IQ OQ		
	Document title	
	Installation Qualification and Operational Qualification Miris HMA	

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Generalities

1. Objectives

The objectives of the IQ are to ensure that equipment documentation, delivery and installation conform to the manufacturer's literature, and to confirm the reference information of the equipment.

The objectives of the OQ are to determine that the equipment operates according to specifications, and to record all relevant information and data to demonstrate it functions as expected according to the manufacturer's specifications.

When IQ/OQ protocol is approved after execution, the instrument will be ready for use in non-critical applications and for further testing.

2. References

2.1 The following documents are referred to within the IQ/OQ protocol

No	Document title	Document ID	Comments
1	Miris HMA™ User Manual	DOC-510/DOC-511	
2	Miris Calibration Control Kit™ Instructions for Use	DOC-551/DOC-552	

3. Definitions, Terms and Abbreviations

3.1 Definitions

Abbreviation	Description
CPG	Cuvette Pressure Guard
HMA	Human Milk Analyzer
IFU	Instructions for Use
IQ/OQ	Installation Qualification / Operational Qualification

4. Signature table

All the trained personnel who have been working on the protocol must fill the information required in the list below and put down their signatures.

5.1 Signatures

Name	Title	Signature	Trained according to [1]	Initials

Installation qualification (IQ)

5. Objective

The objectives of the IQ are to ensure that equipment documentation, delivery and installation conform to the manufacturer's literature, and to confirm the reference information of the equipment.

6. Scope

IQ should be performed at the time of installation, modification, or relocation. The instrument shall be in power-off during the execution of the IQ protocol.

7. Instrument origin and identification

7.1 Instrument references

Instrument name	Miris HMA™ - Human Milk Analyzer
Instrument description	Mid-infrared transmission spectroscopy instrument for determining the macronutrient composition (fat, protein, carbohydrate, total solids, energy) of human milk
Manufacturer	Miris AB Danmarksgatan 26 753 23 UPPSALA SWEDEN www.MirisSolutions.com
Service contact	Tel: +46 18 14 69 07 e-mail: support@MirisSolutions.com
Instrument serial number product number software version	
Date received	
Condition when received	New □ Serviced □
Location installed	
Verified by: *Date and signature:*	

8. Instrument delivery

Unpack and check the contents of the instrument carrying case. Please note that when an instrument is returned after a repair or service, all items listed here may not be included.

8.1 Are any of the standard items missing?

Item	Present	Missing
Miris HMA™ - Human Milk Analyzer	□	□
AC/DC Adapter	□	□
Power cable	□	□
Wireless mouse including batteries	□	□
USB flash drive	□	□
USB hub	□	□
Outlet Tubes, 6 pcs	□	□
Spare parts CPG	□	□
Miris HMA™ User Manual	□	□

Manufacturer informed of any missing items	*Yes* □ *No* □
Comments and follow-up	
Verified by: *Date and signature:*	

8.2 Are there any damages to the instrument or accessories?

No □	Yes □	
	If yes, name the item and describe the damage	
	Corrective action	
	Manufacturer informed	*Yes* □ *No* □
Verified by: *Date and signature:*		

9. Environment and siting

9.1 Since the instrument was last subjected to a change in environmental conditions, has the instrument been allowed to adjust to room temperature (20 - 30°C/68 - 86°F) for a minimum of 4 hours?

Yes □ No □ *If no, ensure this condition is met* □

9.2 Verify that the operating environment of the instrument meets the below requirements

Operating parameter	Specified range	Condition met	Deviation
Ambient temperature	20 - 30° C (68 - 86° F)	□	
Humidity	20 - 80% not condensed	□	
Power supply adapter	Input voltage 100-240 V, ~ 50/60 Hz, 2.3A	□	
Power supply instrument	Output voltage 18 V DC, 100VA	□	
Comments			
Verified by: *Date and signature:*			

10. Instrument safety

10.1 Verify that the Manufacturer's safety recommendations are met

Condition	Verified	Comment
Allow enough space for the instrument	□	
Place on a level, stable surface	□	
Place in an area free from dust, dirt, explosives, corrosive fumes, and extremes of temperature and humidity	□	
Place to avoid draft and vibrations	□	
Do not place in direct sunlight	□	
Ensure correct power supply	□	
In case of unstable power supply, use an UPS (uninterruptible power supply)	□	N/A □
Leave the protective cap covering the RS232 connection when not in use	□	
Read the User Manual before use	□	

