

# Custom Hipersep® Pilot Technical Description



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# 1. SYSTEM CONFIGURATION

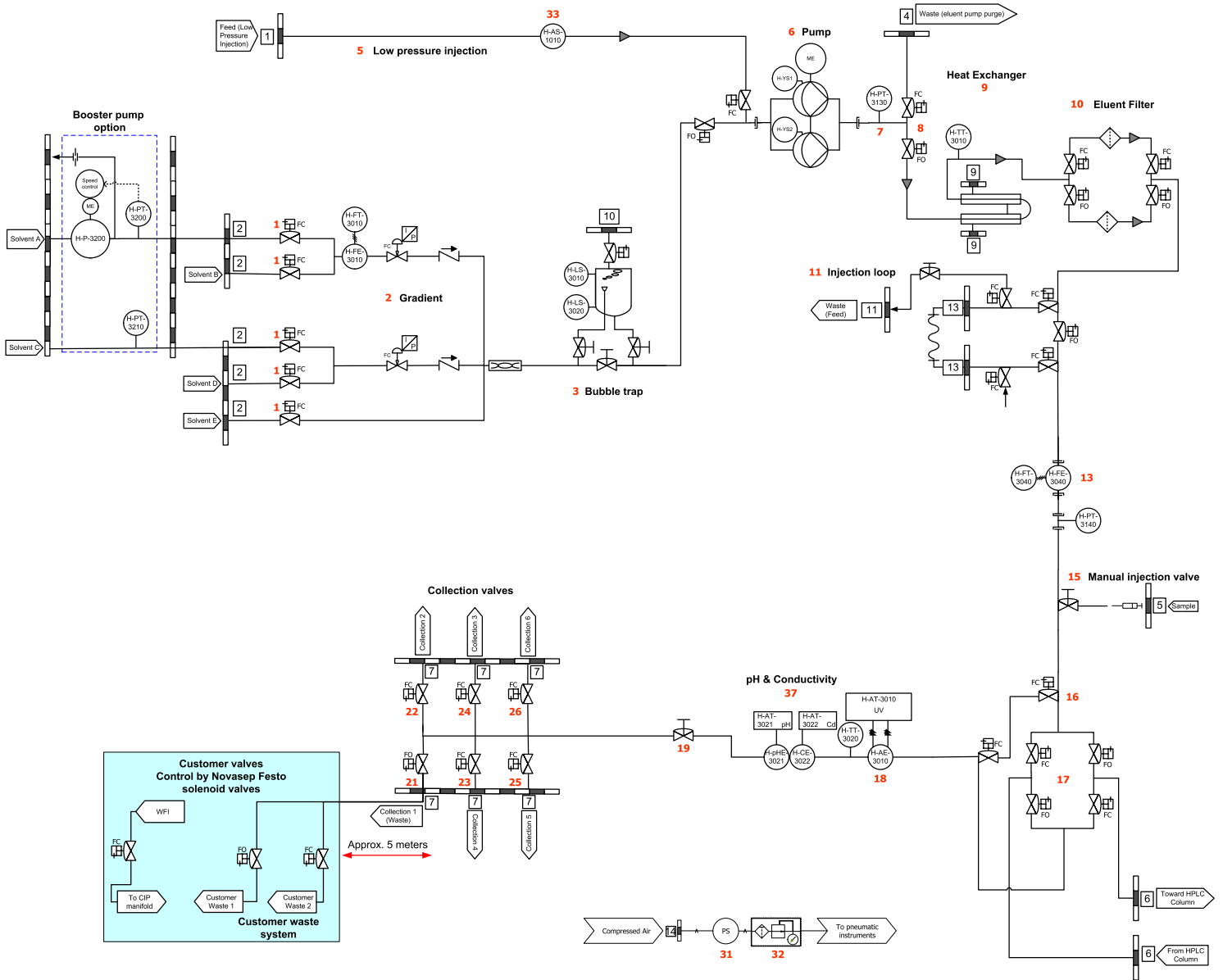
Designation code: **ZIPILCEAABA06CABACNANBN06NN**

