Oxford NANOPORE™ Technologies

Safety and regulatory information

for Oxford Nanopore Technologies products

D-0300 Rev 2. | SD_1060(EN)_V2_01Jul2020

Terminology

The following devices: MinION™ Mk1B, MinION Mk1C, GridION™ Mk1, PromethION™ 24, PromethION 48, MinIT™, VolTRAX™ V2, will generically be referred to as Oxford Nanopore Technologies devices (or devices) in this document.

Related Documents

The material in this online document: Safety and regulatory information for Oxford Nanopore Technologies products (D-0300) is provided in a printed document with the same name (ONT-08-00648-00) that accompanies the device shipment.

Online resources – The Nanopore Community

For all Oxford Nanopore Technologies devices, consult the Nanopore Community at **community.nanoporetech.com** for user manuals, protocols, help and support.

Details provided in this document enable safe operation of Oxford Nanopore Technologies devices, in cases when online resources are not readily accessible when using the devices (e.g. offline testing or in remote locations).

Manufacturing information

Oxford Nanopore Technologies devices are made by:

Oxford Nanopore Technologies
Gosling Building
Edmund Halley Road
Oxford Science Park
OX4 4DQ
United Kingdom

The product is protected by patents and patents pending: **nanoporetech.com/patents**

Intended use

Oxford Nanopore Technologies devices are electronic preparation and analysis systems for use in scientific research. The core technology is built around a nanopore that is able to detect single-molecule events including nucleic acids (DNA/RNA), proteins, and small molecules.

Oxford Nanopore Technologies devices are intended for research use only.

Lifting

Use two people for lifting the GridION Mk1, PromethION 24 and PromethION 48 devices. Other devices weighing less than 1 kg can be lifted by one person.

Do not drop any Oxford Nanopore Technologies devices, as this may prevent the safe operation of the device when in use.

Installation

Place the Oxford Nanopore Technologies device on a flat and stable surface.

Ensure any cables that are to be plugged into the Oxford Nanopore Technologies device are not stretched. Taut cables pose electrical and physical risks to the user.

Special considerations for GridION and PromethION

Ensure that all power supply cables are easily accessible in case it is necessary to disconnect the Oxford Nanopore Technologies device from the power cable in an emergency.

Allow a minimum of 20 cm clearance at the rear and sides of each Oxford Nanopore Technologies device.

Note: See the Nanopore Community and/or device-specific Quick start installation guides provided with each device for full details.

Use

Potential risks to the user may arise if the Oxford Nanopore Technologies devices are not used as instructed by the official documentation on the Nanopore Community.

Oxford Nanopore Technologies devices are not annually serviced for maintenance.

Purpose of material and device safety information

The safety information provides the user with the details needed to install and use the system safely.

WARNING: Indicates a hazardous situation which, if not avoided, could result in death or serious injury. It is important not to proceed until all stated conditions are met and clearly understood.

CAUTION: Indicates a hazardous situation which, if not avoided, could result in minor or moderate injury. It is important not to proceed until all stated conditions are met and clearly understood.

ADVISORY: Indicates instructions that must be followed to avoid damage to the product or other equipment.

The safety notices below are intended to complement and not supersede the normal safety requirements stipulated in the country of use.

Safety Data Sheets (SDS)

ADVISORY
The SDSs for the chemicals supplied by Oxford Nanopore Technologies are available on the Oxford Nanopore Store at: **store.nanoporetech.com**

CAUTION
Read and understand the SDSs before handling, working with, or storing the chemicals being used within the Oxford Nanopore Technologies device.

CAUTION
Minimise contact with the chemicals by wearing protective clothing, safety glasses, and gloves. SDSs will carry specific requirements.

CAUTION
Minimise inhalation of chemicals by using appropriate ventilation. The SDS will carry any specific requirements. Continuously check for any spills or leakages. Follow the clean-up guidelines provided in the SDS if a spill or leak occurs.

CAUTION
All components of the device should be handled, stored, and disposed of in accordance with local, state/provincial or national laws and regulations.

General precautions

CAUTION
Observe the safety regulations of the specific locale in question when handling toxic, radioactive, or pathogenic samples, as defined by the WHO Laboratory Biosafety Manual.

CAUTION
Do not use the device if it has suffered any damage, e.g. to power cables, data transfer cables, power supplies, or flow cells.

ADVISORY
Oxford Nanopore Technologies do not perform altitude testing on Oxford Nanopore Technologies devices. Atmospheric pressure is lower at high altitudes, which may result in the system fan performing poorly and cause subsequent temperature issues.

