



## Agilia® SP PCA

Advanced syringe infusion pumps for  
Patient Controlled Analgesia (PCA)

For PCA and for General Infusion

4 PCA infusion modes with hardware and  
software protection against overdose

Adaptable to all protocols

Up to 19 drug libraries available

Easy and intuitive to use

Stand alone or rack mounted

IT/AGLA SP PCA/4 Pager/LBU/7/1/2019/Cycle 1  
For the use of a registered medical practitioner or a hospital or a laboratory only.

CIN:U24231PN1995PTC014017

# Agilia® SP PCA

## Infusion

### Flow rate range

0.1 - 1200 mL/h, depending on the syringe capacity (0.1 mL/h increment).  
Flow rate can be limited according to drug name (soft and hard limits) with Agilia Vigilant Master Med, IV Medication Safety System.

### 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/m<sup>2</sup>/h, mg/m<sup>2</sup>/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 ;  
0.1 - 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 profil: infusion without any display of the drug names.  
19 Custom profiles configurable with Agilia Vigilant Master Med: Drug library to be created with Agilia Vigilant Master Med.  
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):

- Agilia SP PCA  
> 11 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 Concl 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

### Usability Engineering

IEC 60601-1-6 and IEC 62366