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O2k Installation Qualification (IQ)/ Operational Qualification (OQ) protocol

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Mitochondria and Cell Research

Customer Name	
Customer Address	
Customer ID	
O2k Serial Number	

Approval of the O2k-IQOQ protocol by the customer's representative: all test requirements listed are correct and complete	
Name (Print)	
Signature and Date	

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1 Abbreviations

A	Ampere
Amp	Amperometric
HRR	high-resolution respirometry
IQ	Installation qualification
ISS	Integrated Suction System
O2k	O2k-FluoRespirometer
OQ	Operational qualification
POS	Polarographic oxygen sensor
SOP	Standard operating procedure
TIP2k	Titration-Injection microPump
V	Volt
W	Watt

2 Introduction

2.1 Scope

This document describes an O2k-IQOQ protocol for the O2k-FluoRespirometer (O2k) sold worldwide by Oroboros Instruments GmbH and its distributors. This document is based on and in accordance with the following O2k-Manuals/ O2k-SOPs (MiPNets)/ O2k-Videosupport/ MitoPedia instructions found under following links (collectively defined as O2k-Instructions):

- https://wiki.oroboros.at/index.php/O2k-Manual
- MiPNet07.08 User information: https://wiki.oroboros.at/index.php/MiPNet07.08_User_information
- MiPNet22.11 O2k-FluoRespirometer manual: https://wiki.oroboros.at/index.php/MiPNet22.11_O2k-FluoRespirometer_manual
- MiPNet19.18B POS-service: https://wiki.oroboros.at/index.php/MiPNet19.18B_POS-service
- MiPNet06.03 POS-calibration-SOP: https://wiki.oroboros.at/index.php/MiPNet06.03_POS-calibration-SOP
- MiPNet14.06 Instrumental O2 background: https://wiki.oroboros.at/index.php/MiPNet14.06_Instrumental_O2_background
- https://wiki.oroboros.at/index.php/O2k-Videosupport
- https://wiki.oroboros.at/index.php/MitoPedia:_O2k_hardware
- https://wiki.oroboros.at/index.php/MitoPedia:_DatLab

The O2k-IQOQ protocol is intended as a template and it may be used as is or adapted to suit the end user's exact requirements.

2.2 Responsibilities

Oroboros Instruments GmbH is responsible for the production and maintenance of this document. The customer of the O2k is responsible for the implementation of the O2k-IQOQ protocol in accordance with their own documents. Oroboros Instruments GmbH cannot assume responsibility for the end use of this document.

2.2.1 Assignment of the responsible persons

The qualification can be performed by the customer, by a representative of Oroboros Instruments GmbH or by a distributor of Oroboros Instruments GmbH.
Assignment of the executing persons:

Company and job title	Name (print)	Signature and date

Depending on the quality standard of the customer the IQOQ protocol will be approved by the responsible division or specified representative of the customer. The person or persons listed below will review and approve the documentation and ensure that all items are correct and complete.

Company and job title	Name (print)	Signature and date

3 O2k-IQOQ protocol

The following O2k-IQOQ protocol is not intended as a manual for installing the O2k and thus does not include step-by-step guidance as these details are beyond the scope of the document. For detailed information and step-by-step instructions refer to the corresponding O2k-Instructions detailed in section 2.1.

3.1 Infrastructure requirements

Infrastructure requirements	**Requirements met**	
Electric requirements	**Yes**	**No**
Maximum power input: 120 W		
Maximum current at 100-120 V: 1.0 A		
Maximum current at 220-240 V: 0.5 A		
Lab space requirements		
Minimum of bench space for the O2k: 0.5 m		
External PC/ laptop next to the O2k		
Sufficient space for the ISS, O2k-Titration Set and handling		
Free space on the rear side of the O2k-Main Unit to ensure ventilation		
O2k not exposed to direct sunlight		
Stable room temperature and no direct air stream on the O2k (e.g. from air conditioner)		
Computer requirements		
Minimum configuration: Intel-Core-2 or equivalent CPU, 2GB RAM, USB port, Windows XP or later Windows versions. Recommended configuration: Intel i5 or equivalent CPU, 4GB RAM, Windows 7, SSD.		
Access to the files "Oroboros O2k-Course on HRR" delivered on the Oroboros USB-flash drive.		
DatLab installed on the connecting computer.		

