Product Specification
Getinge 46-series
46-4
Washer-disinfector

<DOC_PS07-0135_PRODSPEC_46-4><REV.B><LANG_EN><2022-04-25>

GETINGE ✳

Contents

Getinge 46-series
46-4
Washer-disinfector
Product Details

Application

The Getinge 46-series is a fully automatic and microprocessor controlled washer-disinfector. Processing cycles are factory programmed with recommended treatment parameters for pre-rinsing, cleaning, post-rinsing, thermal disinfection, final rinsing, and drying. Validated programs secured by access codes. Detergents and rinse agents automatically dispensed during cycles. The 46-series is a proven, robust and well performing washer-disinfector.

Washer-disinfector 46-4 is now available with limited and optimized configuration for hospital departments, wards, disinfection rooms or clinics that can utilize the benefits with a single folding door operation. No need for loading trolleys for operating or daily maintenance of the unit.

The 46-4 model has three fixed spray arms in the chamber, and can accommodate a wide range of load in the lower basic- and upper- wash cart operated on guide rails. The lower 2-level basic wash cart is adapted for use together with the 46-series MIS accessories to enable efficient cleaning of lumen instruments. The basic wash cart (1-level) can be adapted for the MIS system, if updated with the MIS adaption KIT.

Note! The customer is responsible for performing installation qualification, operating qualification, and performance qualification according to EN ISO 15883.

Note! For utilization of capacity, the 46-5 is recommended for reprocessing sterile containers due to the larger chamber and adapted accessories.

Intended use

The intended use of the 46-series washer-disinfector is to clean, thermally or chemically disinfect, and dry surgical goods. Typical goods for cleaning and thermal disinfection are:

- Instrument containers
- Anesthesia equipment
- Bowls
- Basins
- OP shoes
- Dental instruments
- Glassware, bottles and beakers
- Invasive surgical instruments, MIS instruments

Typical goods for cleaning and chemical disinfection are:

- OP shoes

Standards and codes

The Getinge 46-series complies with:

- MDD 93/42/EEC Medical Devices Directive.
- IEC 61010 part 1 and 2 Safety requirements for electrical equipment.
- UL61010-1: 2012 Safety requirements for electrical equipment.
- CAN/CSA-C22.2: Safety requirements for electrical equipment.
- EMC 2014/30/EC Electromagnetic Compatibility Directive.
- WEEE 2012/19/EC Waste Electrical and Electronic Equipment Directive.
- ROHS2 2011/67/EU Restrictions of Hazardous Substances.
- ISO 15883 Parts 1 & 2 Machine and Process design.
- ANSI/AAMI ST15883 Part 1 & 2 Machine and Process design.
- Air gap for water intake, according to EN1717.
- Microbiological test SPRI specification 74203.
- OSHPD pre-approval OPM-0383-13 (2016 California building code). The Seismic Anchoring accessory is required.

Key features

- Rotary spray arms are fixed at the top center and bottom of the chamber.
- The upper wash carts on guide rails have rotary spray arm both from top and bottom, to allow water and detergent to reach all surfaces for cleaning.
- MIS accessories automatically connect to water and drying air to clean and dry the inside of tubular instruments.
- All models are, as standard, equipped with independent temperature monitoring and validation test port according to EN ISO 15883.
- Full size glass door, chamber light, test port for water and a fine-meshed strainer are standard features.
- In the Getinge 46-4, the drying air heats up by electrical heating elements and pulls through a HEPA filter before enter the chamber and efficient dries the load with clean air. The dryer fan motor is a brush-less design with remarkable low sound and energy consumption, and expected long lifespan.
- Optional ICCU for condensing of exhaust (non-vented) is available and fits inside the unit, means no additional installation height of the unit.
- Pressure monitoring to secure the correct water circulation pressure is available for the process.

Control system features

The PACS 350 modular PLC control system controls operation and maintenance of Getinge sterilizers and washer-disinfectors, featuring:

- CPU processor with battery backup
- Digital inputs and outputs for machine control
- Analog measuring inputs
- RS-232/485 COM port for serial communication, as printer etc.
- Up to 20 cycle program memory
- Communication via NetCom (option) with Getinge Online (real-time and historical information of machine performance and wash process)
- Communication via NetCom (option) with T-DOC independent Traceability and management system

The PACS 350 controls all system functions; both visually and audibly alerts the operator of cycle malfunctions and on demand provides visual indication of the chamber temperature.

