISO 19054:2005 rails.

Medical device classification: class 1

Drop sensor

The Drop sensor is an optional device that can be used with the Agilia VP and Agilia VP MC pumps and placed around the drip chamber of the Volumat Lines. All drops falling inside the drip chamber are detected and counted.

Medical device classification: class IIb

Agilia USB cable

USB port to be connected to a PC / «Binder » port to be plugged to the back of the Agilia pump.

GMDN classification: 47487

Medical device classification: class I

Link+ Agilia RS232 cable

RS232 port to be connected to a PC / connector to be plugged to the RS232 port of the Agilia Link.

GMDN classification: 47487

Medical device classification: class I

Link+ Agilia Nurse Call cable

Cable to be connected to the nurse call system of the hospital / connector to be plugged to the nurse call port of the Agilia Link.

GMDN classification: 47487

Medical device classification: class I

Notes

Notes

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Customer contact