

Freigabe von Geräten für den Routinebetrieb

Datum: 18.05.22

Vorgangstyp:

- Störung
- Wartung
- Software Update
- Sonstiges (bitte unten beschreiben)

Durchgeführt von:
(Firma/Servicetechniker/Mitarbeiter)

Bruker Diagnostics/

Gerät(e):

Malditof

Inventarnummer(n):

MIK/A/0036
MIK/A/0037

Durchgeführte Arbeiten:
(ggf. Servicebericht)

Jährliche Wartung gemäss Dokument Nr. 5023971

**Technische Freigabe
durch Geräteverantwortlichen bzw.
Mitarbeiter am Arbeitsplatz:**
(Datum / Uhrzeit / Name / Unterschrift)

11.05.22

16.00 Uhr

Datum

Uhrzeit

Name

Unterschrift

Freigabe durch die Leitung:
(Datum / Name / Unterschrift)

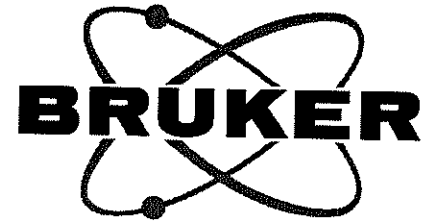
11.05.22

Datum

Name

Unterschrift

Bruker Daltonik MALDI Biotyper Klassifikationsergebnisse



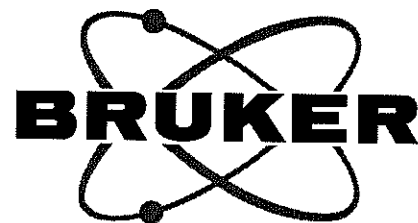
Projektinfo

Projekt-ID: 220510-1040-101111111111
 Kommentar:
 Projekt erzeugt von: tof-user@MGA-MALD01
 Projekt erzeugt am: 2022-05-10T10:54:08.476
 Anzahl der Analyten: 7
 Typ: Standard
 Validierung: erfolgreich
 Validierungsposition: A3:0
 Instrument-ID: 269944.00430
 Server Version: 4.1.100 (PYTH) 174 2019-06-158_01-16-09

Ergebnisübersicht

Analyt-Name	Analyt- ID	Organismus (bester Treffer)	Bewertungs- zahl	Organismus (zweitbester Treffer)	Bewertungs- zahl
<u>A1</u> (+++)(A)	1 (Standard)	<u>Escherichia coli</u>	<u>2.35</u>	<u>Escherichia coli</u>	<u>2.28</u>
<u>A2</u> (+++)(A)	1 (Standard)	<u>Escherichia coli</u>	<u>2.33</u>	<u>Escherichia coli</u>	<u>2.26</u>
<u>A3</u> (+++)(A)	BTS (BTS)	<u>Escherichia coli</u>	<u>2.28</u>	<u>Escherichia coli</u>	<u>2.25</u>
<u>A4</u> (+++)(A)	1 (Standard)	<u>Escherichia coli</u>	<u>2.36</u>	<u>Escherichia coli</u>	<u>2.31</u>
<u>A5</u> (+++)(A)	1 (Standard)	<u>Escherichia coli</u>	<u>2.35</u>	<u>Escherichia coli</u>	<u>2.31</u>
<u>A6</u> (+++)(A)	1 (Standard)	<u>Escherichia coli</u>	<u>2.26</u>	<u>Escherichia coli</u>	<u>2.24</u>
<u>A8</u> (+++)(A)	1 (Standard)	<u>Escherichia coli</u>	<u>2.54</u>	<u>Escherichia coli</u>	<u>2.35</u>

Bruker Daltonik MALDI Biotyper Klassifikationsergebnisse



Projektinfo

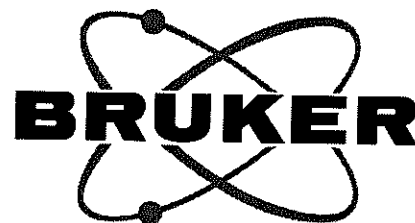
Projekt-ID: 220511-1212-1011112222222
 Kommentar:
 Projekt erzeugt von: tof-user@MGA-MALD01-PC
 Projekt erzeugt am: 2022-05-11T12:58:52.434
 Anzahl der Analyten: 7
 Typ: Standard
 Validierung: erfolgreich
 Validierungsposition: B1:0
 Instrument-ID: 269944.00051
 Server Version: 4.1.100 (PYTH) 174 2019-06-158_01-16-09

