## Index

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>About Lighthouse Benelux</td>
<td>3</td>
</tr>
<tr>
<td>Lighthouse Realtime monitoring systems</td>
<td>5</td>
</tr>
<tr>
<td>Lighthouse Monitoring Software</td>
<td>8</td>
</tr>
<tr>
<td>- Main characteristics of Lighthouse Monitoring Software (LMS)</td>
<td>9</td>
</tr>
<tr>
<td>- LMS Pharma</td>
<td>10</td>
</tr>
<tr>
<td>- LMS Hospital</td>
<td>11</td>
</tr>
<tr>
<td>- LMS Professional</td>
<td>12</td>
</tr>
<tr>
<td>- LMS Express (Real Time)</td>
<td>12</td>
</tr>
<tr>
<td>- Wireless monitoring system</td>
<td>13</td>
</tr>
<tr>
<td>Components of the monitoring system</td>
<td>14</td>
</tr>
<tr>
<td>- Remote particle counters and different type of sensors</td>
<td>14</td>
</tr>
<tr>
<td>- Liquid (remote) particle counters</td>
<td>15</td>
</tr>
<tr>
<td>- Remote microbiological airsamplers (Remote Active Count)</td>
<td>17</td>
</tr>
<tr>
<td>- Environmental sensors</td>
<td>17</td>
</tr>
<tr>
<td>- Other sensors or alarms</td>
<td>18</td>
</tr>
<tr>
<td>Project approach, qualification and training</td>
<td>19</td>
</tr>
<tr>
<td>Cleanroom training &amp; advice</td>
<td>20</td>
</tr>
<tr>
<td>Rental program</td>
<td>20</td>
</tr>
<tr>
<td>Maintenance and Support</td>
<td>21</td>
</tr>
<tr>
<td>References Lighthouse monitoring systems</td>
<td>22</td>
</tr>
</tbody>
</table>
About Lighthouse Benelux

Lighthouse Benelux specializing in monitoring several parameters (air and climate) within the life sciences, pharmaceutical, hospital and high tech industries. Besides monitoring, Lighthouse also supplies cleanroom validation and qualification instruments for particle counting, microbiological sampling, airflow visualization and filter integrity tests.

Lighthouse Benelux is a subsidiary of the global Lighthouse Worldwide Solutions. The headquarters of Lighthouse is situated in San Francisco (California) and the production is located in Medford (Oregon) in the US. Lighthouse has regional offices around the world and distribution in approximately 70 countries. After the start in 2004, Lighthouse Benelux has built a second business building in 2014 where the department for monitoring systems is located. Because of the expansionary growth of the monitoring industry, we decided to give these activities more space for growth and the number of specialists that daily work with monitoring systems is extended.

Lighthouse has a team of software specialists that make sure that the Lighthouse Monitoring Software (LMS) is configured according to the customers’ demands. Our project leaders and the installation team provide full support, installation, documentation, and qualification of a system.

Widely proven overall quality

Lighthouse is in possession of the ISO 9001:2015 certificate and ISO 17025 accreditation. The quality of the products and services of Lighthouse Worldwide Solutions has proven itself international for over 30 years.

Market segments in which Lighthouse has already proven itself:
• Pharmaceutical market: monitoring of aseptic production areas and laboratories
• Medical and Biotechnology industry: monitoring of production cleanrooms, LAF-cabinets, laboratories, and warehouses
• Healthcare: monitoring in hospitals and clinics of OR’s, laboratories, pharmacies, central sterilization department and isolation rooms
• Semiconductor industry: monitoring of cleanrooms, commodities, and critical surfaces
• Food industry: monitoring of production areas which need to comply with the HACCP directive
• Aerospace and research institutes: monitoring of cleanrooms and research laboratories

We give training and instructions to administrators and users of our systems in our own training center and cleanroom. All monitoring systems are being (if desired) fully qualified and documented delivered according to GAMP-5.
About Lighthouse Benelux

We deliver our monitoring systems turn-key and coordinate the project with the customer and all involved organizations like consultants, installers and construct companies, to make sure the realization and qualification are well-matched. At the delivery of your monitoring system, we offer different possibilities of maintenance contracts, which improve the reliability of your system at the highest level. In addition to the annual re-calibration and the required maintenance work, we offer different Service Level Agreements for the support of your system, to make sure that it is available 24/7.