Further comments and follow-up	
Verified by: *Date and signature:*	

11. Installation

11.1 The installation is performed by: user □ specialised technician/engineer □

11.2 Perform/verify the following installation procedure

Item	OK	Deviation
Unpack the instrument (4. Instrument delivery and documentation)	□	□
Control of the environment and instrument placement (5. Environment and siting, 6. Instrument safety)	□	□
Connect the instrument to power supply (see User Manual Chapter 1, Electrical requirements)	□	□
Attach tubes to the outlet (see User Manual Chapter 1, Operating the instrument)	□	□
Place a waste container by the outlet	□	□

Comments including any deviations	
Verified by: *Date and signature:*	

12. IQ summary report

Instrument: Miris HMA™ - Human Milk Analyzer **Manufacturer:** Miris AB

Instrument serial number:

12.1 Assessment of complete Installation Qualification:

No deviations □ Deviations (list below) □

12.2 IQ deviations

Deviation No	Deviation	Impact on operation	Justification for acceptance

Completion of the preceding protocol indicates that this instrument has been adequately delivered and installed. The Installation Qualification has been passed and the instrument may be submitted for Operational Qualification.

Deviations approved by:		**Date:**	
IQ approved by:		**Date:**	

Operational Qualification (OQ)

13. Objective

Objectives of the OQ is to determine that the equipment operates according to specifications, and to record all relevant information and data to demonstrate it functions as expected according to the manufacturer's specifications.

14. Scope

OQ should be performed after installation, modification or relocation, and after the Installation Qualification has been approved.

15. Functional tests

15.1 Perform the following tests and checks sequentially

Action	Refer to	Acceptance criteria	Pass	Fail
Switch on the Miris HMA™ (ON/OFF switch)	-	Display illuminates and button indicator lights comes on	□	□
Fan (no action required)	-	Fan comes on at power-up	□	□
System load (no action required)	User Manual Chapter 1, The start-up procedure	1. Main menu appears 2. Message ”System loaded” is displayed	□	□
Thermal regulation (no action required)	User Manual Chapter 1, The start-up procedure	1. Message “Warming…” is displayed 2. Temperature indicator at top right corner of display reaches 40°C 3. Message “Ready - press a button” is displayed	□ □ □	□ □ □
Perform the instrument start-up procedure: 1. 30 minutes switched on 2. Inject cleaning solution 3. Inject distilled or deionized water	User Manual Chapter 1, The start-up procedure	N/A	Performed □ □ □	
Calibration load (no action required)	-	HMA Homogenized milk (1) is displayed at the top of the display	□	□
Zero-setting check (zero level)	User Manual Chapter 4, Check procedure with zero level adjustment	1. Change% within ±10% 2. Result% within ±0.05 3. Message “No adjustment necessary” is displayed	□ □ □	□ □ □
Control of the calibration	IFU Miris Calibration Control Kit™	Measurement results for the Calibration 1 setting are within the acceptance criteria, for: Fat Crude protein True protein Carbohydrate	 □ □ □ □	 □ □ □ □
Comments				
Verified by: *Date and signature:*				

If any of the functional tests fails, contact Miris AB or your distributor.

16. Training

16.1 Training verification

Trained operators	Read the User Manual	Watched instructional videos (www.MirisSolutions.com)	Practical training	Authorising signature
	□	□	□	
	□	□	□	
	□	□	□	
	□	□	□	
	□	□	□	
	□	□	□	
	□	□	□	
	□	□	□	
	□	□	□	
	□	□	□	
	□	□	□	
	□	□	□	
	□	□	□	
Comments				
Verified by: *Date and signature:*				

17. OQ summary report

Instrument: Miris HMA™ - Human Milk Analyzer **Manufacturer:** Miris AB

Instrument serial number:

17.1 Assessment of complete Operational Qualification:

No deviations □ Deviations (list below) □

17.2 OQ deviations

Deviation No	Deviation	Impact on operation	Justification for acceptance

Completion of the preceding activities and checks indicates that this instrument is operating satisfactorily following delivery and installation. The instrument has passed the Operational Qualification procedure and may now be released for use in non-critical applications and further testing.

Deviations approved by:		**Date:**	
OQ approved by:		**Date:**	