Ergebnisübersicht

Analyt-Name	Analyt- ID	Organismus (bester Treffer)	Bewertungs- zahl	Organismus (zweitbester Treffer)	Bewertungs- zahl
<u>B1</u> (+++)(A)	BTS (BTS)	<u>Escherichia coli</u>	<u>2.31</u>	<u>Escherichia coli</u>	<u>2.26</u>
<u>B2</u> (+++)(A)	1 (Standard)	<u>Escherichia coli</u>	<u>2.35</u>	<u>Escherichia coli</u>	<u>2.35</u>
<u>B3</u> (+++)(A)	1 (Standard)	<u>Escherichia coli</u>	<u>2.27</u>	<u>Escherichia coli</u>	<u>2.26</u>
<u>B4</u> (+++)(A)	1 (Standard)	<u>Escherichia coli</u>	<u>2.33</u>	<u>Escherichia coli</u>	<u>2.33</u>
<u>B5</u> (+++)(A)	1 (Standard)	<u>Escherichia coli</u>	<u>2.30</u>	<u>Escherichia coli</u>	<u>2.29</u>
<u>B6</u> (+++)(A)	1 (Standard)	<u>Escherichia coli</u>	<u>2.31</u>	<u>Escherichia coli</u>	<u>2.28</u>
<u>A8</u> (+++)(A)	1 (Standard)	<u>Escherichia coli</u>	<u>2.36</u>	<u>Escherichia coli</u>	<u>2.35</u>

Bruker Daltonik MALDI Biotyper

Klassifikationsergebnisse



Projektinfo

Projekt-ID: 220511-1755-101222222222233
 Kommentar:
 Projekt erzeugt von: tof-user@MGA-MALD01-PC
 Projekt erzeugt am: 2022-05-11T18:10:41.288
 Anzahl der Analyten: 7
 Typ: Standard
 Validierung: erfolgreich
 Validierungsposition: C1:0
 Instrument-ID: 269944.00051
 Server Version: 4.1.100 (PYTH) 174 2019-06-158_01-16-09

Ergebnisübersicht

Analyt-Name	Analyt- ID	Organismus (bester Treffer)	Bewertungs- zahl	Organismus (zweitbester Treffer)	Bewertungs- zahl
<u>C1</u> (+++)(A)	BTS (BTS)	<u>Escherichia coli</u>	<u>2.28</u>	<u>Escherichia coli</u>	<u>2.24</u>
<u>C2</u> (+++)(A)	1 (Standard)	<u>Escherichia coli</u>	<u>2.27</u>	<u>Escherichia coli</u>	<u>2.19</u>
<u>C3</u> (+++)(A)	1 (Standard)	<u>Escherichia coli</u>	<u>2.28</u>	<u>Escherichia coli</u>	<u>2.23</u>
<u>C4</u> (+++)(A)	1 (Standard)	<u>Escherichia coli</u>	<u>2.28</u>	<u>Escherichia coli</u>	<u>2.26</u>
<u>C5</u> (+++)(A)	1 (Standard)	<u>Escherichia coli</u>	<u>2.31</u>	<u>Escherichia coli</u>	<u>2.30</u>
<u>C6</u> (+++)(A)	1 (Standard)	<u>Escherichia coli</u>	<u>2.23</u>	<u>Escherichia coli</u>	<u>2.22</u>
<u>C7</u> (+++)(A)	111 (Standard)	<u>Escherichia coli</u>	<u>2.36</u>	<u>Escherichia coli</u>	<u>2.34</u>

Service-Bericht

Terminnummer SA-0124994

Bruker Daltonics GmbH & Co. KG
Fahrenheitstrasse 4
28357 Bremen
Deutschland



Kunde und Referenzen

End Customer Kundenvorgangs-Nr. BRKR-0351226

Adresse Bestell-Nr.

Kontakt SAP-Auftrags-Nr. 7368512
Berechnungskat. Contract

Details zum Asset

System microflex LT/SH Ende der Garantie 01.11.2013

Equipment-Nr. 11822977 Servicevertrag 55029228

Seriennummer 269944.00430 Servicevertragstyp Complete Care MBT

System-Status Operational Servicevertrag 31.12.2022
Enddatum

Informationen zum Termin

Betreff Contract PM 2022

Beschreibung Contract PM 2022

Diagnose / Jährliche Wartung gemäss Dokument Nr. 5023971
Getroffene

Maßnahmen /
Lösung

Vor-Ort-Besuch Yes
erfolgreich?

Arbeitsauftragspositionen

Beschreibung	Ja/Nein	Kommentar	System-Status	Datum	Uhrzeit
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Teile und Material

MatNr.	Bezeichnung	Alte Seriennummer	Neue Seriennummer	Parts Usage	Description
1827857	Maintenance kit, Microflex SH			Consumed	

Zeiterfassung

Datum	Arbeitszeit	Entfernung	Entfernung Meilen/Kilometer	Kommentar/Aktion	Übernachtung
09.05.2022	4,00	100,00	km	PM 2022	<input type="checkbox"/>
10.05.2022	3,00	50,00	km	PM 2022	<input type="checkbox"/>

Service-Bericht

Terminnummer SA-0124994

Unterschrift des Kunden

Signatur



Unterzeichner

Datum 11.05.2022 14:38

Typ Customer

Unterschrift des Servicemitarbeiters

Signatur



Unterzeichner

Datum 11.05.2022 14:17

Typ Field Service Agent

REF

1837645	8269956	8604562	8604784
1853665	8600302	8604673	8605089
1853670	8601800	8604736	8605200
1861000	8603464	8604743	8604784-
8265682	8604561	8604758	BD