CODE	DESCRIPTION	SPECIFICATION
ZIP	01. Type	ZIP: custom Hipersep® system type
PIL	02. Size	PIL: Pilot size from 6 to 90L/h
CE	03. Design	CE: European version
A	04. Hazardous location	A: System designed for hazardous area ATEX Zone 2
A	05. Electrical cabinet	A: Electrical cabinet embedded onto the chromatography skid
B	06. Supervision	B: HMI is designed for hazardous area and is embedded into the skid
A	07. Piping material	A: Stainless steel piping
06	08. Main pump number of inlets	06: Six inlets with low pressure injection and with gradient/ILD
C	09. Gradient / ILD	C: Gradient and ILD performed with 2 analog valves
A	10. Bubble trap	A: Bubble trap located at the suction of the eluent pump
B	11. High Pressure (HP) injection	B: Injection using automatic injection loop (manual filling)
A	12. Heat exchanger	A: Pre-column Heat exchanger (Thermal Control Unit TCU is not included)
C	13. Filter on eluent	C: Two filters with switch valves on eluent line
N	14. Filter for HP injection	N: No filter
A	15. Upflow	A: Column Upflow/Backflush valves functionality
N	16. Pressure post column	N: No pressure sensor post column
B	17. pH/Cd/NIR	B: Post column pH and Conductivity probes.
N	18. Nitrogen flush	N: No Nitrogen flush line on the system
06	19. Fraction	06: Ten fractions on the system
N	20. Recycling	N: No eluent recycling functionality on the system
N	21. Hydraulic group power supply	N: No hydraulic group power supply on the system

Features:

DESCRIPTION	SPECIFICATION
<b>Gradient</b>	Binary analog gradient performed from 5 to 95 % in the dynamic range from 6 up to 90L/h, with an absolute accuracy of $\pm 2.0$ %.
<b>Injection volume*</b>	Product injection can be made: <ul style="list-style-type: none"><li>- Manually via injection port The product or tracer is manually injected before the column. This injection is mostly used for HETP calculation.</li><li>- Automatically via Low Pressure line Main eluent pump is used to introduce product onto the column. This injection is particularly used for large volume (more than 100mL). Injection volume accuracy <math>\pm 2\%</math>.</li></ul>

# 2. SYSTEM FLOW CHART



Custom P&ID

### 3. TECHNICAL SUMMARY

#### Elements description:

ITEMS	FLOW CHART LOCATION	DESCRIPTION
Inlets	1	Pneumatic 2-way diaphragm valves used as solvent inlets.
Eluent pump	6	One 2-head diaphragm (PTFE) pump. Able to operate from 6 up to 90 L/h at 100 barg. Equipped with membrane failure indicators.
Pressure Transmitter	7	Used to monitor the pressure and secure the system. They are also used to calculate the pressure drop across the Eluent filter (to detect filter clogging).
Purge Valve	8	Two pneumatic 2-way diaphragm valves. Used to prime the pump and/or purge the inlet lines.
Eluent Flowmeter	13	Mass flowmeter used to control the Eluent pump.
Manual injection valve	15	Manual 3-way diaphragm valve. Used to inject small quantities of feed. This injection mode is typically used to test the chromatographic column, HETP measurement (efficiency).
Column bypass valves	16	Two pneumatic 2-way diaphragm valves used to bypass the chromatographic column.
Column upflow/downflow valves	17	Four pneumatic 2-way diaphragm valves used for upflow/downflow mode of the chromatographic column.
Detection UV	18	Measurement of three adjustable wavelengths simultaneously (200 – 600 nm) equipped with a full flow cell with an optical path length which can be adjusted to 0.50 mm or 1.25 or 2.00 mm.
Manual valve	19	One manual diaphragm valve used to generate a small pressure drop after the UV cell in order to avoid any degassing in the UV cell.
Collection valve - waste	21	One pneumatic 2-way diaphragm valve (fail open). Used to perform the fraction collection. Typically defined as waste valve.
Customer valve – waste 2 & 3	21b	Two pneumatic 2-way diaphragm valve (one fail open and one fail closed). Used to perform customer waste selection and controlled from Novasep software, connected to Novasep Festo solenoid valves.
Customer WFI valve	21b	One pneumatic 2-way diaphragm valve (fail closed). Used to perform WFI CIP on the system and controlled from Novasep software, connected to Novasep Festo solenoid valves.
Collection valve – waste 2 & 3	22 & 23	Pneumatic 2-way diaphragm valve (fail open). Used to perform the fraction collection.
Air Pressure Switch	31	One pressure switch. To secure the use of the system in case of lack of air pressure.
Air pressure regulator	32	One pressure regulator used to adjust the air supply pressure for the air driven devices of the pumping module.
Collection valve	24 to 30	Pneumatic 2-way diaphragm valves (fail closed). Used to perform the fraction collection.
Gradient	2	Binary analog gradient composed by two additional solvent inlets, two regulation valves, one flowmeter and one static mixer.

