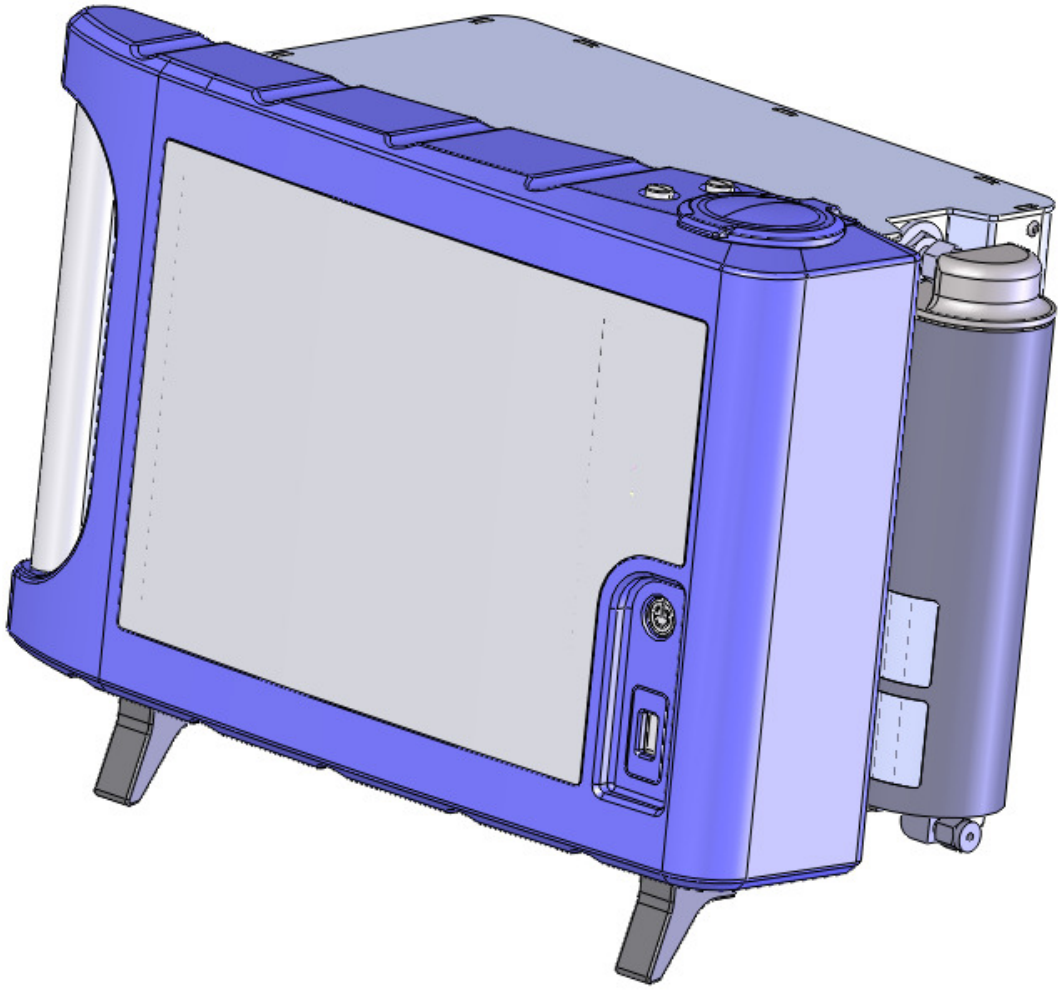
Owlstone Lonestar ® Analyser Safety Notices



 Proprietary and Confidential

Owlstone LONESTAR® Analyser Safety Notices

Issue/Version	Date	Author	Details
OW-003386-TM-002	21/02/2013	Andrew Pauza	Improvements in format, typos and readability from 001
90-0284-001	21/02/2013	Graham Newell	Issued into change control

About this Document

This document contains details of conformance of your Owlstone Lonestar® analyser to regulatory standards, safety information, and general product information. It does not give details for installation or usage. For this information, you must refer to the Owlstone support website:

owlstonenanotech.com

and

http://support.owlstonenanotech.com/forums

This symbol is used to highlight a section explaining particularly important safety considerations

Contents

Notices

Copyright

Disclaimer

Owlstone Ltd makes no representations or warranties, either expressed or implied, with respect to the contents hereof and specifically disclaims any warranties, merchantability or fitness for any particular purpose. Furthermore, Owlstone Ltd reserves the right to revise this publication and to make changes from time to time in the contents hereof without obligation of Owlstone Ltd to notify any person of such revision or changes.