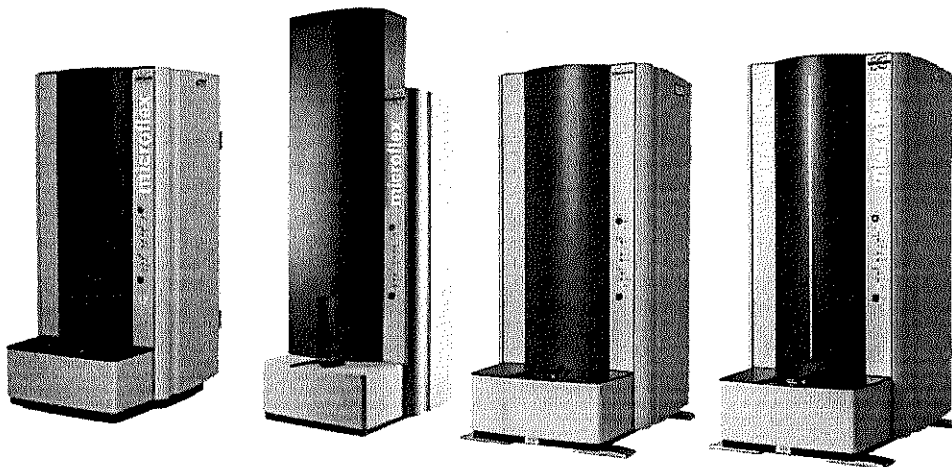
Planned Maintenance

microflex MALDI-TOF Series

Valid only for instruments with the following serial numbers:

Instrument	Serial No.	Part No.
microflex smart LS	ALL	1863882
microflex LT/SH	ALL	8269944 / 8604674
microflex LRF	ALL	8256969 / 8601800
microflex LT/SH smart	ALL	8604832
microflex LT; microflex LT60	ALL	8254472
microflex LRF20 (late)	Dec 2008 onwards	8227917

(valid for DAL00307 and DAL08151)



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Purpose:

This document provides a protocol that verifies and records the Planned Maintenance (PM) of analytical instruments installed by Bruker Daltonics GmbH & Co. KG.

Language: en

Contents

1 Document History	3
2 Purpose	4
3 Failure to Meet Specifications	4
4 Glossary	5
5 Customer Responsibilities	5
6 Planned Maintenance	6
6.1 Declaration of Contamination	6
6.2 Verification of Instrument Problems	6
6.3 Visual Check	6
6.4 Software Status	7
6.5 Vacuum System Check	9
6.6 Performance Check 1	9
6.7 Day 1 instrument assessment for parts replacement	11
6.8 Cooling System	12
6.9 Vacuum System	13
6.10 Laser and Ion Optics	14
6.11 X-Y-Stage	15
6.12 Function Test	16
6.13 High Voltage	17
6.14 Detector Check 2	18
6.15 Performance Check 2	19
6.16 MALDI Biotyper Performance Verification	21
6.17 Safety Check	23
6.18 Finish	23
Appendix A — Equipment Needed for Maintenance	24
Appendix B — Declaration of Contamination	25
B.1 Introduction	25
B.2 Declaration of contamination	25

1 Document History

Revision	Date	Changes	TPS Approval
1.0	28.10.2004	First revision	Dirk Eisentraut
2.0	14.02.2006	LT system added	Dirk Eisentraut
2.1	28.07.2006	Improved vacuum system maintenance	Dirk Eisentraut
3.0	11.05.2007	Adapting to Rev. 3 of validation docs	Dirk Eisentraut
3.1	18.04.2008	Laser air filter exchange added, service interval rough pump increased	Dirk Eisentraut
4.0	07.10.2009	Change to LT60 and LRF60 and update specs	Justin Clark
5.0	26.01.2012	Addition of microflex LT/SH	Justin Clark
6	02.04.2013	DAL number updated / Part numbers updated	Justin Clark
G	02.03.2017	Change of name: PM -> Planned Maintenance; LT/SH smart + LRF20 (late) added; Addition of MALDI Biotyper Validation Check	Karsten Krämer
H	10.04.2018	Editorial change to Declaration of Contamination, new pre-vacuum settings, remove measurement of Protein A, 44kDa, remove signature boxes pages 5 through 19, revise STAR-BL check, replace Protocol Approval page with Planned Maintenance Record pages in 21 languages	Karsten Krämer
I/J	11.01.2021	Skipped Revision I/J	Karsten Krämer
K	10.02.2021	Added microflex smart LS, changed rough vacuum check values to 4.0 mbar, changed rough vacuum set values to 10 mbar, removed validation of FAST measurement for LRF instruments, changed maximum step loss values for X/Y motors to 250 µm, added new section "Day1 instrument assessment for parts replacement". Added Planned Maintenance Record pages in 4 additional languages. Added: Negative Ion-Analysis for lin./ref. mode (LRF only)	Karsten Krämer
K1	08.07.2021	Change of legal manufacturer to Bruker Daltonics GmbH & Co. KG	Karsten Krämer