<b>Low pressure injection</b>	5	Two pneumatic 2-way diaphragm valve. Used to inject large amounts of feed material using the Eluent pump.
<b>Air sensor</b>	33	One Air switch. Used to detect air and to indicate if there is no more feed material on the low pressure feed supply.
<b>Heat Exchanger</b>	9	One multi-tube heat exchanger (0.07 m <sup>2</sup> ) equipped with one temperature transmitter used to indicate the Eluent temperature after the heat exchanger.
<b>Filter on eluent</b>	10	<ul style="list-style-type: none"> <li>- One low volume high pressure filters. Equipped with a mesh woven frit (2 µm relative porosity, 5µm absolute porosity). A quick release chain eases the replacement of the frit.</li> <li>- One pressure sensor used to calculate pressure drop across the Eluent filter (to detect filter clogging).</li> <li>- Four pneumatic 2-way diaphragm valves. Used to bypass the filter.</li> </ul>
<b>Injection loop</b>	11	Five pneumatic 2-way diaphragm valves used to fill, flush and by-pass the injection loop (3 mL). One manual diaphragm valve used to generate a small pressure drop after the filling pump.
<b>pH and Conductivity</b>	37	One pH probe (1 to 14 pH unit) and one conductivity probe (1µS/cm to 500mS/cm with temperature monitoring) located after the column.

Sensors accuracy:

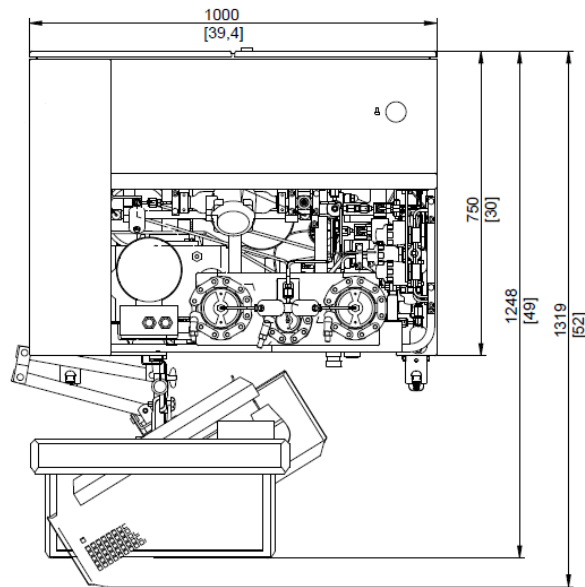
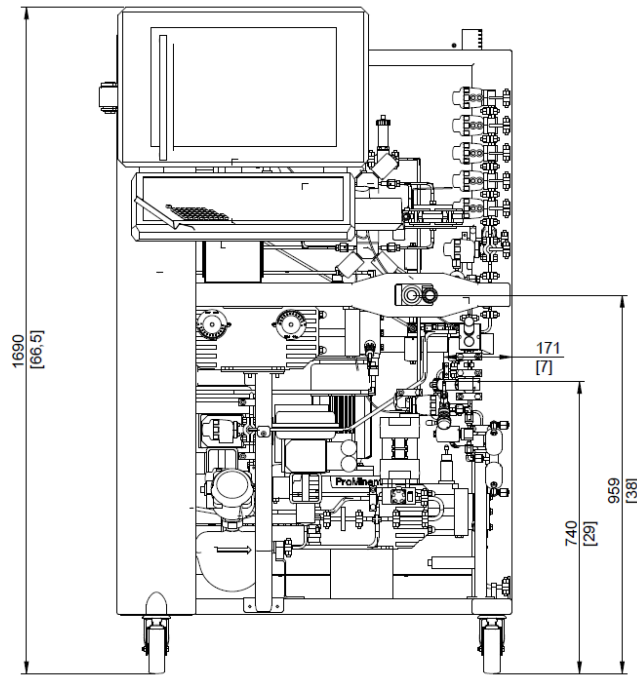
<b>DESCRIPTION</b>	<b>SPECIFICATION</b>
<b>Pressure</b>	±2% of the FS
<b>Mass Flowrate</b>	±0.2% (Flow meter accuracy)
<b>Temperature</b>	±2% of the FS
<b>UV Detector</b>	Wavelength accuracy < 1nm Wavelength reproducibility < 0.05 nm Baseline drift < 5 x 10E-04 AU/h* Noise < 1 x 10E-04 AU* * tested according to ASTM E685
<b>pH</b>	±0.15pH unit
<b>Conductivity</b>	±5% of the FS

## 4. SYSTEM DIMENSIONS

DESCRIPTION	SPECIFICATION
Footprint W x L x H (mm)	1000 x 750 x 1690
Weight	From 400 kg to 500 kg Depending of the selected options
Hold-up Volume (mL)	150 approx.
Electrical Cabinet Location	Embedded into the skid
Distance between Electrical cabinet & the system (only when remote cabinet option is selected)	N/A (Electrical cabinet is embedded into the skid)
Distance between Electrical cabinet & the supervision (only when remote supervision option is selected)	140m
Automation Device Location	In the electrical cabinet
HMI Display Location	Refer to selected system configuration



System drawings:



NB: Dimensions are in mm & Inches (may be subject to modification)  
Mechanical drawings for information, can vary according to selected configuration.

## 5. ENVIRONMENTAL RANGES

### Operating environment:

DESCRIPTION	SPECIFICATION
Ambient temperature range	10-25°C
Humidity	20% to 70% Rh (non-condensing)

### Enclosure Protection Class:

DESCRIPTION	SPECIFICATION
Version	<b>European version</b>
Main Electrical Cabinet - Electrical Protection Classes	IP55
Field Mounted Electrical parts - Electrical Protection Classes	IP66

### Electrical requirements:

DESCRIPTION	SPECIFICATION
Version	<b>European version</b>
Voltage Type AC/DC	AC
Nominal Power supply	230V
Frequency	50 Hz
Power required	3.7 kW
Phase Numbers	1 phase
Switching current capacity (kA r.m.s)	55
Short-circuit current rating SCCR (kA)	N/A
Neutral System / Distributed	TN-S

Process utilities requirements:

DESCRIPTION		SPECIFICATION
Process fluids	Pressure	Operating pressure: 100 barg max Inlets: 0.5 barg min to 0.7 barg max Outlets: >0 and <1 barg
	Capacity	6 to 90 L/h
	Quality	2 µm filtered
	Temperature	Operating range: 5-65°C (65°C after heat exchanger only, max 60°C before heat exchanger)
Compressed Air pressure	Pressure	6 barg
	Capacity	Instrumentation: 0.33 Nm <sup>3</sup> /h Electrical cabinet pressurization: 6 Nm <sup>3</sup> /h
	Quality	40 µm filtered, oil free & dry
	Temperature	10-30°C
Heat Exchanger Fluid	Pressure	6 barg max Pressure drop of 0,7 bar at 1m <sup>3</sup> /h of water
	Capacity	2 m <sup>3</sup> /h
	Quality	Clean
	Temperature	<b>Heat-transfer fluid: 0-90°C</b> <b>Process fluid: 5-65°C after heat exchanger</b>