Notice of Proper Use of Owlstone Ltd Instruments

The supplied system is in compliance with international regulations. If this system is used in a manner not specified by Owlstone Ltd, the protection provided by the system could be impaired

Contacting Owlstone

Visit the Owlstone® website (www.owlstonenanotech.com) for up-to-date contact details.

For general inquires please email info@owlstonenanotech.com

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Service and Maintenance

This equipment contains no user serviceable parts. Disassembly by users is NOT permitted as the unit contains a radioactive Ni-63 ionisation source. If your equipment requires maintenance or service, please contact your Owlstone® representative. Return and repair details are provided below

Owlstone Support

The Lonestar® User Manual, as well as other information and resources for Owlstone customers, are available at our support website:

http://owlstone.zendesk.com/home

For help with any further questions or problems, please contact Owlstone directly on our support address:

support@owlstone.zendesk.com

Warranty

Owlstone Ltd warrants that equipment supplied will perform to the advertised specifications for a period of 12 months. Should any material failure of the product occur within 12 calendar months of delivery Owlstone Ltd will repair or replace the equipment free of charge given our satisfaction that sub-standard performance is genuinely the result of defective material or workmanship and not caused by fair wear and tear.

If required, please contact Owlstone Ltd for further detail regarding exact terms of the warranty.

Returns

Chemical Safety

Owlstone takes chemical safety seriously. Customers are **NOT** permitted to return hardware to Owlstone without prior authorisation. Please consult your Owlstone representative regarding the returns procedure.

Before equipment can be returned customers are required to fill out a Decontamination Certificate and submit to Owlstone for review. After H&S review Owlstone will issue a returns number (RMA#).

The Decontamination Certificate, p/n 90-0027, is provided in your document pack (supplied with the Lonestar®) and can also be downloaded from our support website.

Under no circumstances should equipment be returned to Owlstone without an RMA#.

Packaging

Customers are encouraged to retain the original equipment packaging in case a future need arises for equipment return. Owlstone cannot take responsibility for transit damage to poorly packed equipment.

For further advice regarding correct packaging of Owlstone equipment please contact Owlstone.

Recycling and Disposal

This Product has been designed and manufactured with high quality materials and components, which can be recycled and reused.

This product is required to comply with the European Union's Waste Electrical & Electronic Equipment (WEEE) Directive 2002/96/EC so should not be disposed of in normal waste. In some locations the radioactive source has additional disposal requirements; please consult Owlstone Ltd for details of our recycling and disposal program for this product.

For users outside the European Union consult local authorities for correct disposal or contact Owlstone Ltd.

Warning Labels

Caution: **The Lonestar® analyser contains a radioactive source**, please pay particular attention to sections containing this symbol and refer to the radiation source materials safety data sheet for more details on safe handling

Please consult local regulations about your responsibility in regards to the source. For instance in England and Wales this will be compliance with “the radioactive substance (testing instruments) (England and Wales) exemption order 2006” and “the ionising radiation regulations 1999”.

For the US the Lonestar® analyser is manufactured in compliance with U.S. NRC safety criteria in 10 CFR 32.27 so the purchaser is exempt from any regulatory requirements.

For transport purposes the Lonestar® analyser complies to UN2911 standards for radioactive sources, and is provided with an identification certificate.

High humidity and acidic conditions can potentially damage the Nickel 63 source; if used in this manner or if these conditions could potentially occur please consult an Owlstone service engineer about the use of a secondary external downstream filter to prevent spread of contaminated material

No person shall intentionally or recklessly misuse or without reasonable excuse interfere with the radioactive substance contained within the Lonestar® analyser. The source is enclosed in a non-user serviceable housing with tamper seals.

This warning label indicates parts of the product that will become hot during use. Please take care.

CE Declaration of Conformity (DoC)

Owlstone Ltd performs complete testing and evaluation of its products to ensure full compliance with applicable domestic and international regulations. When the system is delivered to you, it meets all relevant electromagnetic compatibility (EMC) and safety standards as described in the declaration below.

Owlstone Ltd declares under its responsibility that the electronic product LONESTAR (Process Monitoring System) is in conformity with the following standards:

EMC Directive 2004/108/EC

The Lonestar® analyser complies with the following standards

- CR47: 2006 Class A Code of Federal Regulations: pt 15 Subpart B – Radio Frequency Devices – unintentional radiators
- EN61326-1:2006 Electrical equipment for measurement, control and laboratory use – EMC requirements, Group 1, Class B equipment (emission section only)
- EN61326-1:2006 Electrical equipment for measurement, control and laboratory use – EMC requirements, Industrial Location Immunity (immunity section only)
- EN61000-3-2:200 Electromagnetic compatibility (EMC) – part 3-2: Limits – Limits for harmonic current emissions (equipment input current up to and including 16A per phase)
- EN61000-3-3:1995 (+A1/A2) Electromagnetic compatibility (EMC) – Part 3-2: Limits – Limitation of voltage changes, voltage fluctuations and flicker in public low voltage supply systems for equipment with rated current <= 16A per phase and not subject to conditional connection

Low Voltage Safety Compliance

This device complies with Low Voltage Directive 2006/95/EC.