The following table describes important changes from the previous revision of this document:

Section	Changes
6.5.1	Added microflex smart LS, changed rough vacuum check values to 4.0 mbar.
6.6.4	Removed validation of FAST measurement for LRF instruments.
6.9.5	Changed rough vacuum set values to 10 mbar.
6.11.2	Changed maximum step loss values for X/Y motors to 250 µm.
6.7	Added new section "Day1 instrument assessment for parts replacement".
6.6.1.1 / 6.15.1.1	Added new section "Negative Ion Analysis (LRF only)"
6.6.2.1 / 6.15.2.1	Added new section "Reflector negative Ion Analysis"

2 Purpose

Planned maintenance (PM) is a factory-recommended procedure designed to reduce the likelihood of electro-mechanical failures. Failure to perform planned maintenance may reduce the long-term reliability of certain instruments and systems.

3 Failure to Meet Specifications

Any failure to meet specifications during the Planned Maintenance must be documented when it occurs and reviewed by a Bruker Daltonics GmbH & Co. KG representative. Such failures will be investigated and the appropriate course of action will be taken if the instrument and failure are covered under warranty or contractual agreement. If no contractual agreement is in force, an acceptable course of action will be agreed upon by the customer and Bruker Daltonics GmbH & Co. KG.

4 Glossary

Planned Maintenance

Documented schedule of planned maintenance actions aimed at the prevention of breakdowns and failures. The primary goal of planned maintenance is to prevent the failure of equipment before it actually occurs. It is designed to preserve and enhance equipment reliability by replacing worn or malfunctioning components before they actually fail. Planned maintenance activities include equipment checks, partial or complete overhauls at specified periods, lubrication and so on. In addition, Service Engineers can record equipment deterioration to highlight the replacement or repair of worn parts before they cause system failure.

5 Customer Responsibilities

Before starting the Planned Maintenance the customer must complete and sign a "Declaration of Contamination" for the instrument or single assemblies. The customer is responsible for the disposal of material which is replaced during the Planned Maintenance.

The following consumables / equipment should be made available by the customer:


- Precision paper wipes (lint-free)
- Cleaning alcohol available at customer sites, no reagent grade alcohol, denatured alcohol or methanol)
- If the system is used as Biotyper, the correct dissolved BTS for system optimisation is needed:
 - RUO BTS # 8255343 or
 - IVD BTS # 8290190 or
 - US IVD BTS # 8604530
- If STAR-BL is used:
 - Dissolved MBT STAR Calibrator (Antibiotic Calibration Standard) # 1853031 MBT STAR-BL Service Kit or
 - MBT STAR-Carba IVD Kit # 1848467

6 Planned Maintenance

Description		N/A, PASS or FAIL	INITIAL
6.1	Declaration of Contamination		
6.1.1	Declaration of Contamination completed and signed by customer (see Appendix B)	PASS	CSch
6.1.2	Comments (Declaration of Contamination)		CSch
6.2	Verification of Instrument Problems		
6.2.1	Discuss any problems the customer is having with the instrument.	PASS	CSch
6.2.2	Comments (Verification of Instrument Problems)		CSch
6.3	Visual Check		
6.3.1	Instrument is complete and corresponds to the configuration for a Bruker microflex MALDI-TOF Series mass spectrometer, microflex LT/SH or LT/SH smart of LRF.	PASS	CSch
6.3.2	Instrument, covers, modules, cables, external computer are clean and undamaged (note details in Service Report).	PASS	CSch
6.3.3	Comments (Visual Check)		CSch

Performed by: Date/Sign <i>09.05.2022</i> 	Viewed by: Date/Sign
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Description		N/A, PASS or FAIL	INITIAL
6.4 Software Status			
6.4.1	MALDI control and acquisition software installed. Check with customer if update should be carried out.	PASS	CSch
Software	Installed version		
Compass for flex series	1.4		
flexControl Release	3.4.204.19		
flexFirmware Version GTMP/GTSP	3.4.204.19		
GTSMC	2.29.0		
flexAnalysis Release	3.4.79.0		

Performed by: Date/Sign 03.05.27 	Viewed by: Date/Sign
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Description	N/A, PASS or FAIL	INITIAL
6.5 Vacuum System Check		
6.5.1 Vacuum pressures: Source rough (<4.0 mbar): <u>2.2</u> mbar Source high ($\leq 3 \times 10^{-6}$ mbar): <u>1,8 x 10exp-6</u> mbar	PASS	CSch
6.5.2 Check tightness of external load port O-ring by comparing main vacuum difference between 'Probe IN' and 'Probe OUT'. Probe IN: <u>1.8 x 10 exp-6</u> mbar Probe OUT: <u>2.4 x 10 exp-6</u> mbar Difference ($\leq 1 \times 10^{-6}$ mbar)	PASS	CSch
6.5.3 Check the diaphragm pump and tighten mounts if noisy on probe in - out (excessive vibration or rattling).	PASS	CSch
6.5.4 Comments (Vacuum System Check)		CSch
6.6 Performance Check 1 The measured values are the documentation of the system performance. The mentioned original specification might indicate a reduced performance due to wear or system fault. The Bruker representative will evaluate the results and suggest further treatment or repair which are handled according to section 3.		
6.6.1 Linear MALDI-TOF specification		
6.6.1.1 Negative Ion Analysis (LRF only): Ion acceleration up to -20 kV Demonstrated using Cytochrome C (12359 Da) Minimum intensity ≥ 600 Save spectra as: LN_12 kDa	N/A	CSch