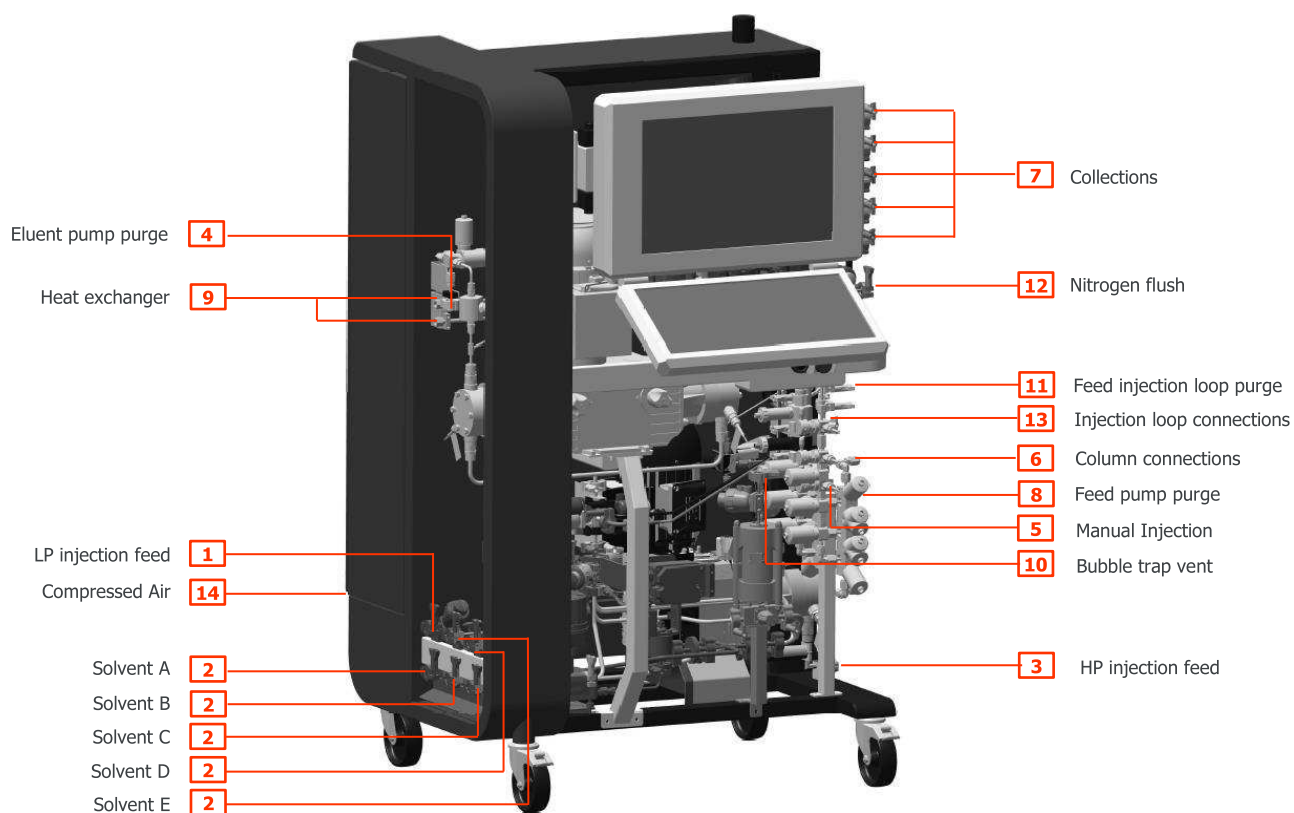
## 6. MATERIALS OF CONSTRUCTION









DESCRIPTION	SPECIFICATION
Tubing material	Stainless Steel 316L
Frame	Stainless Steel 304 Painted Stainless Steel (powder coating)
Gasket Material & other Wetted Part	Stainless Steel (316 & 316L), PTFE, PCTFE, FEP, Kalrez® FFKM, Quartz, Glass
Electrical cabinet	Embedded version: Painted Stainless steel
Tubing internal roughness	< 0.8 $\mu\text{m}$ Ra (32 $\mu\text{-inches}$ Ra)
Valves internal roughness	< 0.8 $\mu\text{m}$ Ra (32 $\mu\text{-inches}$ Ra)
Pumps internal roughness	< 0.8 $\mu\text{m}$ Ra (32 $\mu\text{-inches}$ Ra)
Frame external roughness	Grit 200 (about 1.6 $\mu\text{m}$ Ra / 62 $\mu\text{-inches}$ Ra)
Pipe & Welding Specification	Refer to Novasep URS CC-866 if applicable
Passivation Procedure	Refer to Novasep URS CC-1078 & CC-1042 if applicable
Insulation	No operator protection or insulation on the system, it will be provided and installed by customer after system installation.
Tagging	Color: silver. Material: polyester with solvent resistant protective film.

## 7. STANDARDS & NORMS

DESCRIPTION	SPECIFICATION
Version*	<b>European version</b>
Electrical Design	EC Machine Directive EC Low Voltage Directive EC Electro Magnetic Compatibility Directive
Explosion proof design (Depending of the selected options)	ATEX Zone 2  II 3G IIB T4
Material certificates for wetted parts	3.1 for stainless steel FDA for polymers BSE/TSE free
Software & Automation standards	GAMP guidelines and FDA CFR 21 Part 11 regulations
Tagging	English language. Compliant with UL/CSA, 2005/618/EC MCV amendment to RoHS Directive 2002/95/EC
Documentation provided	Refer to Novasep Quality Plan ISO-MANL

## 8. MECHANICAL INTERFACE CONNECTIONS



TYPE	ITEM	DESCRIPTION	
<b>Solvents inlets (A, B, C, D, E)</b>	<b>2</b>	3/8" Micro clamp	