Personal protection

CAUTION
The adjacent symbol indicates a hot surface. Do not touch this surface shortly before, after, and when the Oxford Nanopore Technologies device is in use as it will remain hot for a period of time before and after it is in direct use.

WARNING
The adjacent symbol indicates that a substance is an irritant. Wear gloves when handling the substance. Dispose of the substance using a licensed waste contractor. The use, storage and disposal of reagents are described in the SDS and must be adhered to; emergency procedures are described therein too.

CAUTION
Specimens and reagents containing materials from humans should be treated as potentially infectious. Use safe laboratory procedures as outlined in publications such as Biosafety in Microbiological and Biomedical Laboratories:
www.cdc.gov/biosafety/publications/bmbl5/index.htm

CAUTION
The operator must take all necessary actions to avoid spreading hazardous biological agents in the vicinity of the system. The facility should comply with the national code of practice for biosafety.

CAUTION
Samples being loaded into the flow cell should be used, stored, and disposed of according to the required safety regulations and laws. Consult the responsible body for safety in your lab for local regulations.

CAUTION
Samples containing infectious agents should be handled with the greatest of care and in accordance with the required safety regulations and laws.

CAUTION
It is good laboratory practice to always wear safety glasses, gloves (2 pairs if working with infectious agents) and a lab coat. There may be other locally advised items which can be added to this recommended list. Consult the responsible body for safety in your laboratory for local regulations and practices.

Use of flow cells, cartridges and reagents

CAUTION
Observe the specific local regulations when handling toxic, radioactive, or pathogenic samples, as defined by the WHO Laboratory Biosafety Manual

CAUTION
Loading excess buffer, sample, or de-ionised water to the flow cell will cause an overflow of the waste compartment. Absorbent material should be used to absorb sample and buffer which will come out through the waste port. All material should be disposed of in line with local regulations for biological waste.

WARNING
Terminate use of the Oxford Nanopore Technologies device from the associated operating computer, or from the device itself, in the unlikely event that the Oxford Nanopore Technologies device is found to be hot during use. Contact: **support@nanoporetech.com** in the event of the device becoming hot.

Note: An exception applies where the adjacent symbol is present

Maintenance

CAUTION
Repairs must only be performed by Oxford Nanopore Technologies, and no components should be replaced. Contact: **support@nanoporetech.com** in the event of damage to the device or the flow cells.

CAUTION
Contact Oxford Nanopore Technologies to ensure that the intended method will not damage the device and/or flow cell before using cleaning or decontamination methods, other than those stipulated by Oxford Nanopore Technologies.

Disposal and recycling instructions

CAUTION
When returning Oxford Nanopore Technologies products, ensure that the devices and/or flow cells are fully decontaminated and do not present any kind of health risk to our staff.

ADVISORY
Visit: **community.nanoporetech.com/support/returns/flow_cells** for information on how to flush and return your used flow cells.

ADVISORY
When returning devices to Oxford Nanopore Technologies, visit:
community.nanoporetech.com/support/returns/devices and follow the instructions herein.

CAUTION
Used plasticware which includes reagents, tubes, and pipette tips, must be collected and disposed of properly, in accordance with local safety regulations and laboratory procedures.

CAUTION
The flow cell buffer, the sample preparation kit buffers and wash kit buffers must not be mixed in ways other than those stated in the user protocols and must be kept away from strong acids and alkalis.

CAUTION
The flow cell buffer, wash kit buffers, and sample preparation kit buffers must be disposed of according to the local regulations. The used liquid product must not be disposed of through domestic water waste infrastructure (e.g. a sink).

CAUTION
The Terms and Conditions for the use Oxford Nanopore Technologies device stipulate any flow cells that have been used with or otherwise been in contact with materials of Biohazard Level 3 or higher ("contaminated flow cells") must not be returned. Proof of legal and appropriate destruction of any contaminated flow cells will be required.

CAUTION
The sequencing device shall be decontaminated before decommissioning, and all local regulations for electronic and electrical waste shall be followed regarding disposal of the components if they are not being returned to Oxford Nanopore Technologies.

CAUTION
If a flow cell is not returned to Oxford Nanopore Technologies, it shall be disposed of as hazardous biological waste, and all local regulations for such waste shall be followed.

EMERGENCY PROCEDURE

IN CASE OF EMERGENCY, SWITCH OFF THE OXFORD NANOPORE TECHNOLOGIES DEVICE AT THE MAINS POWER SOURCE AND UNPLUG THE POWER CABLE FROM THE DEVICE.