Performed by: Date/Sign 10/05/22 	Viewed by: Date/Sign
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Description		N/A, PASS or FAIL	INITIAL	
6.6.1.2	Linear MALDI Mass Resolution for Peptides (Single Peptide): demonstrated using Bombesin (1619.82 Da) Original final test specification ≥ 2000 with ≥ 600 Intensity Measured value : <u>1</u> Save spectra as: LP_1619	FAIL	CSch	
6.6.1.3	Linear MALDI Wide Mass Range Resolution: Recorded in one spectrum Original final test specification (all with ≥ 600 Intensity)	PASS	CSch	
5734 Da (Insulin)	Resolution ≥ 400			Measured: <u>595</u>
8476 Da (Myoglobin M ²⁺)	Resolution ≥ 600			Measured: <u>837</u>
12361 Da (Cytochrome C)	Resolution ≥ 700			Measured: <u>742</u>
16952 Da (Myoglobin)	Resolution ≥ 800			Measured: <u>735</u>
Save spectra as: LP_ProtMix				
6.6.1.4	Linear MALDI Mass Accuracy for proteins: External calibration error on Cytochrome C (12361 Da) Original final test specification ≤ 200 ppm with ≥ 600 Intensity Measured value : <u>81,7</u> Save spectra as: LP_ProtMix_Ext	PASS	CSch	
6.6.1.5	Linear MALDI Sensitivity for 500 fmole BSA (66 kDa) Original final test specification S/N ≥ 50 Measured value : <u>48,6</u> Save spectra as: LP_Sensitivity	FAIL	CSch	
6.6.2	Reflector MALDI-TOF specification Applicable for microflex LRF instruments only			
6.6.2.1	Reflector negative Ion Analysis: Reflector voltage up to -20 kV Demonstrated using Bombesin (1617.8 Da) Minimum intensity ≥ 600 Save spectra as: RN_1617	N/A	CSch	
6.6.2.2	Reflector MALDI mass resolution (single peptide): demonstrated using Somatostatin 28 (3147.5 Da) Original final test specification > 15000 with ≥ 600 Intensity Measured value : _____ Save spectra as: RP_3147	N/A	CSch	

Performed by: Date/Sign <u>10.05.22</u> 	Viewed by: Date/Sign
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Description	N/A, PASS or FAIL	INITIAL
6.8.3 Comments (Cooling System)		CSch
6.9 Vacuum System		
6.9.1 Confirm pressure gauges function.	PASS	CSch
6.9.2 Vent system.	PASS	CSch
6.9.3 Replace the diaphragm pump together with the 4 rubber vibration mounts, if necessary (at least every 3 years). Next replacement due on: _____	PASS	CSch
6.9.4 Check the T-piece and interlock switch (if available) and the neighboring pieces on the turbopump to see if it is clogged with matrix crystals. Note: In case of a blockage, the pre-vacuum takes much longer to reach the set points.	PASS	CSch
6.9.5 Check vacuum settings. Adjust set points with potentiometer at master board (see also TOF Service Note 112). Lock Rough (P600): 10.0 e ±0.0 mbar * Source Rough (P601): 10.0±0.0 mbar * *) Due to the limitation of the microflex hardware (potentiometers P600/ P601), the set points may not be reached. In this case the potentiometer should be set to the end stop (5.5 ... 10.1 e+00 mbar are permissible) Source High (P603): 5.0±0.1 x10 ⁻⁶ mbar Evacuate Total Timeout: 180 s Lock Low Pressure: 4999 µbar	PASS	CSch
6.9.6 Replace external and internal port O-ring. (check 6.5.2).	PASS	CSch
6.9.7 Replace inline filter. (check Appendix A).	PASS	CSch

Performed by: Date/Sign 10.05.2022 	Viewed by: Date/Sign
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Description	N/A, PASS or FAIL	INITIAL
6.9.8 Comments (Vacuum System)		CSch
6.10 Laser and Ion Optics		
6.10.1 Exchange both laser air filters (applicable for MNL1xx laser).		CSch
6.10.2 Check laser. Serial number: <u>1781</u> No. of shots: <u>48773461</u> k shots Note: For the MNL1xx laser, you can get the short form serial number by opening the laser's Marathon control and clicking on ABOUT. You have to shut down all the Bruker software first.	PASS	CSch
6.10.3 Remove ion source, disassemble for cleaning (incl. the lens stack), and clean with ethanol and kimwipes. Note: Never rinse the ion optic with organic solutions when fitted because hydrocarbons (like ethanol) could damage the detector!	PASS	CSch
6.10.4 Check P2-plate thoroughly and inspect for signs of arcing. Replace ion source if burn marks or signs of arcing present.	PASS	CSch
6.10.5 Clean ion optics manually, including all sides of optical lens.	PASS	CSch
6.10.6 Check connections of P1, P2 lens for burn marks / signs of arcing.	PASS	CSch