<b>LP &amp; HP Injection Feed</b>	<b>1 &amp; 3</b>	3/8" Micro clamp	
<b>Pump &amp; Injection loop Purges</b>	<b>4, 8 &amp; 11</b>	1/4" Micro clamp	
<b>Manual Injection</b>	<b>5</b>	Standard syringe fitting – Luer-Lok™ Fitting	
<b>Column &amp; Injection loop connections</b>	<b>6 &amp; 13</b>	1/4" Metal Gasket Face Seal Fittings	
<b>Collection valves (2 to 10)</b>	<b>7</b>	1/4" Micro clamp	
<b>Heat Exchanger</b>	<b>9</b>	1/4" NPT female	
<b>Bubble trap vent Nitrogen flush</b>	<b>10 &amp; 12</b>	1/4" Micro clamp	
<b>Compressed Air</b>	<b>14</b>	One quick connect 10 mm for instrument supply One additional connection for Explosion proof design	

## 9. OPERATOR INTERFACE

### Software:

DESCRIPTION	SPECIFICATION
<b>Software Philosophy</b>	Novasep has based its control software on industrial SCADA-PLC configuration in order to provide easy, flexible and intuitive control software solution for end-users. Novasep strives to provide the highest industry standard.
<b>Software languages</b>	User interface is available in English.
<b>Software documentation</b>	<p>Control software Technical Description</p> <p>21CFR part11 White paper</p> <p>Novasep Quality Plan ISO-MANL</p>
<b>Software validation package NVS21363 (Optional)</b>	<p>CD-ROM of the validation activities under the responsibility of the supplier from design documents to software release and including:</p> <ul style="list-style-type: none"> <li>- Novasep validation procedures</li> <li>- Functional specification</li> <li>- Software design specification</li> <li>- Software risk analysis</li> <li>- Traceability matrix</li> <li>- Software validation document protocol</li> <li>- Executed tests and results</li> <li>- Software validation document report</li> <li>- Software validation certificate</li> </ul>