Control panel

The machine is controlled and operated from the control panel, located above the soiled-side door. The panel interface is a durable LCD display with two rows (20 characters on each row). A screen saver extends the life of the backlit LCD display. Touching any key illuminates and reactivates the display.

The following indicators and function keys are located on the display:

- Program running
- Program complete
- Alarms
- Reset alarms
- Start cycle
- Program selection 1–6

The software memory supports up to 20 programs. There are six programmable buttons under the display for the most common programs. The other programs are accessed by entering the menu.

Standard features (no selection needed)

- Control panel with 6 program buttons
- Single folding door operation
- Tempered glass door with safe Vision In Process
- Painted steel framework
- Electrical heating of the water in the sump
- Fine debris filter in the chamber
- Unrestricted air gaps for potable water intakes
- 2 x detergent dosing pumps
- 2 x suction lance for 5 L (1 gal.) detergent containers
- CW and HW inlet, bottom connection through flexible hoses (included)
- Efficient heating insulation for the chamber, pipes and heating system
- Guide rails for upper wash cart
- Pressure monitoring of the process water
- Dryer with heater and HEPA filter

Optional features (selection needed)

Note!   To fulfill EN ISO 15883, flow monitoring and one of the process (batch) reports need to be selected and included in the unit. For more information, see the following pages and the order sheets.

- Built in Internal Condensing Cooling Unit (ICCU) to reduce the humid and hot air from the exhaust
- Additional detergent dosing pumps 3+4
- Detergent flow monitoring of dosing pumps (required for EN ISO 15883)
- Drain cooling
- Line breaker for main power
- NetCom for communication with Getinge online and T-DOC
- Signal exchange box for an external interface
- Process report (required for EN ISO 15883)
- DiW valve

References

Documentation

The following documentation is available for the machine and can be downloaded from Getinge Extranet.

Documentation	Contents	Paper	Electronic media	Available languages
User manual	Instructions for daily use.	✓	✓	Local EU-language.
Installation manual	Instructions for assembly, installation and commissioning.	✓	✓	English, German, French or Swedish.
Quick Guide	Simple instructions for frequently performed tasks. Should be accessible and visible in the working area.	✓	✓	Local EU-language.
Declaration of Conformity	Declaration of conformity with requirements in applicable directives.	✓	-	English.
Electrical diagrams	Collection of circuit diagrams.	-	✓	English.
Service manual	Instructions for service and preventive maintenance.	-	-	English, German, French or Swedish.
Spare Parts	List of available spare parts.	-	-	English.
Program sheets	Descriptions of Program groups (including programs and phases).	-	✓	English.
Installation drawings	Drawings for preparations and installation of the machine.	✓	✓	English.

- = Not included in the machine delivery   ✓ = Included in the machine delivery

Languages selectable for the control panel

|	
Bulgarian (bg)	Japanese (ja)
Czech (cs)	Latvian (lv)
Danish (da)	Lithuanian (lt)
Dutch (nl)	Norwegian (no)
English (en)	Polish (pl)
Estonian (et)	Portuguese (pt)
Finnish (fi)	Romanian (ro)
French (fr)	Russian (ru)
German (de)	Slovak (sk)
Hungarian (hu)	Slovenian (sl)
Icelandic (is)	Spanish (es)
Italian (it)	Swedish (sv)

