

<b>IQ OQ</b>		
	Document title	
	<b>Installation Qualification and Operational Qualification Miris Ultrasonic Processor</b>	



**Figure 1.** The Miris Ultrasonic Processor

- 1. Sound reducing cabinet
- 2. Power supply unit



<b>IQ OQ</b>		
	Document title	
	<b>Installation Qualification and Operational Qualification Miris Ultrasonic Processor</b>	

## Table of contents

Generalities.....	3
1. Objectives .....	3
2. References .....	3
3. Definitions, Terms and Abbreviations .....	3
4. Signature table .....	4
Installation qualification (IQ).....	5
5. Objective .....	5
6. Scope .....	5
7. Equipment origin and identification .....	5
8. Equipment delivery .....	6
9. Environment and siting .....	7
10. Equipment safety .....	7
11. Installation.....	8
12. IQ summary report.....	10
Operational Qualification (OQ).....	11
13. Objective .....	11
14. Scope .....	11
15. Functional tests.....	11
16. Training .....	12
17. OQ summary report.....	13



IQ OQ		
	Document title	
	<b>Installation Qualification and Operational Qualification Miris Ultrasonic Processor</b>	

## Generalities

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### 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 Miris Ultrasonic Processor 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 Ultrasonic Processor User Manual	DOC-865	

### 3. Definitions, Terms and Abbreviations

#### 3.1 Definitions

Abbreviation	Description
IQ/OQ	Installation Qualification / Operational Qualification



<b>IQ OQ</b>		
	Document title	
	<b>Installation Qualification and Operational Qualification Miris Ultrasonic Processor</b>	

**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



<b>IQ OQ</b>		
	Document title	
	<b>Installation Qualification and Operational Qualification Miris Ultrasonic Processor</b>	

# Installation qualification (IQ)

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## 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 Miris Ultrasonic Processor shall be in power-off during the execution of the IQ protocol.

## 7. Equipment origin and identification

### 7.1 Equipment references

Equipment name	Miris Ultrasonic Processor
Equipment description	Miris Ultrasonic Processor reduces the particle size distribution in milk. This device is intended for use in laboratories by laboratory personnel.
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
<b>Equipment</b> serial number product number	
Date received	
Condition when received	New <input type="checkbox"/> Serviced <input type="checkbox"/>
Location installed	
Verified by: Date and signature:	

IQ OQ		
	Document title	
	<b>Installation Qualification and Operational Qualification Miris Ultrasonic Processor</b>	

8. Equipment delivery

Unpack and check the contents of the equipment package. Please note that when a Miris Ultrasonic Processor 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
Sound reducing cabinet (Figure 1)	<input type="checkbox"/>	<input type="checkbox"/>
Power supply unit (Figure 2)	<input type="checkbox"/>	<input type="checkbox"/>
Convertor housing with probe (Figure 2)	<input type="checkbox"/>	<input type="checkbox"/>
Tube holder	<input type="checkbox"/>	<input type="checkbox"/>
Power cable (Figure 3)	<input type="checkbox"/>	<input type="checkbox"/>
Emery cloth 3 pcs	<input type="checkbox"/>	<input type="checkbox"/>
Rubber carpet	<input type="checkbox"/>	<input type="checkbox"/>
Miris Ultrasonic Processor User Manual	<input type="checkbox"/>	<input type="checkbox"/>



Figure 2. Power supply unit and Converter housing with probe on top

Figure 3. Power cable

Manufacturer informed of any missing items	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Comments and follow-up		
Verified by: Date and signature:		



IQ OQ		
	Document title	
	<b>Installation Qualification and Operational Qualification Miris Ultrasonic Processor</b>	

**8.2 Are there any damages to the equipment or accessories?**

No <input type="checkbox"/>	Yes <input type="checkbox"/>	
	<i>If yes, name the item and describe the damage</i>	
	<i>Corrective action</i>	
	<i>Manufacturer informed</i>	Yes <input type="checkbox"/> No <input type="checkbox"/>
<i>Verified by:</i> <i>Date and signature:</i>		

**9. Environment and siting**

**9.1 Verify that the operating environment of the equipment meets the below requirements**

Operating parameter	Spec+ified range	Condition met	Deviation
Power supply	Input voltage 110/230 V, ~ 50/60 Hz, 2.3A	<input type="checkbox"/>	
<i>Comments</i>			
<i>Verified by:</i> <i>Date and signature:</i>			