Changes that you make to your system may void compliance with one or more of these EMC and safety standards. Changes to your system include replacing a part or adding components, options, or peripherals

not specifically authorized and qualified by Owlstone Ltd. To ensure continued compliance with EMC and safety standards, replacement parts and additional components, options, and peripherals must be ordered from Owlstone Ltd or one of its authorized representatives.

FCC Compliance Statement

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference, in which case the user will be required to correct the interference at his or her own expense.

Safety Notice

Caution: Read these operating instructions fully before use and pay particular attention to sections containing this symbol

Always observe the following safety precautions:

- Only connect to an earthed supply socket. THE MAINS ADAPTOR IS CLASS 1 CONSTRUCTION AND MUST BE EARTHED (GROUNDED)!
- Ensure the mains outlet is easily reached to disconnect the unit
- Use only the supplied mains adaptor and leads supplied
- The equipment is heavy; use the handle provided to lift and carry the unit
- Always disconnect the equipment from the mains supply before moving
- This equipment is for use in moderate climates only. NEVER use the equipment in damp or wet conditions
- Avoid excessive heat, humidity, dust & vibration
- Do not use where the equipment may be subjected to dripping or splashing liquids

Harmful substances

The Lonestar® analyser can be used with a wide range of samples some of which could be toxic or harmful. The Lonestar® analyser is not a fully sealed unit, therefore for this reason it is essential that the user conduct a risk assessment for the substances to be used in the Lonestar® and establish safety protocols to cope with the release of such materials under the normal operation of the unit. These protocols must include suitable installation (e.g. in a fume cupboard, provision of extraction, etc.) and operational procedures to protect the operator.

The Lonestar® analyser is not designed to be a fully sealed unit. Therefore when used with any toxic or harmful compound, appropriate precautions such as operation under a fume hood is required.

Check chemical compatibility: Materials in the flow path include PTFE, stainless steel, aluminium, silicon, graphite, circuit board and Viton®. Ensure test atmospheres are neither corrosive nor reactive with materials

in the flow path and can be safely operated at 60°C. If in doubt please contact an Owlstone representative using the contact details provided.

Note that the relative humidity sensors are for indication only. Typically the humidity sensors are accurate to +/-5%, but they can be affected by the exact makeup of the process sample and can be easily altered or damaged by certain chemicals.

System Contents

The Lonestar® analyser is shipped with the following components:

- Lonestar® analyser process monitor
- 3 piece scrubber o-ring, 48 x 1.5mm, Viton, 75 Shore
- External mains power supply
- Mains power cable– appropriate to country of use
- USB keyboard
- Peli transport case (see Figure 1)

A documentation pack is supplied that contains:

- Radiation Source Certificate
- Wipe Test Certificate
- Decontamination Certificate
- MSDS sheet for Ni63
- MSDS sheet for Activated Carbon
- Lonestar® analyser Safety Notices (this document)

If any of these items are missing or damaged then contact Owlstone Ltd immediately.

Please retain all items and packaging, including the Peli Case, which is required to return the unit to Owlstone for annual service. No responsibility is accepted by Owlstone for damage arising from the use of non-approved packaging.

Figure 1 - Peli Case with Lonestar® analyser

About Owlstone

Owlstone develops and commercializes innovative new technologies to address the critical need for compact, dependable and cost-effective chemical and biological detection solutions for a wide range of markets.

Owlstone was formed through the recognition of the opportunities created by the application of micro- and nano- technology to develop improved sensing solutions.

Owlstone is focused on the innovation of detection technologies to address unmet needs, developing solutions that are flexible enough to target a range of markets with the potential for growth by enabling new application opportunities.

From homeland security to home safety, Owlstone is working with leading manufacturers and integrators across a range of markets to develop products incorporating our microchip chemical sensing solution.

Owlstone is headquartered in the United States and has laboratory facilities in the United Kingdom. Owlstone Ltd was founded in 2003 with a seed investment of two million dollars from Advance Nanotech, Inc., a New York based company specializing in the investment in and commercialization of nanotechnologies.