Getinge 46-series
46-4
Washer-disinfector
Technical Data and Drawings

The drawings in this product specification should not be used for installation. For the latest versions and complete drawings for installation, see the separate Installation manual.
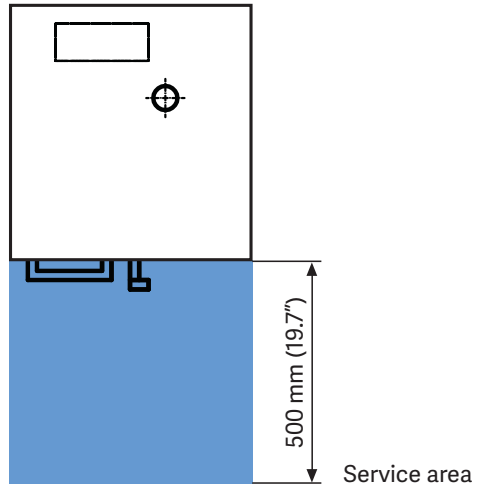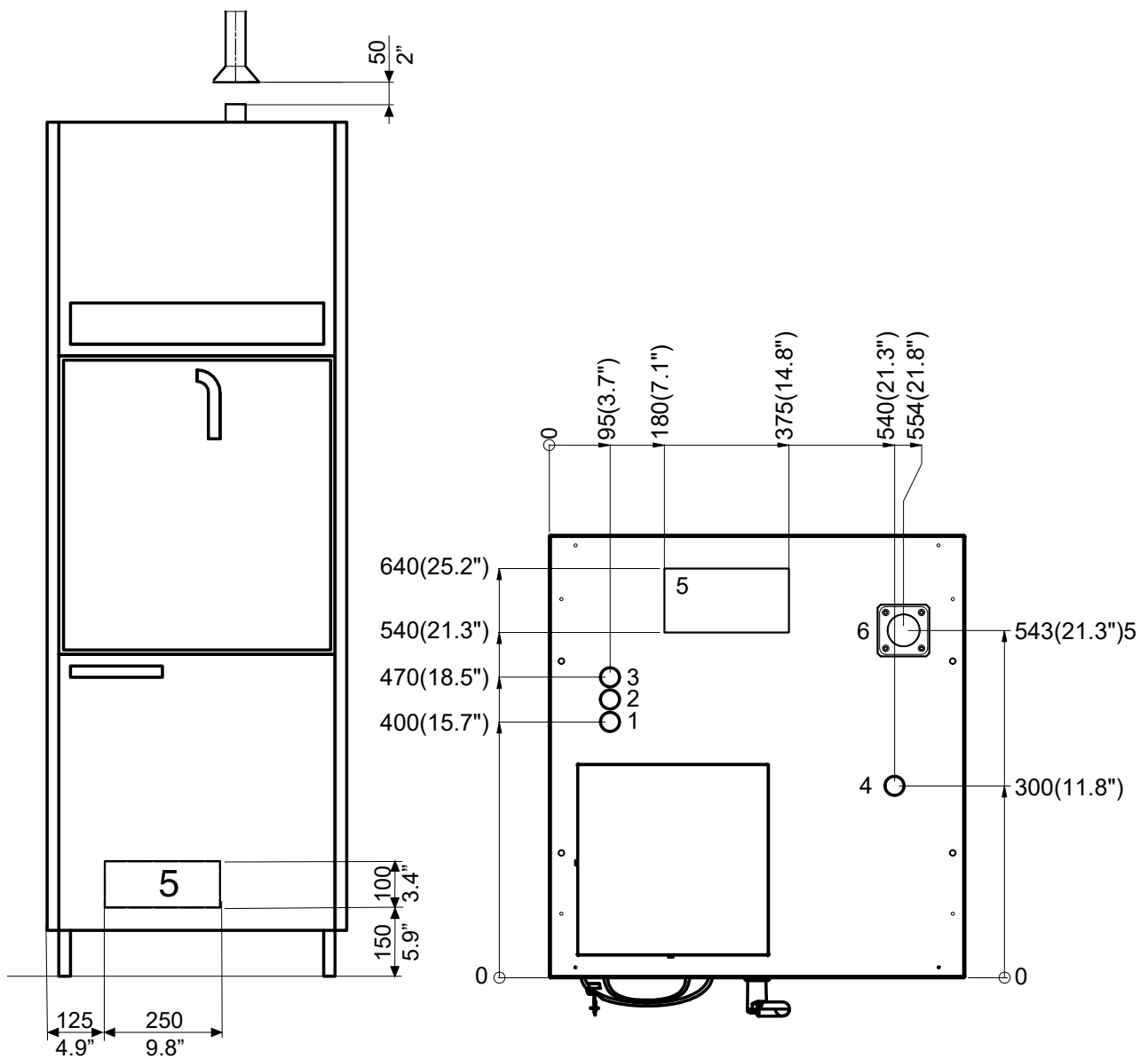
Dimensions - side view
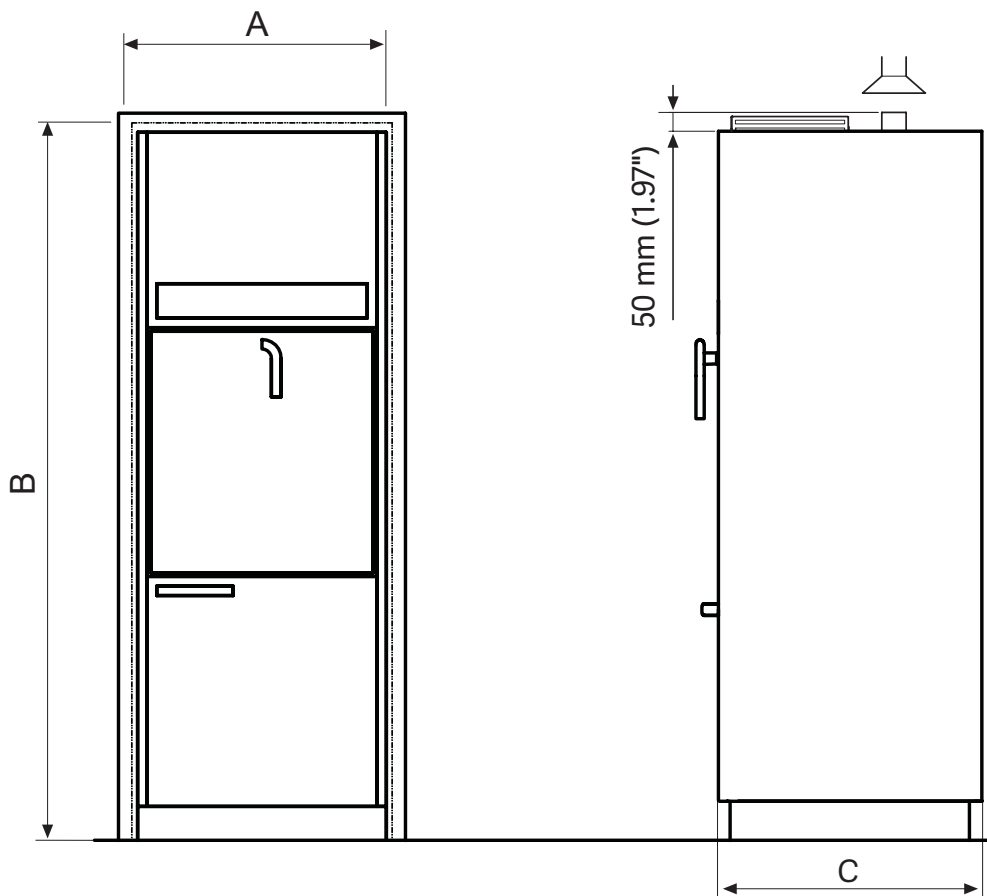
Dimensions

