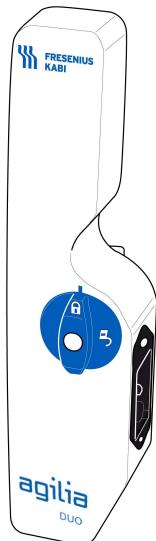


MEDICAL DEVICES

agilia

Agilia Duo

Two channel accessory



INSTALLATION INSTRUCTIONS

 **FRESENIUS  
KABI**  
caring for life

# Symbols descriptions



Refer to the Installation Instructions



cCSA<sub>US</sub> mark



Product reference / part number



Output terminal - connector



Alternating Current (AC)



Name and address of the manufacturer / Date of manufacture



Fragile, handle with care



This way up



Keep away from rain



Temperature limitation



**Warning symbol:** Warning of a potential hazard that could result in **serious personal injury** and/or **product damage** if the written instructions are not followed



**Caution:** Federal law restricts this device to sale by or on the order of a physician (See 21 CFR 801.109(b)(1)).



CE Mark according to European Directive 93/42/EEC



Product lot number



Input terminal – connector



Part included in a recycling process



Name and address of the manufacturing facility



Humidity limitation



Atmospheric pressure limitation



General symbol for recyclable material



Eco packaging symbol



**Information symbol:** Recommendations to be followed.

The UDI (Unique Device Identifier) is represented in AIDC (Automatic Identification and Data Capture) and readable text:

- (01) Product Identifier GTIN (Global Trade Identification Number)
- (21) Product Serial Number
- (11) Date of Manufacture
- (240) Product Reference
- (10) Lot number

## Table of contents

|          |   |           |
|----------|---|-----------|
| <b>1</b> | <b>INTRODUCTION</b>                                   | <b>5</b>  |
| 1.1      | SCOPE .....   | 5         |
| 1.2      | INTENDED USE .....                                    | 5         |
| 1.3      | INTENDED USERS .....                                  | 5         |
| 1.4      | INTENDED PATIENTS .....                               | 5         |
| 1.5      | USE ENVIRONMENT .....                                 | 6         |
| <b>2</b> | <b>COMPATIBILITY MATRIX</b>                           | <b>6</b>  |
| <b>3</b> | <b>PACKAGING</b>                                      | <b>7</b>  |
| <b>4</b> | <b>AGILIA DUO INSTALLATION</b>                        | <b>7</b>  |
| 4.1      | ATTACHING TWO PUMPS TOGETHER .....                    | 8         |
| 4.2      | ATTACHING THE AGILIA DUO .....                        | 9         |
| <b>5</b> | <b>CLEANING AND DISINFECTING</b>                      | <b>11</b> |
| 5.1      | WHEN TO CLEAN AND DISINFECT THE AGILIA DUO.....       | 11        |
| 5.2      | RECOMMENDED AGENTS.....                               | 11        |
| 5.3      | INSTRUCTIONS FOR CLEANING AND DISINFECTING .....      | 12        |
| <b>6</b> | <b>TECHNICAL CHARACTERISTICS</b>                      | <b>15</b> |
| <b>7</b> | <b>GUIDANCE AND MANUFACTURER'S DECLARATION ON EMC</b> | <b>15</b> |
| <b>8</b> | <b>RECYCLING AND DISPOSAL</b>                         | <b>16</b> |
| <b>9</b> | <b>LIFE CYCLE</b>                                     | <b>16</b> |



# 1 Introduction

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The Agilia Duo is a two channel accessory designed to connect and power Agilia infusion pumps. This convenient rack centralizes power of two pumps and reduces the number of electric power cords.

## 1.1 Scope

These Installation Instructions are applicable to the Agilia Duo two channel accessory.



### **Warning:**

*The user must adhere to the instructions specified in this document. Failure to observe these instructions may result in damage to the equipment, injury to patients or injury to users.*

## 1.2 Intended Use

The Agilia Duo is intended to centralize mains power for two attached Agilia large volume and syringe pumps. It is intended for use by healthcare professionals in healthcare facility.