Service that improves continuity!

Good maintenance is essential for the quality and continuity of your monitoring systems and instruments. Lighthouse Benelux offers high-grade service. Maintenance and repairs to your products and systems are well planned with short turnaround times. That applies for the Lighthouse systems, but also for products of all other brands. Just like the calibration of your products in our mobile laboratory, we can do maintenance and repairs on location. That way waiting times are being limited to a minimum and critical shipments are unnecessary. That is also part of the high-quality service you can expect from us. Customized Service Level Agreements give customers with monitoring systems the certainty and continuity that is necessary to operate and produce 24/7.
Lighthouse Realtime monitoring systems

Lighthouse monitoring systems are developed for 24/7 registration of critical process parameters. This can be very diverse parameters such as particles and climate technical aspects (temperature, pressure, air velocity, relative air humidity), but also operational parameters like door contacts, alarms and other notifications can be registered and documented. Every system is being equipped to the needs of the customer and if desired, linked to the other systems like building management systems, management information systems, electronic patients file, etc.

Unregarded your wishes, regulations or product improvement, for every aspect of Contamination Control we offer a customized solution.

Applications for monitoring systems:

**Filling lines**
Remote particle counters and microbiological airsamplers are being used to monitor in filling lines of pharmaceutical production processes (*GMP Annex1; “For Grade A zones, particulate and microbial monitoring should be undertaken for full duration of critical processing, including equipment assembly”*). The remote particle counter stays out of the process, but the isokinetic probes and airsampler heads are placed in the process which makes the cleaning very simple. Both particle counters and microbiological airsamplers can be operated from the Lighthouse monitoring software.

**Isolators and RABS**
The idea behind isolator technology is the limitation of the sterile area as small as possible (filling & capping). This aseptic condition (*GMP-Class A*) needs to be monitored with registration of acceptable viable and non-viable levels. Lighthouse offers diverse solutions for a well thought-through monitoring system, equipped for and resistant to sterilization processes (e.g. VHP).
Radio pharmacy
The production of pharmaceutical radionuclide (Isotopes) takes place in a Cyclotron. The preparation and packaging of a full radiopharmaceutical needs to be done in a “Hot Cell” and needs to comply to the GMP (appendix 1: Production of sterile medicines). These shielded nuclear radiation rooms (GMP-Class A) can be equipped with a real-time monitoring system for monitoring particles and differential pressure. Besides monitoring, also the environmental protection of employees in Radio Pharmaceutical departments, (working with radioactive isotopes) is guarded.

Cleanroom monitoring
Monitoring in cleanrooms in several industries is of great importance for the right cleanliness of these rooms. Particle counters and also environmental monitoring make sure that all right parameters that are predetermined are being monitored, registered and that when there is an exceedance it will be alarmed. The importance of monitoring is considerable to prevent production loss that can lead to enormous damage. During the production of small (nano) components, the presence of 0.1 micron particles can already cause severe damage. For cleanrooms in pharmacies and the pharmaceutical industry the guidelines of GMP apply.

Microbiological Safety Cabinets and LAF-cabinets
Microbiological Safety Cabinets and cytostatic LAF-cabinets are increasingly used in a GMP environment. Because of products that are filled under GMP regime, these cabinets have to be monitored according to GMP Annex 1. By a combination of requirements, correct use of the space and implementation of the right sampling positions (viables and non-viables), a monitoring system can indicate “compliance” during use and register incidents. This means that depending on the applications in the cleanroom like aseptic preparations a higher grade (B or C) is required. These cleanrooms need to have minimal monitoring on differential pressure, viable- and non-viable concentrations.

Room monitoring
Cleanrooms are built for the protection of contamination for clean production and processes. Besides particle contamination like microbiological activity, also molecular contamination, and nanoparticles are often critical contaminants which can interfere a clean production process. Not only the quality of the air (airborne), but definitely also of surfaces and commodities are important to capture. If there is an exceedance of a norm or alarm limit, the operator and the quality system will be informed. Next, to automatic airborne particles measurement there are also sensors for particle deposition (fall-out). Microbiological detection and molecular detection can be connected to LWS systems. This already complies to the newest ISO 14644.
**Packaging of critical products**
The packaging of medicine, nutrition supplements, and other critical products need to be monitored by the GMP guidelines or by the HACCP guidelines. Placement of sampling probes on the most effective locations is very important and has a big influence to the measurement results. Also, monitoring and control of packaging and warehousing are necessary.

