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	Doc#: BGL-IS-ATT-000055	Revision: 1
Service ID: 171473	Instrument: CliniMACS Prodigy S/N: 275	Date: 26.Mar.2024

Service report

Customer		Instrument	
Address	Az. Osp. Santobono-Pausilipon	Current software ver.	1.4.30 (build 184)
	Dr. Mario Toriello	Ownership	Sold
	Ospedale Pausilipon - 2.piano	Cost center	3270
	Banca Sangue Cordonale - BASCO	Service coverage	Essential Service
	MANIPOLAZIONI	Coverage valid till	30.Nov.2025
Via Posillipo 226			
IT 80123 Napoli			
Phone No.	0812205511	Customer asset ID	N/A

Service Type
Maintenance

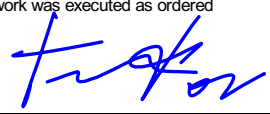
Reason for Service / Customer request	Complaint No.	N/A
Annual maintenance (Service plan 622430 - 1 of 2, 01.12.2023 - 30.11.2025) FCA-61 - Light protection sticker FCA-64 - Manage Apps FCA-63 - Drum Run Duration Counter		

Failure description
N/A

Service activities
Performed annual maintenance following the procedure, performed electrical safety check and correct functioning check. Successful. Performed Software update 1.4.38 - FCA-61_Light_protection_sticker - fca-64_Rev01_Manage_Apps.

Measuring equipment				
Equipment type	ID#	Manufacturer / model	Last calibration date	Calibration valid till
Electrical Safety Tester	59114	Benning ST 710	8.May.2023	7.May.2024
Pin Gauge	68100	Veith Pin Gauge - 2.1mm	20.Apr.2022	N/A
Pin Gauge	68101	Veith Pin Gauge - 2.3mm	14.Apr.2022	N/A
Pocket balance	59102	KERN & Sohn GmbH CM 320-1N	19.Oct.2023	18.Oct.2024

Labor time					
Service Engineer	Service date	Time started	Time finished	Labor time (hrs.)	Travel time (hrs.)
Luca Vigilante	26.Mar.2024	09:00	13:30	4,5	2

Confirmation		
Service accomplished successfully	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Service work was executed as ordered 
Device released for further use	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
Napoli	26.Mar.2024	 Signature of Engineer
Location	Date	



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Spare parts consumption

Material No.	Description	Pos	Qty.	Lot No.	S/N
200-075-723	Hood Light Protection Cover	N/A	1	6230300448	N/A
200-075-721	CMPR Maintenance Kit	N/A	1	6230600086	N/A

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CliniMACS Prodigy Service Protocol

1 - Decontamination

Test / activity	Result
Perform decontamination	<input checked="" type="checkbox"/> done <input type="checkbox"/> N/A

2 - Visual Inspection

Test / activity	Result
Perform a visual inspection and note findings	<input checked="" type="checkbox"/> done
Check if gas lines are correctly labelled	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail

3 - Initialization

Test / activity	Result
No errors on startup. All components initialize correctly.	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail
Drum rotation counter: 74382481	<input checked="" type="checkbox"/> done

4 - Software update


Test / activity	Result
Perform an Instrument check without failed tests	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail
Backup logfiles and IR sensor adjustment values	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail
Reboot instrument. No errors on startup. All components initialize correctly.	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail
Current software version: 1.4.30 (build 184) Update to software version: 1.4.38 (build 20)	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail
For SW 2.X and installed Application Services: Installation of Application Services version: 1.4	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> N/A
For SW 2.X and activated User Management: Creation of an admin account	<input type="checkbox"/> pass <input type="checkbox"/> fail <input checked="" type="checkbox"/> N/A
For SW ≥ 2.1 and network connectivity: Check of network connection (Ping from connected customer computer)	<input type="checkbox"/> pass <input type="checkbox"/> fail <input checked="" type="checkbox"/> N/A
Reboot instrument. No errors on startup. All components initialize correctly.	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail
Software version ≥1.4.19: Check of matching software versions "Build" and "ICC version"	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail
Perform an Instrument check without failed tests	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail
Reboot instrument. No errors on startup. All components initialize correctly.	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail
Hand out the release notes to the customer	<input checked="" type="checkbox"/> done <input type="checkbox"/> N/A
Hand out customer information "User Management and Audit Trail" and keyboard to the customer (for SW version 2.X)	<input type="checkbox"/> done <input checked="" type="checkbox"/> N/A
Hand out customer information "Network connectivity" to the customer (for SW version ≥2.1)	<input type="checkbox"/> done <input checked="" type="checkbox"/> N/A

5 - Yearly PM: Activities

Test / activity	Result
Exchange PM parts: Heat Exchange Coupling Foil, Silicone Gasket 7.5 mm, Silicone Gasket 5 mm and Red O-Ring	<input checked="" type="checkbox"/> done
Exchange drive belt of chamber drive unit	<input type="checkbox"/> done <input checked="" type="checkbox"/> N/A
Exchange supplementary bag (if expired)	<input type="checkbox"/> done <input checked="" type="checkbox"/> N/A
Magnet Unit: grease ball bearings with Molykote	<input checked="" type="checkbox"/> done <input type="checkbox"/> N/A
Clean pump interior (surface and pressure sensors)	<input checked="" type="checkbox"/> done
Clean chamber drive unit	<input checked="" type="checkbox"/> done
TCU: Clean Inner Heat Sink, fans and cooling fins	<input checked="" type="checkbox"/> done
Check if 8 screws of Chamber Drive Unit cover are tightened	<input checked="" type="checkbox"/> done

6 - CPU Time

Test / activity	Result
Time of both CPUs matches	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail
Time adjusted	<input type="checkbox"/> done <input checked="" type="checkbox"/> N/A