Please refer to the Instructions For Use of the Agilia pumps used with this accessory for more details.

## 1.3 Intended Users

The Agilia Duo is intended for use by qualified healthcare professionals.

The Agilia Duo is intended to be used by the same population as the compatible Agilia large volume and syringe pumps.

For more information, please refer to the Instructions for Use and the System components booklet accompanying the Agilia large volume and syringe pumps before operating with the Agilia Duo.

## 1.4 Intended Patients

The Agilia Duo is an accessory to a range of Agilia infusion pumps. See the Instructions For Use of the Agilia pumps for intended patient populations.

## 1.5 Use environment

The Agilia Duo is intended for use in healthcare environments.



**Warning:**

*The Agilia Duo should be utilised under specified operational, storage and transport conditions to ensure its proper performance.*

### 1.5.1 Operating conditions

- Operating temperature range: 41°F (5°C) to 104°F (40°C).
- Operating pressure range 700 hPa (525 mmHg / 10.15 PSI) to 1060 hPa (795 mmHg / 15.37 PSI).
- Operating humidity range: 20% to 90%, no condensation.

### 1.5.2 Storage and transport conditions

- Storage and transport temperature: 14°F (-10°C) to 140°F (+60°C).
- Storage and transport pressure: 500 hPa (375 mmHg / 7.25 PSI) to 1060 hPa (795 mmHg / 15.37 PSI).
- Storage and transport humidity: 10% to 90%, no condensation

To ensure safety and proper operation, read the Instruction for Use accompanying the Agilia infusion pumps before operating with the Agilia Duo.

## 2 Compatibility

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The Agilia Duo is compatible with Agilia Connect large volume and syringe pumps and Volumat MC Agilia North America pumps.

For a list of devices compatible with your product refer to the Agilia Connect Device Compatibility Guide. The matrix is available through your Fresenius Kabi representative.



**Warning:**

- Use ONLY compatible Agilia devices with the Agilia Duo.

## 3 Packaging

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The Agilia Duo packaging contains the following elements:

- 1 Agilia Duo.
- 1 Installation Instructions.



### Information:

*If the contents in the packaging are not complete or are damaged, please contact your Fresenius Kabi sales representative.*

## 4 Agilia Duo installation

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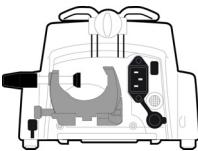


### Warning:

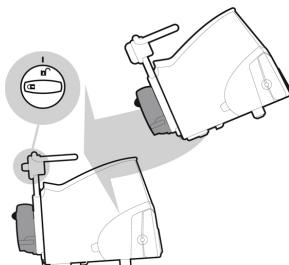
- *All connection and disconnection operations must be executed by appropriately qualified staff only.*
- *Fasten pole clamps firmly on the pole to avoid any movement of the pumps. Ensure that the pumps are securely attached and positioned.*
- *Agilia Duo is ONLY compatible with Agilia pumps.*
- *Agilia Duo must NOT be used with only one Agilia pump.*
- *Agilia Duo is designed to connect a maximum of two pumps.*

## 4.1 Attaching two pumps together

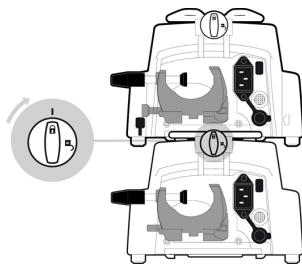
You can attach two pumps together either for transport, or before fixing them to a pole or to use them on a table.



1. Fold both pumps' pole clamps up.



2. Slide the slot on the bottom of the upper pump onto the handle of the lower pump.



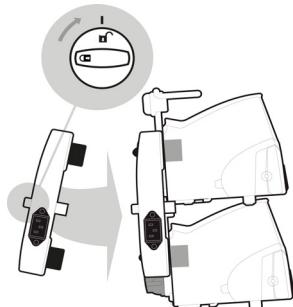
3. Turn the attachment lock knob on the lower pump handle clockwise until the locked symbol lines up with the marker.