**Biotechnology**
Monitoring of particles, temperature, humidity, and viablies is of importance to (micro) biological research. Also during storage and distribution monitoring is very important.

**Hospitals and clinics**
In hospitals monitoring of all air technical and environmental parameters has a large influence on the quality of care. Monitoring is possible for several departments like operating rooms, pharmacy, isolation rooms, central sterilization department and all important equipment throughout the hospital like fridges, freezers etc. Monitoring provides continuous information on environmental like temperature, humidity, airflow and differential pressure, but also gives insight in the air quality with particles, viablies and helps users in making the right decisions (start/stop surgery, etc.).

**Storage and distribution of medicine**
There are strict standards of climate control for storage and distribution of critical products such as medicines. This applies for example for storage of medicines in refrigerators and freezers in a hospital or a pharmacy, but also for storage at distribution companies. Lighthouse monitoring systems provide registration of temperature and humidity.

**Nutrition and nutritional supplements**
For the production of nutrition and nutritional supplements monitoring of parameters like viablies, temperature and humidity are necessary to guarantee the quality of nutrition and nutrition supplements. This production increasingly takes place in classified (cleanroom) areas and must comply with requirements of GMP, GDP and HACCP with respect to production, distribution, and storage.

**Fluid monitoring**
Fluids like Ultra Pure Water (UPW) and Water for Injection (WFI) are specified for contamination such as particles, TOC, bacteria, conductivity, and temperature. Lighthouse takes care of integration of the right measurement instruments, whether or not linked to a monitoring system. Solid particles can be detected from 25 nanometer to 20 micron.
Lighthouse Monitoring Software

Lighthouse Monitoring Software (LMS) has been developed specially for environments in which accuracy and reliability are key prerequisites. LMS was designed according to GAMP-5 regulations.

LMS contains specific built-in functionalities and safety features that make the software extremely suitable for realizing monitoring systems that comply with data protection standards, such as the FDA 21 CFR part 11. Additional operational assurance means that LMS can be run redundantly, so that, in case of computer or server failure, the monitoring system will continue uninterruptedly, without any loss of measurement data. Lighthouse guarantees 99.9% availability of its monitoring systems.

LMS collects, presents and analyses measurement data on process-critical parameters, such as dust particles and viable concentrations and alarms user in case of any alarms. Almost any type and brand of other sensors can be connected to LMS for reporting and alarming.

Production space in the pharma

Overview of an OK within a hospital

RAC measurements at hopperbowls in a filling line

The Lighthouse Monitoring Software is available in a number of market specific variants:

- LMS Pharma: For pharmaceutical and life sciences industry
- LMS Hospital: For all departments in hospitals such as pharmacy, operating rooms, medicine storage, CSSD and isolation rooms
- LMS Professional: For industrial environments such as the semiconductor industry
Main characteristics of Lighthouse Monitoring Software (LMS)

- Easy user interface
- Fully integrated network, user access via web viewing
- Multi-level, ‘drill-down’ mapping
- Real-time and historical trend graphs and data tables
- Report templates available, customized reports can be created
- User view screens can be modified to personal preference
- Room overview screens
- Unlimited expandable
- Education, qualification, and training
- Compliance with GAMP-5 regulation, including electronic signatures and data security

Extensive alert management options

- Light and sound indicators, with beacons and touchscreens
- Alerts and messages via e-mail and SMS

Supporting a large range of sensors

- All Lighthouse particle counters, as well as options to integrate those of other brands
- Sensors for measuring temperature, humidity, air velocity, pressure differential, conductivity, CO₂, vacuum and gas pressure
- Microbiological air sampling

Optimal security

- 21 CFR part 11 compliant
- Audit Trail with adjustable viewing screens and reports
- Individual user security, including password renewals, automatic log-out after a certain time, and access control (with the option of using MS Windows passwords (LDAP))

Integration using existing IT infrastructures

- Can be installed on the virtual servers
- Can be installed on a PC server (connected to the network)
- Communication between server and measuring station, based on TCP/IP
- Support of various operating systems, such as Windows 7, 8.1, 10, server 2008 server 2012.