Electromagnetic Compatibility (EMC), Radio and Electrical safety advice

Note: This equipment has been tested and found to comply with the limits for a ***Class A or Class B*** digital device, pursuant to Part 15 of the FCC rules:
- **Class A Devices** – PromethION 24, PromethION 48
- **Class B Devices** – MinION Mk1B, GridION Mk1, MinIT, VolTRAX V2

The ***Class A or Class B*** classification also applies to the IEC CISPR 11 limits, as the devices above - excluding MinIT - have been tested to EN 61326-2-1:2013 referencing EN 61326-1.

The following additional standards have been used for compliance testing against:

MinION Mk1C:
- ETSI EN 301 489-17 V3.1.1 referencing ETSI EN 301 489-1 V2.1.1

MinIT:
- ETSI EN 301 489-17 V3.2.0 referencing ETSI EN 301 489-1 V2.1.1

Note: MinION Mk1C is currently undergoing testing for CE/FCC approval.

1. Emissions of the devices can exceed the limits stated in EN 61326-1:2013 when the devices are connected to auxiliary equipment.
2. Auxiliary equipment should be CE/FCC approved to mitigate for non-compliant Electromagnetic Interference (EMI).
3. Ethernet cables from the Ethernet port must not be longer than 100 m; eSATA (Serial ATA working group) cables from the eSATA port must not be longer than 2 m. Cables from other signal ports, other wired network ports, control ports, and DC power ports of products containing radios (e.g. MinION Mk1C and MinIT), and associated auxiliary equipment, must not be longer than 3 m.
4. The devices are intended to be operated under a controlled electromagnetic (EM) environment, such as a laboratory. Under these conditions, radio frequency (RF) transmitters, such as mobile telephones, may not be used in close proximity.
5. The devices complying to the FCC and CE Standards have a minimum performance criteria of i) remaining powered ii) retaining basecalled data as FASTQ or FAST5 file formats, as appropriate or iii) being able to output and interpret raw data in the absence/after certain types EM interference.

FCC Part 15 Statement – unintentional transmitters

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC rules. This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Special considerations for MinIT and MinION Mk1C

Power supply units

Customers are advised to use the 19 VDC power supply provided with the device.
The power source must be safety isolated with a fuse or circuit breaker if a different power source is used. This must be in line with the rated values for MinIT and MinION Mk1C and be previously approved according to national standards and regulations.

Radio features

The FCC ID for MNT-001 is 2ARGS-MNT-001

MIN-101C contains FCC ID: 2ARGS-P3310
MIN-101C contains IC: 7361A-P3310

Warning statement for modifications

WARNING: The FCC requires that you be notified that any changes or modifications to this device not expressly approved by Oxford Nanopore Technologies could void the user's authority to operate the equipment.

FCC Part 15 Statement – RF exposure statement

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled EM environment. This equipment should be installed and operated with minimum distance 20 cm between the radiator and your body. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

OPERATING REQUIREMENTS AND CONDITIONS

The design of MinIT/MinION Mk1C complies with U.S. Federal Communications Commission (FCC) guidelines respecting safety levels of radio frequency (RF) exposure for Mobile devices. W52/53 (i.e. 5 GHz Wi-Fi) is for indoor use only.

Note: MinIT and MinION Mk1C support the following standards of 5GHz Wi-Fi channels:
- 802.11a
- 802.11n
- 802.11ac

For Canada:

OPERATING REQUIREMENTS AND CONDITIONS

This radio transmitter 7361A-P3310 has been approved by Innovation, Science and Economic Development Canada to operate with the antenna included. Other antennas are strictly prohibited for use with this device.

The device for operation in the band 5150–5250 MHz is only for indoor use to reduce the potential for harmful interference to co-channel mobile satellite systems.

Note: high-power radars are allocated as primary users (for example priority users) of the bands 5250-5350 MHz and 5650-5850 MHz and that these radars could cause interference and/or damage to LE-LAN devices.

ISED RSS-GEN STATEMENT

This device complies with Innovation, Science and Economic Development Canada license-exempt RSSs. Operation is subject to the following two conditions:

1. This device may not cause interference; and
2. This device must accept any interference, including interference that may cause undesired operation of the device.