Performed by: Date/Sign <i>10.05.2022</i> 	Viewed by: Date/Sign
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Description	N/A, PASS or FAIL	INITIAL
6.10.7 Comments (Laser and Ion Optics)		CSch
6.11 X-Y-Stage		
6.11.1 Confirm that the X-Y stage is working well and moves smoothly.	PASS	CSch
6.11.2 Check logfiles for step loss. The maximum step loss should be within ± 250 μm .	PASS	CSch
6.11.3 Grease spindles, if necessary (squeaking stage).	PASS	CSch
6.11.4 Check all available targets for damage (note IDs of damaged targets in 6.11.6).	PASS	CSch
6.11.5 Close ion source and start pumps.	PASS	CSch
6.11.6 Comments (X-Y-Probe Movement Unit)		CSch


Performed by: Date/Sign <i>10.05.2022</i> 	Viewed by: Date/Sign
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Description	N/A, PASS or FAIL	INITIAL
6.12 Function Test Note: This test will be done on the next day when the high vacuum has reached the set points.		
6.12.1 Vacuum pressures: Source rough (< 4.0 mbar): <u>2,2</u> mbar Source high ($\leq 3 \times 10^{-6}$ mbar): <u>$2,9 \times 10^{-6}$</u> mbar	PASS	CSch
6.12.2 Check the tightness of the load port O-ring by comparing main vacuum difference between Probe IN and Probe OUT. Probe IN: <u>$2,9 \times 10^{-6}$</u> mbar Probe OUT: <u>$4,2 \times 10^{-6}$</u> mbar Difference ($\leq 1 \times 10^{-6}$ mbar)	FAIL	CSch
6.12.3 Check Pre-Cursor Ion Selector (PCIS). Applicable for microflex LRF only	PASS	CSch
6.12.4 Automatic Source Cleaning Verification (if available). Verify that the Source Cleaning works by moving the target to the out position and clicking on the "Start Cleaning" button. When the source cleaner is active the 'laser light' will be visible. This indicates that the source cleaner is functional.	PASS	CSch
6.12.5 Check Load Port Safety Switch (if available). Open the load port lid. If the cleaning process could not be started, the message: "Interlock error in source cleaning circuit" is returned.	PASS	CSch
6.12.6 Comments (Function Test)		CSch

Performed by: Date/Sign 	Viewed by: Date/Sign
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Description	N/A, PASS or FAIL	INITIAL
6.13 High Voltage		
6.13.1 High voltage test during probe movement (positive) Set: IS1 = 20 kV IS2 = 20 kV Lens = 10 kV Move around the corner spots (e.g. A1 -> A12 -> H12 -> H1 on a MSP 96 target). During this test the high voltage status indicator must be "green" and the monitor value for high voltage and high vacuum must be stable.	PASS	CSch
6.13.2 High voltage test during probe movement (negative) Applicable for microflex LRF only Set: IS1 = -20 kV IS2 = -20 kV Lens = -10 kV Move around the corner spots (e.g. A1 -> A12 -> H12 -> H1 on a MSP 96 target). During this test the high voltage status indicator must be "green" and the monitor value for high voltage and high vacuum must be stable.	N/A	CSch
6.13.3 Reflector mode negative (Reflector = -20 kV). Applicable for microflex LRF only. Check that the High Voltage indicator is stable "Ready". Verify that neither a Ramping nor a High Voltage Error has occurred.	N/A	CSch
6.13.4 Comments (High Voltage)		CSch

Performed by: Date/Sign


10.05.2022 

Viewed by: Date/Sign


Description	N/A, PASS or FAIL	INITIAL
6.14 Detector Check 2		
6.14.1 Run Detector Check tuning tool. If needed, re-adjust the detector gain voltage and note it: Linear Mode: <u>2881</u> V Reflector Mode: <u> </u> V	PASS	CSch
6.14.2 Comments (Detector Check 2)		CSch