Disable sleep mode of the computer during data acquisition to avoid errors of data transmission.		
Comments:		
Performed by (signature and date)		

3.2 List of components

Check components:	Available	
	Yes	No
Box1 (or Peli case)		
O2k-Main Unit		
2 O2k-Chamber Holders (including 2 O-rings and 2 V-rings)		
2 POS-Holders (screwed into O2k-Main Unit)		
2 POS-Connectors		
Intact quality control seal		
Box 2		
Components according to order and dispatch list		
Suitability of the delivered cable and the national electric system		
EU: O2k-Main Power Cable, 230 V, Europe, 21111-01		
US: O2k-Main Power Cable, 120 V, US-CA, 21112-01		
AU/ NZ: O2k-Main Power Cable, 230 V, AU-NZ, 21113-01		
Comments:		
Performed by (signature and date)		

3.3 POS Service

POS Service	Performed	
	Yes	No
POS Service according to the O2k-Instructions (particularly MiPNet19.18B).		
Comments:		
Performed by (signature and date)		

3.4 Assembly of the O2k

Assembly of the O2k	Performed	
	Yes	No
Electrically ground yourself by touching the O2k steel housing to avoid possible damage of the electronics.		
O2k-Chamber assembly performed according to the O2k-Instructions (particularly MiPNet22.11).		
O2k POS assembly performed according to the O2k-Instructions (particularly MipNet22.11).		
Note the POS number (marked on the cylindrical body of each POS) for each chamber: Chamber A oxygen sensor (POS) number:_____ Chamber B oxygen sensor (POS) number:_____		

Comments:	
Performed by (signature and date)	

3.5 Set up DatLab

O2k control, data acquisition and analysis	**Performed**	
	Yes	**No**
DatLab installed and connected to the O2k according to the O2k-Instructions (particularly MiPNet22.11).		
Assign a label (Power-O2k or P-number) to the connected O2k _____		
Enter the POS number of the polarographic oxygen sensor for chamber A and B.		
Select the required channels for data recording e.g. Amperometric, Amp (fluorescence channel).		
Comments:		
Performed by (signature and date)		

3.6 Chamber volume calibration

Chamber volume calibration	Performed	
	Yes	**No**
O2k-Chamber volume calibration performed according to the SOP detailed in MiPNet22.11 and the respective video support.		
Comments:		
Performed by (signature and date)		

3.7 Assembly of Smart Fluo-Sensors

If applicable for your O2k: Smart Fluo-Sensors (O2k series H).

Assembly of the Fluorescence-Control Unit/ Smart Fluo-Sensors	**Performed**	
O2k series H	**Yes**	**No**
Smart Fluo-Sensor assembly performed according to the O2k-Instructions (particularly MiPNet22.11).		
Fluo-Sensors are illuminated (can be regulated in DatLab).		
Comments:		
Performed by (signature and date)		

3.8 Calibrations

Calibrations	**Performed and OK**	
	Yes	**No**
POS-calibration performed according to the O2k-Instructions (particularly MiPNet06.03). Media: _____ Temperature [°C]: _____ Chamber A R1 [V]: _____ Chamber A R0 [V]: _____ Chamber B R1 [V]: _____ Chamber B R0 [V]: _____		
POS-calibration chamber A: R0 < 2% (max. 5%) of R1		
POS-calibration chamber B: R0 < 2% (max. 5%) of R1		
Instrumental O2 background performed according to the O2k-Instructions (particularly MiPNet14.06). Media: _____ Temperature [°C]: _____ Standard oxygen levels: Chamber A *a*° (default -2.00): _____ Chamber A *b*° (default 0.025): _____ Chamber B *a*° (default -2.00): _____ Chamber B *b*° (default 0.025): _____		
Calibration values are loaded and saved in DatLab.		
Comments:		
Performed by (signature and date)		

4 IQOQ Results and approval

OQ Results	Approval
All applicable sections were filled and signed.	
No differences or errors were found during the IQOQ. The IQOQ was successfully completed and the system is approved without restrictions.	
Small differences or errors were found during the IQOQ. The differences and errors are documented. In spite of these differences and errors the system is approved without restrictions.	
Small differences or errors were found during the IQOQ. The differences and errors are documented. In spite of these differences and errors the system is approved with following restrictions:	
Considerable differences or errors were found during the IQOQ. The system is not approved, and the corresponding tests must be repeated and documented to approve the system:	

Approved by (signature and date)	