A	Width	650 mm (25.5")
B	Height	1860 mm (73.2")
C	Depth	690 mm (27.1")

Dimensions - top view

500 mm (19.7")

Service area

Connections electrical heating

1   Distilled/deionized water by a 150 mm (6") flexible hose (supplied) from underneath.

2   Hot water connection by a 700 mm (27") flexible hose (supplied) from underneath.

3   Cold water connection by a 700 mm (27") flexible hose (supplied) from underneath.

4   Electrical connection, 500 mm (19.7") above floor.

5   Drainage, adjustable within this range (C/L of outlet pipe).

6   Exhaust air at ceiling (46-4).

Dimensions and volumes

Outer dimensions

	Height	Depth	Width
46-4 with dryer	1860 mm (73.2")	690 mm (27.2")	650 mm (25.6")

Chamber dimensions (effective)

	Height	Depth	Width
46-4	590 mm (23.2")	620 mm (24.4")	550 mm (21.7")

Chamber volumes

	Operational volume	Total volume
46-4	201 L (53.1 gal.)	280 L (74.0 gal.)

Weight including water and load

	Total weight	Loading per machine foot	Floor area loading per machine foot
46-4 Single door (with dryer)	285 kg (628.32 lb.)	0.70 kN (157.37 lbf)	386 kN/m² (8061.78 lbf/ft²)

Package sizes and weights

	Weight	Height	Depth	Length
46-4 Single door (with dryer)	237 kg (522.5 lb.)	2200 mm (86.6")	850 mm (33.5")	980 mm (38.6")

Utility requirements

Water connections

Water type	Connection	Pressure	Flow rate minimum	Temperature maximum
Cold water	ISO G-1/2" Female	100-800 kPa (14.5-116.0 Psi)	20 L/min (5.3 gal./min)	20 °C (68 °F)
Hot water	ISO G-1/2" Female	100-800 kPa (14.5-116.0 Psi)	20 L/min (5.3 gal./min)	45-60 °C (113-140 °F)
Dist. water/De-ion water	ISO G-3/4" Male	100-800 kPa (14.5-116.0 Psi) [1]	20 L/min (5.3 gal./min)	90 °C (194 °F)

[1] PTFE tape is recommended for sealing the connections.

Ventilation requirements

Air quantity	Maximum 80 m³/h (2825 ft³/h)	Refers to the air flow during the drying phase.
Temperature	Maximum 90 °C (194 °F)	Refers to the start of the drying phase. The temperature falls to about 60 °C (333.1 °F) after a few seconds, and stays roughly at this level for about 20 minutes.
Air humidity	60-100 %	

Operating and environmental conditions

Operating conditions

Air humidity	Maximum 80 % up to 31 °C (88 °F) decreasing linearly to 50 % at 40 °C (104 °F)
Temperature	5-40 °C (41-104 °F)
Installation height	Maximum 2000 m (6561.7 ft) above sea level
Pollution degree	2
Overvoltage category	CAT II
Connection to mains supply	Permanent
Mains supply voltage fluctuations	+/-10 %

Storage and transport conditions

Note! The machine must be kept in its package during storage and transport.

Surrounding temperature	-20 to 70 °C (-4 to 158 °F)
Surrounding air humidity	Maximum 90 % at 30 °C (86 °F)

Technical data

Water consumption

46-4	Approximately 18-19 L/phase (4.8-5.0 gal./phase)

Heat emission to the room

Max 2000 W	Hot air during drying without the optional ICCU condenser.
Max 1100 W	During disinfection at 90°C (194°F)

Heat emission from front and door

100 W	Hot air during drying
55 W	During disinfection at 90°C (194°F)

Circulation system

Design pressure	200 kPa (20.0 Psi)
Working pressure max	100 kPa (14.5 Psi)
Design temperature	100°C (212°F)
Working temperature	93°C (200°F)

Material

Chamber	Stainless steel 316L (1.4404)
Exterior panels	Stainless steel 304, (1.4301)

Sound level

The calculated sound power level implies different LpA sound levels in different types of spaces. With a larger room volume, the sound level decreases slightly and with a smaller room volume, it increases slightly. The table below shows examples of what to expect in practice.

Type of room	Sound level (dBA*)
Average Process	58,4
Average Wash	62,0
Average Drying	55,7

* Measured 2,6 m from unit and 1,5 m above floor level. Measurement made in small room with no sound absorbent or furniture.

Electrical data

Electrical heating

Voltage (V)	Connection	Frequency (Hz)	Maximum operating current (A)	Maximum fuse (A)
415	3N+PE	50	15.0	C16
400	3N+PE	60	14.6	C16
400	3N+PE	50	14.6	C16
380	3N+PE	60	14.0	C16
380	3N+PE	50	14.0	C16
240	3+PE	60	20.7	C25
230	3+PE	60	25.4	C30
230	3+PE	50	25.4	C32
220	3+PE	60	26.5	C30
208	3+PE	60	25.5	C30
200	3+PE	60	24.8	C32
200	3+PE	50	24.8	C32

Getinge 46-series
46-4
Washer-disinfector
Order Information

About this form

This part of the document is an order form. Mark your selections.

☐ Standard selection (included in base price)

◯ Optional selection (not included in base price, additional cost)

Customer reference

State project name, project no., customer name, etc.

Documentation

State the country for the correct language in the enclosed manuals.

Language/control panel

Select the language, for the touchscreen. See the table in the section "Languages selectable for the control panel" on page 6.

Model

46-4

Program group selection

☐ HOSPITAL A_0 600 (general programs with thermal disinfection, for markets other than indicated below)

☐ LIFE SCIENCE (adapted for Life Science and LAB)

Main voltage power supply

Note! Only one selection is possible.