Performed by: Date/Sign <i>M. D. 2022</i> 	Viewed by: Date/Sign
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Description	N/A, PASS or FAIL	INITIAL												
6.15 Performance Check 2 The measured values are the documentation of the system performance. The mentioned original specification might indicate a reduced performance due to wear or system fault. The Bruker representative will evaluate the results and suggest further treatment or repair which are handled according to section 3.														
6.15.1 Linear MALDI-TOF specification Note: Verify laser alignment after fitting ion source in instrument by attention especially to low mass peaks.														
6.15.1.1 Negative Ion Analysis (LRF only): Ion acceleration up to -20 kV Demonstrated using Cytochrome C (12359 Da) Minimum intensity ≥ 600 Save spectra as: LN_12 kDa	N/A	CSch												
6.15.1.2 Linear MALDI Mass Resolution for Peptides (Single Peptide): demonstrated using Bombesin (1619.82 Da) Original final test specification ≥ 2000 with ≥ 600 Intensity Measured value : <u>2717</u> Save spectra as: LP_1619	PASS	CSch												
6.15.1.3 Linear MALDI Wide Mass Range Resolution: Recorded in one spectrum Original final test specification (all with ≥ 600 Intensity) <table border="1" data-bbox="220 1131 1200 1355"> <tbody> <tr> <td>5734 Da (Insulin)</td> <td>Resolution ≥ 400</td> <td>Measured: <u>458</u></td> </tr> <tr> <td>8476 Da (Myoglobin M²⁺)</td> <td>Resolution ≥ 600</td> <td>Measured: <u>625</u></td> </tr> <tr> <td>12361 Da (Cytochrome C)</td> <td>Resolution ≥ 700</td> <td>Measured: <u>740</u></td> </tr> <tr> <td>16952 Da (Myoglobin)</td> <td>Resolution ≥ 800</td> <td>Measured: <u>924</u></td> </tr> </tbody> </table> Save spectra as: LP_ProtMix	5734 Da (Insulin)	Resolution ≥ 400	Measured: <u>458</u>	8476 Da (Myoglobin M ²⁺)	Resolution ≥ 600	Measured: <u>625</u>	12361 Da (Cytochrome C)	Resolution ≥ 700	Measured: <u>740</u>	16952 Da (Myoglobin)	Resolution ≥ 800	Measured: <u>924</u>	PASS	CSch
5734 Da (Insulin)	Resolution ≥ 400	Measured: <u>458</u>												
8476 Da (Myoglobin M ²⁺)	Resolution ≥ 600	Measured: <u>625</u>												
12361 Da (Cytochrome C)	Resolution ≥ 700	Measured: <u>740</u>												
16952 Da (Myoglobin)	Resolution ≥ 800	Measured: <u>924</u>												
6.15.1.4 Linear MALDI Mass Accuracy for proteins: External calibration error on Cytochrome C (12361 Da) Original final test specification ≤ 200 ppm with ≥ 600 Intensity Measured value : <u>85,2</u> Save spectra as: LP_ProtMix_Ext	PASS	CSch												
6.15.1.5 Linear MALDI Sensitivity for 500 fmole BSA (66 kDa) Original final test specification S/N ≥ 50 Measured value : <u>78,2</u> Save spectra as: LP_Sensitivity	PASS	CSch												

Performed by: Date/Sign <i>11.05.2022</i> 	Viewed by: Date/Sign
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Description				N/A, PASS or FAIL	INITIAL
6.16.5 Automatic Calibration using MBT STAR Calibrator				PASS	CSch
6.16.6 MALDI specification for MBT STAR Calibrator Demonstrated by automatic measurement of MBT STAR Calibrator (Antibiotic Calibration Standard) # 1853031 MBT STAR-BL Service Kit, or # 1848467 MBT STAR Carba IVD Kit				N/A	CSch
Mono Mass	Resolution	Intensity (at 240 shots)	Measured		
243.10200 Da	≥ 400	1000 ... 30000	_____		
379.09000 Da	≥ 400	1000 ... 50000	_____		
403.29500 Da	≥ 800	1000 ... 30000	_____		
573.31400 Da	≥ 1000	1000 ... 30000	_____		
607.27000 Da	≥ 1000	1000 ... 30000	_____		
757.39900 Da	≥ 1200	1000 ... 30000	_____		
Save spectra as: MBT_STAR_BL Create the report of the Biotyper performance by using the recent SpecCheck tool. Printout of the report is attached. <input type="checkbox"/>					
6.16.7 Comments (MALDI Biotyper Performance Verification)					CSch

Performed by: Date/Sign <i>11.05.2012</i> 	Viewed by: Date/Sign
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Description	N/A, PASS or FAIL	INITIAL
6.17 Safety Check		
6.17.1 Check all safety related parts for visible damage.	PASS	CSch
6.17.2 Check that all safety and warning labels are still in place.	PASS	CSch
6.17.3 Check that modules and racks are secured in place.	PASS	CSch
6.17.4 Check that protective conductors are complete and properly connected.	PASS	CSch
6.17.5 Check that the service switch is set to Normal position (RED LED on backplane OFF).	PASS	CSch
6.17.6 Comments (Safety Check)		CSch
6.18 Finish		
6.18.1 Close all instrument covers.	PASS	CSch
6.18.2 Print out spectra from Performance check 2 (only required if the PM will not be followed by an OQ/PV procedure).	PASS	CSch
6.18.3 Make a copy of system data (NVRAM, ISSET files, FC methods) and save to the data folder C:\BdalSystemData\BrukerService\PM_YYYYMMDD. Make an image of the C: drive as backup and copy this on an USB stick. Use acronis for this.	PASS	CSch
6.18.4 Update CRM Database. Update customer contact information. Software/library version (see 6.4) is up to date: <input checked="" type="checkbox"/>	PASS	CSch
6.18.5 Comments (Finish) Update BDAL Library Revision 10 to Revision 11		CSch