Extensive back-up, redundancy and failover functions

- Automatische back-up and archiving options
- Full redundancy for configuration and measurement data (optional)
- Redundant View Client options (optional)

Connections to other (automation) systems

- Supporting industrial protocols, such as OPC and ODBC
- Drivers for a large number of PLC brands and instruments

Connections to EPD and GBS systems

- To link relevant measurement data with patient records e.g. via HL7 datalink
LMS Pharma monitoring

LMS Pharma is specially developed for use in pharmaceutical and laboratory environments. Besides monitoring of particles also viables, pressure difference, temperature and humidity can be monitored in pharmaceutical cleanrooms, filling lines and LAF/Microbiological cabinets according to the classifications of GMP. Next to that, also the temperature in freezers, coolers, incubators, autoclaves, and other storage media can be recorded and registered and will be alarmed when they are out of specification.

Parameters of the LMS Pharma system:

- Particle counting
- Microbiological airsampling
- Differential Pressure
- Temperature
- Humidity
- Air Velocity
- Air volume
- Doorcontacts malfunctions of devices like freezers, coolers, incubators etc.
- CO₂
- TOC
- Conductivity
- Alarmbeacons (lights and sound)
- Touchscreens with room lay-outs and alarms

System design Grade A

Lighthouse has knowledge and experience with the design of practical monitoring systems in grade A surroundings. Specific choices have to be made on the basis of risk analysis like for example the positioning of sampling probes and the use of tubing lengths. The sampling probes need to be placed as close to the exposed product or aseptic preparation process as possible. US FDA recommends placing the probes with a maximum of 30 cm from the exposed product in the airflow.

In case there is a turbulent airflow, the probe needs to be placed in vertical position. By means of flow studies the measurement positions are being determined. These flow studies can be part of the section “risk based” qualification range.
Air quality and quality assurance systems are business critical for hospitals and clinics. To assure patient safety and quality assurance, monitoring systems must be used with an independent recording of operating conditions of rooms, equipment, and processes. Lighthouse Benelux offers customer specific monitoring systems for every hospital department with complete documentation and qualification.

**What can Lighthouse do for your hospital or clinic?**

With the overall monitoring solutions of Lighthouse, your hospital or clinic can work with one integrated system. In the system, all departments can be accommodated with separation of rights of the different departments and users. Your hospital only has to invest in one system and has all the monitoring efficient, safe and always available. More detailed information on hospital monitoring can be found in the brochure Ziekenhuis Monitoring.
LMS Professional monitoring

LMS Professional is specifically developed for applications in industrial environments. The monitoring systems can be built for all parameters such as airborne and falling particles, particles on surfaces, as well as particles in process gasses and liquids. Also, contamination parameters such as molecular contamination (AMC), electrostatic charges and discharges, vibration, TOC or other critical process parameters can be logged, monitored, and reported. LMS Professional is a web-based system and can be rolled out across various locations worldwide. Data can be shared with overriding information management systems or linked to automated reporting modules.

LMS Express en LMS Express RT software

LMS Express software is designed to manually download and display data from the Lighthouse particle counters, such as Solairs, Handhelds, and Remote particle counters. The software has its own database which fully complies with the GMP/FDA guideline 21 CFR Part 11.

LMS Express Real Time (RT) can collect data from the Lighthouse instruments including real-time monitors in addition to manual download. LMS Express and LMS Express RT users can generate built-in reports for the classification of the cleanroom. LMS Express RT can be used for small monitoring systems that can be operated and managed on one computer. The software is easy to install and configure by customers themselves.