50 Hz units

☐ 415 V, 3N+PE, 50 Hz
☐ 400 V, 3N+PE, 50 Hz
☐ 380 V, 3N+PE, 50 Hz
☐ 230 V, 3+PE, 50 Hz
☐ 200 V, 3+PE, 50 Hz

60 Hz units

☐ 400 V, 3N+PE, 60 Hz
☐ 380 V, 3N+PE, 60 Hz
☐ 240 V, 3+PE, 60 Hz
☐ 230 V, 3+PE, 60 Hz
☐ 220 V, 3+PE, 60 Hz
☐ 208 V, 3+PE, 60 Hz
☐ 200 V, 3+PE, 60 Hz

Internal Condensing Cooling Unit (ICCU)

☐ No built-in condenser ICCU

◯ Built-in condenser ICCU to reduce humid and hot air from the exhaust.

Detergent dosing pumps

☐ Dosing pump 1: Cleaning detergent. Dosing pump 2: See the following table

◯ Dosing pump 3: For additional process chemical

◯ Dosing pump 4: For additional process chemical

Pre-configured Dose pump	HOSPITAL A_0 600	LIFE SCIENCE
1 **Cleaning detergent**	✓	✓
2 **Rinse Aid**	✓	-
2 **Neutralizing chemical**	(*)	✓
4 **Disinfection chemical**	(*)	-
- = Not used in programs ✓ = Used in programs * = Used in hidden program		

Detergent flow monitoring

Note!   This is required to comply with EN ISO 15883.

With flow control the dosing is volume based. Liquids with a higher viscosity than 10 cSt can clog the flow monitoring function.

☐ No flow monitoring

◯ Detergent flow monitoring for 2 dosing pumps

◯ Detergent flow monitoring for 3 dosing pumps

◯ Detergent flow monitoring for 4 dosing pumps

Drain cooling

As hot solutions from the drain tank and condensate from the heat exchanger enter the water trap, cold water is automatically injected to reduce the temperature to 60 °C (140 °F) or less before it enters the building waste system.

☐ No drain cooling

◯ Monitored drain cooling with 60 °C (140 °F) maximum drain temperature

Line breaker

☐ No line breaker

◯ Line breaker

NetCom

NetCom is a factory installed communication solution for exporting process information to a USB connected storage drive (USB included in NetCom option) or to T-DOC Independent Traceability and management system and/or Getinge Online (real time and historical information about the machine performance and the wash process).

NetCom is required for:

- Communication with Getinge Online (real-time and historical information of machine performance and wash process).
- Communication with T-DOC independent Traceability and management system.

☐ No NetCom

◯ NetCom (USB included)

Signal exchange

Electrical dry contacts provided for external communication of process running, process complete, and alarms.

☐ No signal exchange box

◯ Signal exchange box

Process report

Note! Process report is required to comply with EN ISO 15883 and can be done either with a built-in paper printer or digitally with USB/NetCom.

Cycle printouts/batch report data can be printed. The information includes program start date and time, phase description, disinfection time, amount of detergent (if flowmeters are used), temperature, and alarms triggered during a program.

☐ No Built-in printer

◯ Built-in printer

Deionized water valve (DiW)

As standard, all models are equipped with 1.5 m (59") hoses and valves for cold and hot water. The hoses are connected at floor level. Additional connection for deionized water can be selected.

☐ No DiW connection

◯ DiW valve

Thermal disinfection type

The method of disinfection can be selected and set accordingly on delivery.

☐ Disinfection phase time and temperature controlled

☐ Disinfection phase time and temperature controlled, additional A_0 value calculated and printed