Performed by: Date/Sign <i>11.05.2022</i> 	Viewed by: Date/Sign
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Appendix A — Equipment Needed for Maintenance

Part Number	Description
8242974	Prepared MSP-Target (if necessary)
1827857	Maintenance kit, microflex SH. Content: 8261977 1 pc Inline-Filter, complete 8255998 2 pc Exchange filter for FE40F130 8220076 1 pc _Ring, O- NBR (PERBUNAN) -35°C/+100°C; 7 8220077 1 pc _Ring, O- NBR (PERBUNAN) -35°C/+100°C; 7 8211588 1 pc _Ring, O- FKM (VITON) -20°C/+200°C; 315.0 8230214 1 pc _Filter, AIR; 8 x 8 x0.5 INCH FOR MTX 8202756 High Vacuum Grease; NyeTorr 5200 syringe
8604655	Membrane Pump MVP 030-3DC (regarding 6.9.3)
8604065	Vibration Mount (4 pc) (regarding 6.9.3)

Appendix B — Declaration of Contamination

Safety requirements prior to instrument servicing

B.1 Introduction

The employer (user) bears the responsibility for the health and safety of his employees. This fundamental claim also extends to personnel who come into contact with devices and components during repair or service.

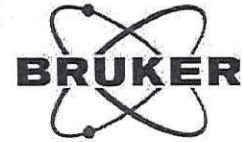
B.2 Declaration of contamination

Note Decontamination must be carried out after components have been used.

If the following Declaration of Contamination form is not fully completed and submitted, work on the devices or components cannot be carried out. Any additional decontamination costs incurred will be invoiced to the customer.

Make the Declaration of Contamination available to Bruker or to the Service agent prior to the service appointment.

Aufzeichnung über planmäßige Wartung für DAL00307/08151
Planmäßige Wartung (PM) microflex



Gerät: microflex IVD CA GP RÜO

Seriennummer: 263944.00430

Nummer des zugehörigen Wartungsberichts: -

Wartungsintervall: 2 1 Jahr

Name des Unternehmens: -

Abnahme/Genehmigung des Protokolls durch Bruker

Ich bestätige, dass die in diesem Wartungsdokument aufgeführten Verfahren und Informationen maßgeblich sind.

Zertifizierter Servicetechniker von Bruker

Christian Schulz
Name/Position (in Druckbuchstaben) Unterschrift Datum 11.05.2022

Abnahme/Genehmigung des Protokolls durch den Kunden

Ich bestätige, dass die in diesem Wartungsdokument aufgeführten Verfahren und Informationen maßgeblich sind.

Ich bestätige, dass die planmäßige Wartung zufriedenstellend ausgeführt wurde und alle zutreffenden Vor-Ort-Prüfkriterien bestanden wurden.

Autorisierter Vertreter des Kunden

M. de la Rangelie
Name/Position (in Druckbuchstaben) Unterschrift Datum 11.05.2022

Bemerkungen

Declaration of Contamination of devices and components

This form must only be completed and signed by authorized and qualified personnel

1. Devices and components				
Part name	Part number	Serial number	Delivery date	
<i>Microflex</i>		<i>265944.00430</i>		
2. Short description of repair				
<i>Maintenance</i>				
3. Condition of devices and components				
3.1 Have the devices and components been used?			YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>	
3.2 Are the devices and components free of health hazard pollutants ?			YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>	
If "NO" to 3.2, mark the kind(s) of contamination with a cross.				
<input type="checkbox"/> radioactive *)	<input checked="" type="checkbox"/> microbial *)	<input type="checkbox"/> chemical *)	<input type="checkbox"/> explosive *)	
<input type="checkbox"/> toxic	<input type="checkbox"/> corrosive	<input type="checkbox"/> other harmful substances		
If there is a potential microbiological contamination, specify the contaminating microorganisms with a cross:				
<input type="checkbox"/> L1	<input checked="" type="checkbox"/> L2	<input type="checkbox"/> L3/L4		
If there is a potential microbiological contamination, surface disinfection with 70% ethanol is mandatory. Are the surfaces, devices or components treated with disinfectant solutions (70% ethanolic solutions)?				
YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>				
Kind of harmful substances or dangerous reaction products determined by the process with which the devices and components were in contact :				
Product name (Manufacturer)	Chemical description (possibly formula)	Danger class	Countermeasures on the release of harmful substances	First aid measures in event of accidents
<i>Skille U.S.A.</i>				
*) Devices or components with biological, explosive, chemical or radioactive contamination are only accepted with written evidence and/or certification of successful decontamination according to the legal regulations.				

4. Legally binding statement (in block letters)
 Hereby I / we assure that the given details in this form are correct and complete. The preparation of contaminated devices and components for work or shipment will be performed in accordance with legal regulations.

Company / Institute :

Address Postal code, City:

Telephone: Email:

Fax:

Name: Company Stamp:

Job position:

.City / Date: Legally binding signature: *[Signature]*