	MinION Mk1B	MinION Mk1C	MinIT	VolTRAX V2
Model number	MIN-101B	MIN-101C	MNT-001	VOL-V2002
Supply voltage (V)	5 DC	PSU[1]: 100-240 AC (50/60 Hz) MinION Mk1C: 6.3-19.6 DC	PSU[1]: 100-240 AC (50/60 Hz) MinIT: 15 DC	5 DC
Maximum rated current (A)	1.0	10.0	MinIT: 2.0	3.0
Maximum rated power (W)	5	60	30	15
Size (H x W x D) (mm)	23 x 33 x 105	32 x 142 x 118	40 x 65 x 120	65 x 58 x 134
Weight (kg)	0.10	0.44	0.29	0.37
Installation ports	1 x USB Type-B	1 x USB 2.0 port 1 x RJ45 Ethernet port (1 Gbps / 100 Mbps / 10 Mbps) 1 x eSATA port (3 Gbps) 1 x Micro SD card 1 x Pin – 19 VDC power port	1 x USB 2.0 port 1 x USB 3.0 port 1 x RJ45 Ethernet port (1 Gbps) 1 x Pin - 15 VDC power port	1 x USB Type-C
Software installed	MinION driver[2]	Ubuntu OS, MinKNOW™	Ubuntu OS, MinKNOW	VolTRAX driver[2]
Compute specification	N/A	1 TB SSD storage Jetson TX2 module comprising: 8 GB RAM, 256 core GPU, 6 core ARM64	512 GB SSD storage, Jetson TX2 module comprising: 8 GB RAM, 256 core GPU, 6 core ARM64	N/A
Environmental conditions	Functional range of electronics is within environmental temperatures of -5°C to +40°C Users should allow 30 cm clearance to the rear and sides of the device.			
	Designed to sequence or prepare in library in environmental temperatures of +18°C to +25°C	Designed to sequence or prepare in library in environmental temperatures of +10°C to +30°C	Designed to operate or prepare a library in environmental temperatures of +18°C to +25°C	

[1]PSU – power supply unit;
[2]Device drivers – are used to correctly configure a computer that the device is plugged in to.

	GridION Mk1	PromethION 24		PromethION 48	
Model number	GRD-X5B003	PRO-SEQ024 Sequencing Unit	PRO-PRC024 Data Acquisition Unit	PRO-SEQ048 Sequencing Unit	PRO-PRC048 Data Acquisition Unit
Supply voltage (V)	100-240 AC (50/60 Hz)	100-240 AC (50/60 Hz)	P1: 100-240 AC (50/60 Hz) P2: 100-127 AC (50/60 Hz)	100-240 AC (50/60 Hz)	P1: 100-240 AC (50/60 Hz) P2: 100-127 AC (50/60 Hz)
Maximum rated current (A)	6.5	12.0	P1: 12.0 P2: 14.0	12.0	P1: 12.0 P2: 14.0
Maximum rated power (W)	650	1200	P1: 2200 P2: 1200	1200	P1: 2200 P2: 1200
Size (H x W x D) (mm)	220 x 365 x 370	190 x 590 x 430	440 x 178 x 470	190 x 590 x 430	440 x 178 x 470
Weight (kg)	11.00	28.00	25.00	28.00	25.00
Installation ports	1 x RJ45 port (1 Gbps) 1 x HDMI/Display port to monitor 1 x USB for keyboard 1 x USB for mouse 1 x C13 power port	2 x PCIe adapter 2 x USB mini-B port 1 x USB Type-B port 1 x C13 Power port	2 x 2 kW C13 power ports (P1/P2) 1 x VGA monitor 6 x USB Type-A ports 2 x RJ45 port (10 Gbps) 2 x Fibre optic ports - DCHP capability (10 Gbps) 2 x SFP+ modules[3] 2 x Mini USB-USB port 2 x PCIe adapter	3 x PCIe adapter 3 x USB mini-B port 1 x USB Type-B port 1 x C13 Power port	2 x 2 kW C13 power ports (P1/P2) 1 x VGA monitor 6 x USB Type-A ports 2 x RJ45 port (10 Gbps) 2 x Fibre optic ports - DCHP capability (10 Gbps) 2 x SFP+ modules[3] 3 x Mini USB-USB port 3 x PCIe adapter
Software installed	Ubuntu OS, GridION OS, MinKNOW	N/A	Ubuntu OS, PromethION OS, MinKNOW	N/A	Ubuntu OS, PromethION OS, MinKNOW
Compute specification	4 TB SSD storage, 64 GB RAM, Intel i7 7700K CPU, 1 x Nvidia GV100	N/A	30 TB SSD storage, 384 GB RAM, Intel CPU, 2 x Nvidia GV100	N/A	60 TB SSD storage, 384 GB RAM, Intel CPU, 4 x Nvidia GV100
Environmental conditions	Functional range of electronics is within environmental temperatures of -5°C to +40°C Designed to sequence in environmental temperatures of +18°C to +25°C (for GridION Mk1) or +18°C to +22°C (for PromethION 24 and PromethION 48) Users should allow 30 cm clearance to the rear and sides of the device. WARNING: Rear of instrument heats up during operation				

[3]SFP+ modules are not supplied with PromethION 24 and PromethION 48

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