Features LMS Express:
- Easy installation
- Size range standard reports incl.:
  - Federal standard 209E
  - ISO 14644-1:2015
  - EU GMP Annex 1
- Export of data to Excel or CSV
- 21 CFR Part 11 compliant
- Built-in Audit Trail, with commitments of interventions
- Includes database with an archive

Extra features LMS Express RT (Real-time):
- Real-time data collection via USB, serial port and Ethernet
- Real-time graphs, tables and status data
- Real-time maps with internet camera support
- Alarming, alarm log in and confirmation
- Built-in OPC-DA server
- SQL database
Wireless monitoring system

Also, for wireless monitoring and recording of temperature, humidity, pressure, CO₂ and analog input signals of devices, Lighthouse has a system that meets the strict requirements of the GMP. The wireless system is based on sensors that can log their measurement data into an internal memory. This data is transmitted via radio communication (with a preset interval) to a receiver that is connected to the customers network. The measurement data is collected in a secured database and the software allows the corresponding actions such as alarms to be set. This system is especially suitable for monitoring of equipment on several locations and warehouses. Next to that is easy to use for small cleanroom environments when there is no need for particle monitoring.

Key features of the Lighthouse Wireless monitoring system:

**Easy configuration**
- Real-time and historical trend charts and data tables
- Standard reports present
- Easy (self) expandable

**Alarming possibilities**
- E-mail, SMS and voice messages
- Alarm confirmation possible via telephone wide range of sensors and signal modules
- Temperature, humidity, pressure difference and CO₂
- Analogue inputs (0 - 5V or 4 - 20mA)
- Potential free alarm contact modules (e.g. for connection to a building management system)
- Optical alarm signal with acoustic alarm

**Security**
- 21 CFR Part 11 compliant
- Audit Trail
- Individual user security including password renewal, auto log out after set time and access control

**Infrastructure and operating systems**
- Installation on (virtual) servers or PC/laptop
- Communication between server and radio receivers based on TCP/IP over the existing network infrastructure
- Support for various operating systems such as Windows 7, 8 and 10, Windows Server 2008, 2012 and 2016
Components of the monitoring system

Remote particle counters and different type of sensors

**Remote airborne particle counters**

Lighthouse has a wide range of various types of particle counters for each desired measurement. The available models are with integrated pump or models that need to be connected to a central vacuum pump. There are special models for measurements in isolators and rooms where VHP resistant products are needed. The flow rates of remote particle counters are 0.1 CFM or 1.0 CFM (2.83 LPM or 28.3 LPM) and size ranges from 0.1µm up to 100µm are possible.

**Remotes particle counters selection table**

![Particle Counter Selection Table]

**Remotes with external vacuum**

**Apex range**

- Features:
  - Size range 0.2µm - ≥ 10µm
  - Flow rates 0.1 CFM (2.83 LPM) - 1.0 CFM (28.3 LPM)
  - 2 - 4 size channels
  - Communication: Modbus RS-485 or Ethernet (POE)
  - 3,000-data records
  - Stainless steel enclosure
  - Led status indicators
  - Optional display
  - VHP resistant

**Remote range**

- Features:
  - Size range 0.2µm - ≥ 25µm
  - Flow rates 0.1 CFM (2.83 LPM) - 1.0 CFM (28.3 LPM)
  - 2 - 4 size channels
  - Communication: Modbus RS-485, 4-20mA output
  - Led status indicators
  - External alarm outputs
  - Stainless steel enclosure

**Remote 1100/1104LD**

- Features:
  - Size range 0.1µm - ≥ 1.0µm
  - Flow rate 1.0 CFM (28.3 LPM)
  - 8 size channels
  - Communication: Modbus RS-485
  - Led status indicators
  - Stainless steel enclosure
  - External alarm outputs
Remote 50104 (Boulder Counter)

Features:
- Size range 0.5µm - ≥ 100.0µm
- Flow rate 1.0 CFM (28.3 LPM)
- 2 - 4 size channels
- Communication: Modbus RS-485
- Led status indicators

Remotes with pump

Features:
- Size range 0.2µm - ≥ 25µm
- Flow rates 0.1 CFM (2.83 LPM) - 1.0 CFM (28.3 LPM)
- 4 - 6 size channels
- Communication: Modbus RS-485 or Modbus Ethernet
- Led status indicators
- External alarm outputs
- Up to four 4-20 mA inputs for external sensors
- Internal vacuum pump with flow control

Remotes with NEMA enclosure

Features:
- Size range 0.2µm - ≥ 5.0µm
- Flow rate 0.1 CFM (2.83 LPM) - 1.0 CFM (28.3 LPM)
- 2 - 4 size channels
- Communication: Modbus RS-485, 4-20mA output
- Internal vacuum pump with flow control
- Led status indicators
- Stainless steel enclosure (NEMA 316L)

Liquid (remote) particle counters

Lighthouse has a wide range of various types of liquid particle counters and batch samplers. These can detect particles from 25nm up to 200µm and the flow rates are available from 30ml/min up to 100ml/min.