☐ Disinfection phase A_0 value controlled

Accessories

Article No.	Description
6001891675	Seismic anchoring
6002031101	Gross debris filter
499183100	Upper wash cart
503305400	Basic wash cart (1-level)
6028110001	2-level basic wash cart (MIS KIT included)
6002387101	MIS KIT for Basic wash cart to enable the MIS system (not needed for 2-level basic wash cart)
6002296801	MIS Central module
6028199101	AN rack (requires basic wash cart with MIS KIT or 2-level basic cart)
6002272401	Injector cart with 62 injectors for baby bottles or glassware etc
6028093601	Stand for OP shoes, 10 pairs (used in basic wash cart, or 2-level with removed shelf)
499540900	Stand for soles, 15 pairs (used in upper wash cart on guide rails)
498850200	Stand for kidney bowls
498850300	Stand for bowls 211 mm
498859600	Stand for bowls 111 mm
498859700	Stand for bowls 151 mm
502450202	Dental Injector pipe for 18 hand-pieces (requires MIS KIT or 2-level basic cart)
502481102	Dental Injector pipe for 36 hand-pieces (requires MIS KIT or 2-level basic cart)
501115400	Stand for 9 pcs of dental trays, fits in the upper wash carts on guide rails

Example of wash carts

Upper wash cart (499183100)

Upper wash cart for use on the chamber guide rails.
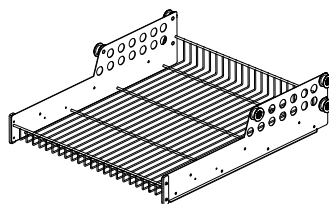
Basic wash cart (50335400)

The basic wash cart has no connection for MIS or AN rack.
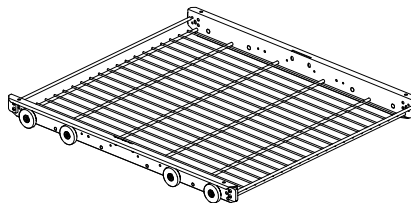
MIS KIT (6002387101)

Required to adapt a basic wash cart for use with MIS or AN rack.
The picture shows the KIT mounted at the basic wash.
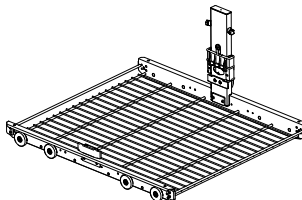
2-level basic wash cart (602811001)

With removable spray-arm and shelf. With the top shelf removed the cart is adapted to be used for trays, OP shoes, AN, MIS accessories with water connection to manifold. The left pictures shows the wash carts with 2-levels. The picture to the right shows the same wash cart prepared for MIS or AN rack.
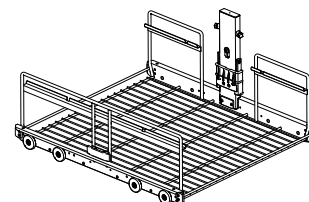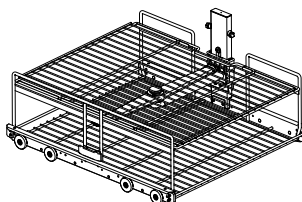
Injector wash cart (6002272401)

62 injectors with holders for baby bottles or glassware. Injectors can independently be removed and replaced by plastic plugs #503382500 if larger bottles and more space is required.
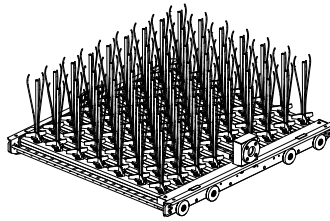

Example of accessories for basic wash carts

These accessories are available for use with the 2-level basic wash cart, which is prepared for all accessories below. The pictures to the left shows the separate accessory and the picture to the right how it is fitted on the wash cart.
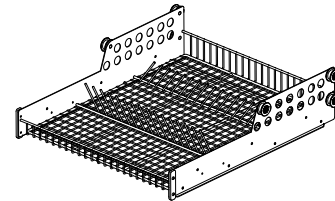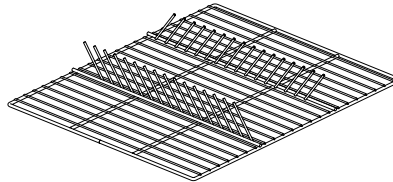
Rack for OP shoes (6028093601)

The rack for 20 pcs of OP shoes to be used with basic wash cart. Picture shows combination with the 2-level basic wash cart.
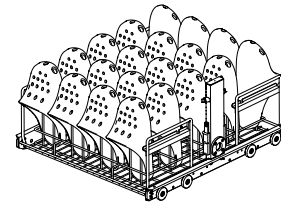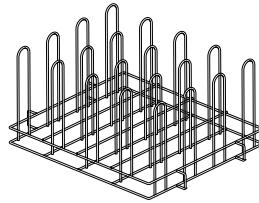
Rack for OR shoe insoles (499774600)

15 pairs of insoles can be placed in the upper wash cart on guide rails, in combination with the OP shoes (on basic wash cart).