Automation communication:

DESCRIPTION	SPECIFICATION
Software	Hipersep® SC, Novasep Software Version V13
Operating System (OS)	Windows® 10
Siemens Controller	S7-1507S
Data exchange	Novasep software is set-up to send data (read) towards external system. Novasep provides an Ethernet connection and OPC communication for historical trends and alarms exchange.
Domain controller	The user administration is done on windows active directory
Time synchronization	The time synchronization is connected to a network time source via NTP

Automation interface:

DESCRIPTION	SPECIFICATION
Automation interface	One Digital input dry contact (DI) for remote Power off. One Digital input dry contact (DI) for remote Process stop. One Digital output dry contact (DO) for status of the unit (RUN or STOP).

Manual interaction devices:

DESCRIPTION	SPECIFICATION
Power supply	Main switch located on the electrical cabinet.
Emergency stop	Shut down the chromatography system in case of emergency.
Reset button	Reset the power supply once emergency stop button is disengaged.



## 10. SPARE PARTS KITS & ACCESSORIES

### Spare parts:

NVS CODE	Qty	DESCRIPTION	Recommended kit qty for full option
<b>NVS32796 Pump Maintenance kit type PRO 35022/35024/35019 (for Eluent and Feed pumps)</b>			
	1	PTFE membrane for the Eluent & Feed pumps	
	1	Check valve for the Eluent & Feed pump inlet	3
	1	Check valve for the Eluent & Feed pump outlet	
<b>NVS32828 Filter Maintenance kit type NVS 77.5</b>			
	3	Ø77 mm SS316L mesh woven frit for eluent filter (2 µm)	
	6	O-ring for eluent filter	1
	12	O-ring for eluent filter	
<b>NVS32793 Filter Maintenance kit type NVS 47</b>			
	3	Ø47 mm SS316L mesh woven frit for feed filter (2 µm)	
	6	O-ring for feed filter	1
	12	O-ring for feed filter	
<b>NVS32806 UV Maintenance kit type JM</b>			
	1	Deuterium lamp for UV detector	1
<b>NVS32831 pH Maintenance kit type HM VP/120Ex</b>			
	1	pH Electrode 0 – 14 pH units	1
<b>NVS32832 Cd Maintenance kit type HM VP/120Ex</b>			
	1	Conductivity probe 1 µS/cm to 500 mS/cm	1
<b>NVS32830 Valve Maintenance Kit type BK 2031</b>			
	4	PTFE membrane for low pressure valves	7
<b>NVS35028 Pump Oil kit</b>			
	20	Oil for Eluent & Feed pump (FDA grade)	1

### Accessories:

NVS CODE	DESCRIPTION
<b>NVS35271</b>	<b>Piping kit Hipersep® Pilot Outlet 1/4" Tri-Clamp®</b>
	Set of 2 FDA PTFE flexible hoses explosion proof + tri-clamp collars + seals and caps + certificates
<b>NVS35272</b>	<b>Piping kit Hipersep® Pilot Inlet 3/8" Tri-Clamp®</b>
	Set of 2 FDA PTFE flexible hoses explosion proof + Tri-Clamp® collars + seals and caps + certificates
<b>NVS35465</b>	<b>Piping kit Hipersep® Pilot Column</b>
	Set of 2 FDA PTFE flexible hoses 1/4" + 3 meters of FDA PEEK flexible hoses 1/8" + certificates
<b>Contact us</b>	<b>Thermal Control unit for Hipersep® Pilot</b>

## 11. SERVICES

Novasep offers a large range of services:

- FAT
- Installation assistance
- SAT
- IQ/OQ protocol and execution
- Services contracts
- Upgrade (hardware and software)
- Trainings (theoretical and practical)

To know more and receive a quotation, please contact your local representative.



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