4. Make sure the two pumps are securely attached together.

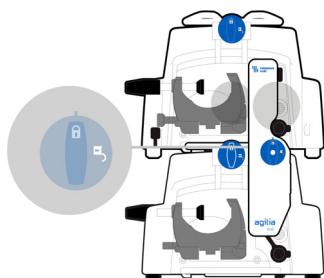
5. Before installing two pumps with the Agilia Duo on a pole, fold the two pole clamps down. Then, secure them tightly to the pole.

| Symbol  | Location             | Description       |
|---|----------------------|-------------------|
|  | Attachment Lock Knob | Locked Position   |
|  | Attachment Lock Knob | Unlocked Position |

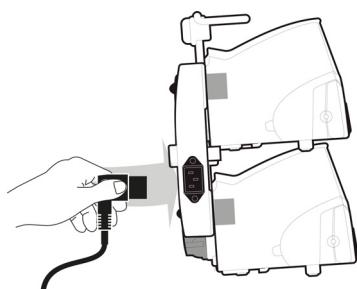
## 4.2 Attaching the Agilia Duo



1. Insert the two black connectors of the Agilia Duo into the two black power sockets on the back of the connected Agilia pumps.



2. Turn the attachment lock knob clockwise until fully locked and secure.



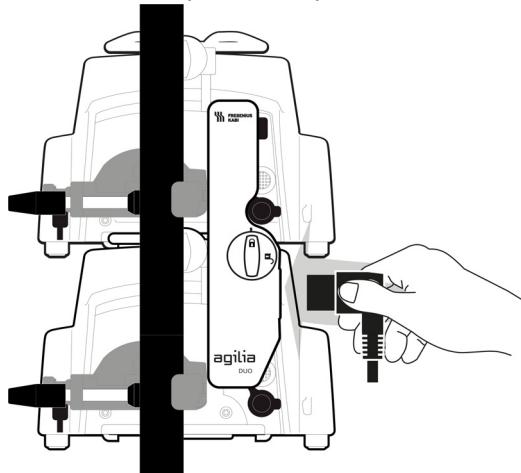
3. Insert the power cord into the black power socket on the side of the Agilia Duo.

4. Insert the other part of the power cord into the AC power supply.

| Symbol | Location             | Description       |
|--------|----------------------|-------------------|
|        | Attachment Lock Knob | Locked Position   |
|        | Attachment Lock Knob | Unlocked Position |

Example of final installation on a pole:

1. Attach Two Pumps Together making sure they are securely attached.
2. Install them on a pole. Please refer to the relevant Agilia pump Instructions For Use.
3. Attach the Agilia Duo.
4. Insert the power cord into the black power socket on the side of the Agilia Duo.
5. Insert the other part of the power cord into the AC power supply.



## 5 Cleaning and disinfecting

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To avoid the risks of infection and microbial transmission, make sure to adequately clean and disinfect the equipment.

The disinfecting procedure must be done immediately after cleaning. Disinfecting the Agilia Duo without prior cleaning is not effective.

The Agilia Duo is not intended to be sterilized; sterilization may result in damage to it.

### 5.1 When to Clean and Disinfect the Agilia Duo

Thoroughly clean and disinfect the Agilia Duo in the following cases:

- After each patient use
- On a routine basis when the Agilia Duo is not in use
- In case of contamination by blood or bodily fluids when the Agilia Duo is in use
- Before storage

### 5.2 Recommended Agents

#### Recommended Agent

Cleaning      Didecyldimethylammonium chloride  
(example: Wip'Anios Excel by Anios)

Disinfecting      Didecyldimethylammonium chloride  
(example: Wip'Anios Excel by Anios)

## 5.3 Instructions for Cleaning and Disinfecting

Follow the instructions provided to ensure effective cleaning and disinfecting of the equipment.

