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Agilia® Infusion System Large Volume Pump with **Vigilant Drug'Lib**® Software

Implementation Guide

Agilia Infusion System
Large Volume Pump with **Vigilant Drug'Lib** Software
Implementation Guide

The Agilia Infusion System Large Volume Pump packs all essentials into a small, lightweight, portable device with a clinician-friendly interface and infusion sets that adapt to the facility workflow.

This implementation guide will serve as a resource as the Agilia Infusion System Large Volume Pump is integrated into the clinical environment. The implementation is comprised of 4 main phases:

- ☐ Planning
- ☐ Education
- ☐ Go-Live
- ☐ Post-implementation

It is recommended that the implementation planning begin 6-8 weeks before the actual implementation. During this time, the facility team will be supported by Fresenius Kabi Clinical Implementation Team and various resources to assist with the adoption of the technology. Fresenius Kabi is committed to a successful integration of the Agilia Infusion System Large Volume Pump into your organization. The first step is to identify the members of your implementation team.

Facility Team

A successful implementation will be the result of the combined talent of the multi-disciplinary facility team and the Fresenius Kabi Clinical Implementation Team. The Fresenius Kabi Clinical Implementation Team will consist of nurses, pharmacists, account executives and certified technicians.

Executive Sponsor:

- Supports the team by ensuring the allocation of resources, personnel and time

Project Manager:

Schedules/coordinates meetings and personnel to collaborate with Fresenius Kabi Clinical Implementation Team

- Liaises between the facility and the Fresenius Kabi team
- Manages project timelines
- Allocates resources and personnel to support Go-Live
- Conducts joint review of implementation and determines next steps

Hospital Supply Management:

- Plans disposable logistics, including evaluation of inventory levels and stocking requirements

Refer to the product Operator's Manual and/or Instructions For Use for a complete list of warnings and precautions associated with the device.

Facility Pharmacist:

- Advises regarding IV medication administration
- Leads development of customized drug parameters/data set; validates data entry; Vigilant Drug'Lib Software user testing/end-user verification; final data set approval

Facility Clinical Educator(s)/Care Area Representatives:

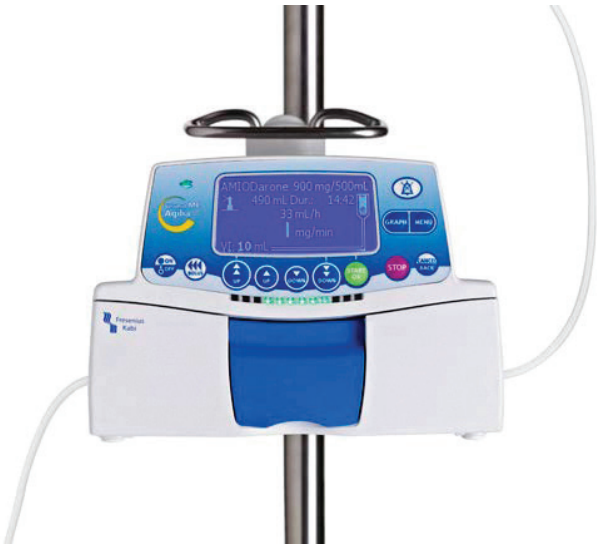
- Details IV practice needs for the facility and matches facility needs with the Agilia Infusion System Large Volume Pump
- Serves as consultant regarding pump configuration settings and options
- Performs end-user verification of drug library
- Coordinates/schedules clinical education
- Identifies Train the Trainer/Super-User participants
- Staffs and supports hands-on training sessions
- Coordinates pump and tubing change out
- Supplements training as needed

"Super-Users":

Super-Users support the education process and are in-house resources to the staff. This group will also contain the Train the Trainer personnel who will ensure that new staff receive appropriate education before using the Agilia Infusion System Large Volume Pump.