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7 - Buzzer

Test / activity	Result
Buzzer emits loud alarm signal	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail

8 - Speaker / USB

Test / activity	Result
Speaker produces sound when USB stick is plugged in (4x)	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail

9 - Sensors

Test / activity	Result
Liquid sensor values change from 1=no liquid to 0=liquid and back	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> N/A

10 - Magnet Unit

Test / activity	Result
Magnet moves smoothly to front position and back	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail

11 - Pump Unit

Test / activity	Result
Adjustment of pump gap	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> N/A
Alignment of sensor disc	<input checked="" type="checkbox"/> done <input type="checkbox"/> N/A
Pump lid sensor value changes from 0=closed to 1=open and back	<input type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> N/A
Pump rotation sensor value alternates between <1> and <0>	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> N/A
Pump turns cw and ccw. Audible difference between speed 1999 and 2000.	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> N/A
Pump immediately stops rotating when lid is opened. Error message is displayed.	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail <input type="checkbox"/> N/A

12 - Chamber Drive Unit


Test / activity	Result
Adjustment of hood mechanic	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail
Built-in drive shaft identified and set in the system	<input checked="" type="checkbox"/> done <input type="checkbox"/> N/A
Chamber lock state switches from 0=not locked to 1=locked and back	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail
Motion controller indicates rotation speed of 2500 ± 100 rpm	Measured value: 2500 rpm <input checked="" type="checkbox"/> pass <input type="checkbox"/> fail

13 - Valves

Test / activity	Result
Pressure hold test	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail
All valves close & open at the same time without any problems (with tubes inserted)	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail

14 - Microscope Camera

Test / activity	Result
Clean lens with lint-free cloth and Isopropanol 99 %	<input checked="" type="checkbox"/> done
Microscope shows clear image without dust or dirt particles	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail
Microscope shows clear and sharp image (with Testchamber 320-004-743)	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail

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15 - Upper Chamber Adapter

Test / activity	Result
All FLL-Line LEDs working	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail
All FLL-Ring LEDs working	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail
Test trigger: FLL-Line flashes	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail
Heater temperature rises to 400 in mode "heating"	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail

16 - Interlayer Camera

Test / activity	Result
Clean lens with lint-free cloth and Isopropanol 99 %	<input checked="" type="checkbox"/> done
Focus adjustment	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail
Red marks aligned to calibration marks on chamber	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail

17 - Temperature Conditioning Unit

Test / activity	Result
All fans rotate (Chamber, TEC Tower and TEC board)	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail
Maximum difference of 2.0 °C between lowest and highest sensor value T _{low} : 29,6 °C T _{high} : 30,1 °C	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail
Cooling / heating test successful	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail

18 - Baghanger Illumination

Test / activity	Result
Light sequence: red – green – blue – yellow – white – bright white	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail

19 - Barcode Reader

Test / activity	Result
Reference barcodes scanned correctly	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail

20 - Tube Sealer


Test / activity	Result
Test tubing completely sealed	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail

21 - External alarm socket

Alarm contact	Acceptance criteria	Result
Alarm contact 1 state "1", Alarm contact 2 state "1"	Red LED is on	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail
Alarm contact 1 state "1", Alarm contact 2 state "0"	Red LED is on	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail
Alarm contact 1 state "0", Alarm contact 2 state "1"	Blue and Yellow LED is on	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail
Alarm contact 1 state "0", Alarm contact 2 state "0"	Blue and Green LED is on	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail

22 - Gas Mixing Block

Test / activity	Result
Line pressure 1.0 - 2.5 bar Pressure comp. air: N/A Pressure CO ₂ : N/A Pressure N ₂ : N/A	<input type="checkbox"/> pass <input type="checkbox"/> fail <input checked="" type="checkbox"/> N/A
Pressure hold test passed (-50 ml/h > Leakage flow <= 50 ml/h)	Leakage flow: N/A <input type="checkbox"/> pass <input type="checkbox"/> fail <input checked="" type="checkbox"/> N/A
CO ₂ concentration: 5.0 % - acceptance criteria: 4.0% - 6.0%	CO ₂ concentration: N/A <input type="checkbox"/> pass <input type="checkbox"/> fail <input checked="" type="checkbox"/> N/A
Set standard parameter	<input type="checkbox"/> done <input checked="" type="checkbox"/> N/A
Check default settings under FRAMrd	<input type="checkbox"/> done <input checked="" type="checkbox"/> N/A

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23 - CliniMACS Formulation Unit

Test / activity	Result
All valves close & open at the same time without any problems (with tubes inserted)	N/A
All valves close & open consecutively without any problems (with tubes inserted)	N/A
Water filled tube detected by liquid sensor	N/A

24 - Electrical safety test according to DIN VDE 0701-0702

Test item	Specification	Measured value	Result
Protective Earth Resistance	< 0,3 Ω	0,08 Ω	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail
Insulation Resistance	> 1 MΩ	19,87 MΩ	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail
Auxiliary Leakage Current	< 3,5 mA	1,0 mA	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail

25 - Test run (T_CAM_Pro)

Test item	Specification	Measured value	Result
Calibration marks	Minimum 3 calibration marks found	5	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail
Pixel offset <small>(only applicable for SW version ≤ 1.2.1)</small>	Pixel offset = 100 +/- 30	N/A	<input type="checkbox"/> pass <input type="checkbox"/> fail <input checked="" type="checkbox"/> N/A
Volume test	Volume test OK	N/A	<input checked="" type="checkbox"/> pass <input type="checkbox"/> fail

26 - Labeling

Test / activity	Result
Attach next maintenance label	<input checked="" type="checkbox"/> done <input type="checkbox"/> N/A