- Use the agents according to the manufacturer's instructions. This may include wearing personal protective equipment (gloves, lab coat, glasses, and so on), or diluting the agent according to the manufacturer's guidelines.
- For disinfectants, respect the contact time required for the antimicrobial agents to act (the time the agent must be left on the Agilia Duo for disinfection to be effective).

The following information is provided to protect staff against electric shock, and to protect the Agilia Duo from damage that can cause it to malfunction.

### ***Information:***



- *Only qualified staff can clean and disinfect the Agilia Duo.*
- *Do not place the Agilia Duo in an autoclave or immerse it in liquid.*
- *Do not spray liquids directly on connectors. Instead, use a cleaning cloth or disposable wipes.*

### 5.3.1 Cleaning instructions

#### Prerequisites

- The Agilia Duo is unplugged from the infusion pumps.
- The air is at room temperature (68 to 77 °F, or 20 to 25 °C).
- The operator is wearing suitable protective equipment.

#### Protocol

1. Place the Agilia Duo on a cleaned surface or disposable underlay.
2. With a fresh ready-to-use wipe, remove gross filth and heavy soils loads. Then thoroughly clean all exposed surfaces of the Agilia Duo from top to bottom. Be sure to also thoroughly wipe down plastic housing and blue attachment lock knob  
A minimum cleaning of 1 minute is recommended (allow to remain visibly wet for 1 minute), until all organic matter is dissolved and removed.  
Do not allow any part of the Agilia Duo to become saturated or submersed in liquid.  
Do not permit liquids to run, leak, or drip inside of the Agilia Duo housing.
3. Allow the Agilia Duo to completely dry at ambient room temperature.

### 5.3.2 Disinfecting instructions

#### Prerequisites

- The cleaning protocol has been performed.
- The Agilia Duo is unplugged from the infusion pumps.
- The air is at room temperature (68 to 77 °F, or 20 to 25 °C).
- The operator is wearing suitable protective equipment.

#### Protocol

1. Place the precleaned Agilia Duo on a cleaned surface or disposable underlay.
2. Wipe down all external precleaned surfaces of the Agilia Duo (same surfaces as cleaned in the cleaning procedure). Do not allow any part of the Agilia Duo to become saturated. Be sure to also wipe down plastic housing and blue attachment lock knob. Do not permit liquids to run, leak, or drip inside of the Agilia Duo housing.
3. Using a new ready-to-use wipe, repeat the step 2 and ensure that the minimum contact time for this step is 3 minutes for bactericide activity (surface remain visibly wet for 3 minutes). Respect the indicated contact time from the manufacturer recommendations for the required antimicrobial activity.
4. Allow the Agilia Duo to completely dry at ambient room temperature.

For cleaning and disinfecting of the infusion pumps, please refer to their relevant IFU, section Cleaning and Disinfecting.

## 6 Technical characteristics

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|                                  |  |
|----------------------------------|--|
| <b>Power supply</b>              | 100 V - 240 V ~<br>50/60 Hz                        |
| <b>Maximum power input</b>       | 20 - 30 VA   |
| <b>Maximum power output</b>      | 15 VA per outlet                                   |
| <b>Height/Width/Depth</b>        | Approx. 6.77 x 1.68 x 2.12 in (172 x 42.6 x 54 mm) |
| <b>Weight</b>                    | Approx. 183 g                                      |
| <b>Compliance with standards</b> | IEC 60601-1 (Ed. 3.1) and collaterals              |

## 7 Guidance and manufacturer's declaration on EMC

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Please refer to the instructions as per Agilia pumps Instructions For Use, section Guidance and manufacturer's declaration on EMC.

## 8 Recycling and Disposal

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Devices with this label must not be disposed of with the general waste. They must be collected separately and disposed of according to local regulations.



### ***Information:***

*For more information on waste processing regulations, contact your Fresenius Kabi representative or local distributor.*

## 9 Life cycle

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The accessory can be used 10 years in normal conditions.





## Local contacts for servicing

Complete this box with your contacts:

This document may contain inaccuracies or typographical errors.  
Modifications may therefore be made and will be included in later editions.

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Revision date: January 2017



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