Facility Biomed Engineering:

- Provides work space for the Fresenius Kabi technical team
- Coordinates training with the Fresenius Kabi Technical Service team on data set upload procedure including necessary knowledge and skills for data set uploads now and in the future
- Records inventory
- Assists with staging and mobilization of pumps
- Coordinates with the Fresenius Kabi Technical Service Team with support needs



Implementation Phases

PLANNING PHASE

During the planning phase, attention is given to the composition of the implementation teams, liaison roles are established, timelines agreed upon, data set information is gathered, IV tubing needs identified.

Project Planning:

- ☐ Identify team members and provide the Fresenius Kabi team with contact information
- ☐ Clarify expectations with regard to the roles in both teams
- ☐ Define project scope and deliverables
- ☐ Establish timeline
- ☐ Identify working spaces and meeting locations for all phases of the project
- ☐ Schedule first working session with all team members from the facility and Fresenius Kabi
- ☐ Determine communication techniques to engage and inform all personnel to maximize the adoption of the new technology

Disposables Planning:

- ☐ Analyze disposable order history with pricing
- ☐ Identify clinical practices, especially any specialized practices
- ☐ Provide summary document of all disposable needs – inventory, swap out, ordering, usage, timing of crash carts, etc.
- ☐ Enter new model codes into hospital ordering/tracking system

Data Set Development:

- ☐ Identify or define IV medication formulary and protocols and relevant policies and guidelines
- ☐ Define care areas and identify drugs to be included in each care area
- ☐ Install Vigilant Drug'Lib Software
- ☐ Educate facility pharmacist on drug library/data set build process (allow minimum of 2 hours)
- ☐ Develop initial care areas, drug libraries, and configuration settings
- ☐ Perform user interface test to verify drug library and configurations
- ☐ Review "Data Set Change Request" document and communication path for on-going management of the drug libraries
- ☐ Revise drug libraries and configurations based on user testing to align data set with identified clinical practice
- ☐ Sign-off on approved final data set

Education Planning:

- ☐ Identify when, where and who will be educated on the Agilia Infusion System Large Volume Pump, this includes how to continue to support education of new staff and any who were not in the original training sessions
- ☐ Plan logistics for completion of online interactive learning modules by all identified personnel (allow 90 minutes for each person)
- ☐ Identify suitable learning environment, materials and biomed team requirements to ensure pumps are ready for learning programs[1]
- ☐ Plan logistics for delivery of facilitator-led learning sessions for each participant (allow 90 minutes for each session). It is intended that at least 80% of all staff will be trained before Go-Live day
- ☐ Identify areas for location of practice pumps and convey this information to staff during the education phase
- ☐ Reach agreement on education achievement documentation

BioMed Activities:

- ☐ Organize workspace for device reception and check-in
- ☐ Acknowledge receipt of devices and packages
- ☐ Assist facility with tagging equipment per facility protocols
- ☐ Perform visual check of devices, data set, battery life and inform the Fresenius Kabi team of any inconsistencies

Go-Live Planning:

- ☐ Establish and communicate Go-Live date (check against timeline for feasibility) and ensure preparedness of all hospital personnel
- ☐ Plan logistics for pump switchover and determine distribution of pump disposables[2]
- ☐ Communicate the order of facility units to receive new pumps. Identify person responsible for each unit's Go-Live and provide him/her a list of action items
- ☐ Identify staging area
- ☐ Document all supplies needed for Go-Live day and provide document to all relevant staff

[1] Refer to Education Checklist at end of document which lists supplies and needs for successful education program

[2] This includes a list of patients currently receiving IV medication and process to collect, document and remove old pumps

Education Phase

Education of the staff is of paramount importance to the successful transition to new pumps and adoption of the Dose Error Reduction Software. The education is a two-tiered approach to fully prepare the staff – an on-line component and a hands-on component. The hands-on lab gives the staff an opportunity to perform a series of tasks allowing for tactile reinforcement of the interactive program.