**10. Equipment safety**

**10.1 Verify that the Manufacturer's safety recommendations are met**

Condition	Verified	Comment
Place on a level, stable surface	<input type="checkbox"/>	
Place in an area free from dust, dirt, explosives, corrosive fumes, and extremes of temperature and humidity	<input type="checkbox"/>	
Place to avoid draft and vibrations	<input type="checkbox"/>	
Ensure correct power supply	<input type="checkbox"/>	
In case of unstable power supply, use an UPS (uninterruptible power supply)	<input type="checkbox"/>	N/A <input type="checkbox"/>
Read the User Manual before use	<input type="checkbox"/>	


<i>Further comments and follow-up</i>	
<i>Verified by:</i> <i>Date and signature:</i>	

IQ OQ		
	Document title	
	<b>Installation Qualification and Operational Qualification Miris Ultrasonic Processor</b>	

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 equipment (see chapter 8. Equipment delivery)	<input type="checkbox"/>	<input type="checkbox"/>
Control of the environment and equipment placement (see chapter 9. Environment and siting and chapter 10. Equipment safety)	<input type="checkbox"/>	<input type="checkbox"/>
Place the Power supply unit inside the bottom compartment of the Sound reducing cabinet.	<input type="checkbox"/>	<input type="checkbox"/>
<p>Mount Convertor housing accordingly:</p> <ul style="list-style-type: none"> <li>Place the Convertor housing with probe in the laboratory stand clamp inside the cabinet. You may need to loosen the height adjustment knob and lower the clamp to do so</li> <li>Secure the clamp to the upper section of the converter housing only</li> <li>Put the Convertor housing cable through the hole on the upper part of the Sound reducing cabinet</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>
 <p><b>Figure 4.</b> Converter housing placed in the laboratory stand inside the cabinet. Cable is directed through the hole in the upper part of the cabinet.</p>		



IQ OQ		
Document title		
<b>Installation Qualification and Operational Qualification Miris Ultrasonic Processor</b>		

Plug the Converter housing cable into the socket at the back of the Power supply unit.



**Figure 5.** Back of Power supply unit where the circle indicates the socket where the Converter housing cable should be plugged in.



Connect the Power cable into the Power socket at the back of the Power supply unit.



**Figure 6.** Back of the Power supply unit where the circle indicates the socket where the Power cable should be plugged in.



Connect the Power cable to a power supply



*Comments including any deviations*

Verified by:  
Date and signature:



IQ OQ		
	Document title	
	Installation Qualification and Operational Qualification Miris Ultrasonic Processor	

12. IQ summary report

**Equipment:** Miris Ultrasonic Processor

**Manufacturer:** Miris AB

**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 Miris Ultrasonic Processor has been adequately delivered and installed. The Installation Qualification has been passed and the equipment may be submitted for Operational Qualification.

<b>Deviations approved by:</b>		<b>Date:</b>	
<b>IQ approved by:</b>		<b>Date:</b>	



IQ OQ		
	Document title	
	<b>Installation Qualification and Operational Qualification Miris Ultrasonic Processor</b>	

# 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
Turn on the Miris Ultrasonic Processor by pressing (I)	User Manual Chapter 3, Operating the Miris Ultrasonic Processor	Display illuminates	<input type="checkbox"/>	<input type="checkbox"/>
Make sure the probe is not in contact with any surface. Set the timer on the Miris Ultrasonic Processor to 3 seconds. Set the amplitude to 100%. Start the sonicating process.	User Manual Chapter 3, Operating the Miris Ultrasonic Processor	The sonication process starts with a high pitch sound  Probe output power indicator does not exceed 10%	<input type="checkbox"/>	<input type="checkbox"/>
<i>Comments</i>				
<i>Verified by: Date and signature:</i>				

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



<b>IQ OQ</b>		
	Document title	
	<b>Installation Qualification and Operational Qualification Miris Ultrasonic Processor</b>	

16. Training

16.1 Training verification

Trained operators	Read the User Manual	Watched instructional videos (www.MirisSolutions.com)	Practical training	Authorising signature
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Comments</i>				
<i>Verified by: Date and signature:</i>				



IQ OQ		
	Document title	
	<b>Installation Qualification and Operational Qualification Miris Ultrasonic Processor</b>	

17. OQ summary report

**Equipment:** Miris Ultrasonic Processor

**Manufacturer:** Miris AB

**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 equipment 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.

<b>Deviations approved by:</b>		<b>Date:</b>	
<b>OQ approved by:</b>		<b>Date:</b>	