AN rack (6028199101)

To be used with the 2-level wash cart. Capacity: 3 x AN hoses, with hose support (maximum length 1500 mm). Injectors for breathing bags and bellows. Separate tray for mask can be placed inside the rack.
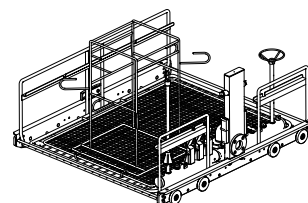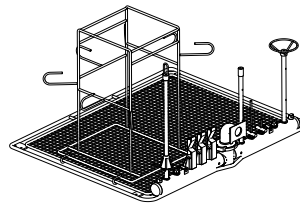

MIS Center module (6002296801)

36 different injector flush outputs for lumen instruments. The center module can be used with the 2-level basic wash cart. Fine mesh filter and adapter for manifold is included with the module. Instrument trays can be placed on both side on the center module.

46-series MIS configuration in combination with the 2-level wash cart.

Other 46-series MIS configuration can be used in combination with the 2-level wash cart.
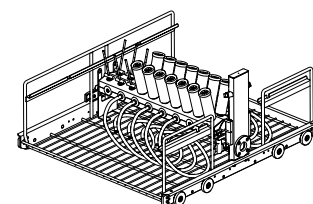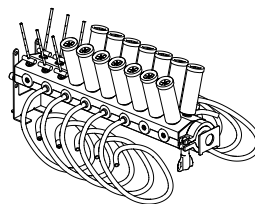
**Note!** MIS configured as a separate accessory.

Dental Injection pipe 18 (502450202)

The V-shaped injector pipe cleans and disinfects up to 18 hand-pieces. To be used in a 2-level basic wash cart (or basic wash cart with MIS KIT).
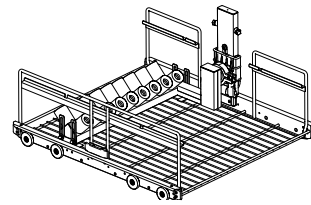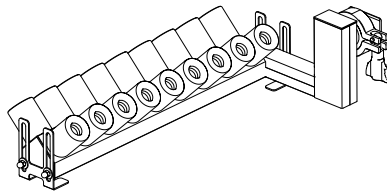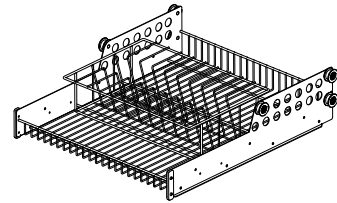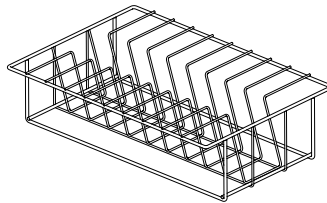
Dental Injection pipe 36 (502481102)

The V-shaped injector pipe cleans and disinfects up to 36 hand-pieces. to be used in a 2-level basic wash cart (or basic wash cart with MIS KIT).
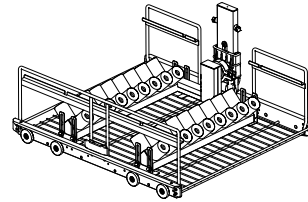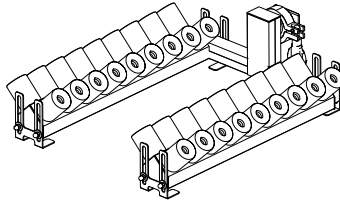
Dental tray rack (501115400)

Tray for up to 9 pcs of dental trays. Fits in the upper wash cart with guide rails.

<DOC_PS07-0135_PRODSPEC_46-4><REV.B><LANG_EN><2022-04-25>

GETINGE ✳

Getinge is a global provider of innovative solutions for operating rooms, intensive care units, sterilization departments and for life science companies and institutions. Based on our firsthand experience and close partnerships with clinical experts, healthcare professionals and medtech specialists, we are improving the everyday life for people – today and tomorrow.