- Ensure all supplies (in particular, required disposables and IV fluids) are available and ready in the education rooms
- Confirm completion by all identified personnel of on-line interactive learning modules
- Educate Super-Users
- Distribute communications regarding new technology to all personnel
- Ensure all required staff attend assigned education sessions
- Ensure Super-Users support education sessions as per previous agreement
- Monitor attendance at assigned education sessions where personnel receive hands-on experience with the pump
- Inform personnel of the availability of practice pumps and encourage them to refine skills developed during the facilitator-led sessions
- Review completed documentation of education attained compared to assigned education sessions to determine if criteria has been met to proceed with Go-Live date

Go-Live Phase

The culmination of all planning and education is to ensure a smooth, seamless transition to the Agilia Infusion System Large Volume Pump. During this phase, many staff will get to experience for the first time how the Agilia Infusion System Large Volume Pump, which is lightweight, clinician-friendly and loaded with features and functionality, helps care for patients. Go-Live day begins with a "team meeting" to review all planned activities and ensure all personnel are available, as required. Contact information for the implementation team is made available to all personnel so that questions can be answered as quickly as possible.

Devices

- Devices are delivered to each facility unit in order as listed during planning phase[3]
- Final visual check of correct data set for each facility unit

Personnel

- Super-Users are working with personnel per their assigned lists
- Personnel are reminded of location of practice pumps for any last minute refreshers

Patients

- Communication is provided that helps patients feel comfortable with the changes that are going on around them
- Pumps for those patients currently on IV medication are swapped out at a time most convenient to care of the patient

[3] Old pumps are collected, documented and removed

Facility Units

- All utility cart supplies are checked to ensure that the new tubing is available when needed
- All crash carts are checked by two different personnel to ensure they are ready for use with the system

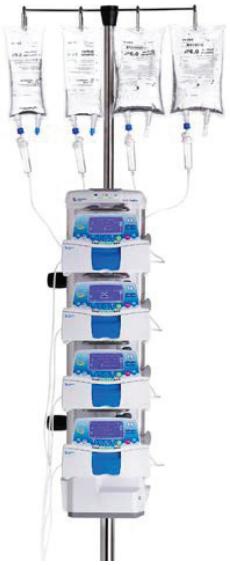
Post Implementation Phase

The purpose of the post implementation phase is to celebrate adoption of the Agilia Infusion System Large Volume Pump as one way of meeting the facilities' patient care goals. It is also a time to determine the process for ongoing support of the facility as well as determine lessons learned and best demonstrated practices.

- Post implementation agenda is developed
- Teams meet and discuss
  - Goals achieved
  - Address any outstanding issues
  - Next steps to be undertaken
  - Requests of the Fresenius Kabi team for further support
  - Confirm the process for ensuring ongoing education of facility personnel (particularly new staff)
- Outline process for making Data Set revisions/changes
- Confirm process for cleaning and maintenance of devices
- Ensure personnel are familiar with the "Agilia Infusion Set Performance Report" and how to access Fresenius Kabi personnel who can assist with ongoing use of the Agilia Infusion System Large Volume Pump
- Agreement is reached on intervals for ongoing communications and reviews
- Methods for assessing effectiveness of education program and other implementation activities are agreed upon and implemented

ATTACHMENTS:

- Sign off/approval sheet for Final Data Set
- Education criteria sign-off
- Agilia Infusion Set Performance Report
- Contact information for Fresenius Kabi for ongoing support
- Instructions of completion of online learning interactive modules
- Configuration worksheet for data set development
- Configuration/Drug library change request form



Agilia Infusion System Large Volume Pump with **Vigilant Drug'Lib** Software

Designed to empower nurses and pharmacists with its simplicity, the Agilia Infusion System Large Volume Pump with Vigilant Drug'Lib Software is a common sense choice in smart infusion pumps that helps you put patient safety first.

We are delighted to be working with you to implement this system into your facility.

Fresenius Kabi has provided this Implementation Guide as a tool for suggestions on implementing the Agilia Infusion System Large Volume Pump in your facility. As such, facilities and their staff members should not consider this guide as a sole information source. Rather, this guide should be used in conjunction with your facility's standard operating procedures and Agilia Instructions for Use.

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