Liquid particle counters selectie tabel
Remote LPC

Features:
• Size range 0.1µm - ≥ 100µm
• Flow rate 100ml per minute
• 2 - 4 size channels
• Communication: Modbus RS-485 of 4-20mA output
• Led status indicators

Remote LPC LE

Features:
• Size range 1µm - ≥ 200µm
• Flow rates 30 & 50ml per minute
• 4 - 8 size channels
• Communication: Modbus RS-485 of 4-20mA output
• Led status indicators

NanoCount range

Features:
• Size range 25nm - ≥ 200nm
• Flow rates 30, 80 & 100ml per minute
• 4 size channels
• Communication: Modbus Ethernet or Modbus RS-485 or 4-20mA output
• Internal vacuumpump with flow control
• Led status indicators
• Stainless steel enclosure (NEMA)
Remote microbiological airsamplers (Remote Active Count)

Microbiological air sampling needs to be carried out in many pharmaceutical environments, hospitals and laboratories. This can be combined within a monitoring system, in order for the sampling to be started automatically during preparation times or surgical procedures, or other measurement periods.

The microbiological air samplers are connected to the monitoring system via a network connection. The start and stop moments and sampling periods can be logged and reported. Various models are available, with integrated start/stop module or operated separately, where the remote air sampler is able to function stand-alone on LMS Express RT software. These products can be fitted inside LAF cabinets, isolators and on OR surgery and instrument tables.

Flow rates:
10ltr/min, 28ltr/min en 100ltr/min.

Environmental sensors

Lighthouse uses transmitters (4-20mA) in all its sensors that enable a reliable transmission of signals over longer distances without distortion of the measurement values. Lighthouse sensors are also ‘pluggable’; they can be easily plugged in and out for calibration or replacement. All sensors are calibrated before they are installed in a system.

Temperature
Temperature sensors are available for ranges between -200°C and +400°C. There are different models suitable for rooms, ducts and equipment like freezers, refrigerators and incubators.

Temperature and (air) humidity
Temperature and humidity sensors are available in wall and duct models. The range of the basic T-RH sensor is between 0 - 50°C and 0 - 100% RH, but other options are also available.

Differential pressure
Lighthouse uses high quality differential pressure sensors for monitoring in cleanrooms and HEPA filters. The most common models have a measurement range -50+-50 Pascal or 0-100 Pascal, but other ranges are also available.

Air velocity
Air velocity sensors are important for measuring the correct flow of, for example, a down-flow plenum in the OR or in the HVAC ducts of a cleanroom. Models are available in various air velocity ranges of between 0...2m/s and 0...10m/s.
Door movements
In various monitoring systems, counting the number of door movements is one of the main components of the monitoring system. OR entrance doors, doors on refrigerators and freezer equipment and other door movements are monitored and logged. For example, insight is provided into how often OR doors were opened and for how long they remained open during surgical procedures (connection to the electronica patient data files is possible).

Other sensors or alarms
Other types of measurements for continuous registration and monitoring are also important for many of our customers. These consist of, for example, sensors for gases such as CO₂, oxygen or anesthesia gases, or other types of alert outputs to our system, such as alerts from equipment or lights on/off.

Integrating existing sensors
Lighthouse can supply sensors, but is also able to integrate alerts from already existing sensors into its monitoring system. Solutions can be found for any situation, thus offering you a complete monitoring system.

Beacons and (touch)screens
Each monitoring system can be custom fitted with alert beacons (with or without sound) and (touch)screens. Local displays and panels provide users with insight into the status of one or more areas/rooms. They can also be integrated into existing (OR) panels.
Lighthouse Monitoring systems are developed, installed, tested and qualified in accordance with the GAMP-5 guidelines (V-model) to ensure that the high set requirements are met for the right operations and quality control.

The agreed project steps can be recorded in a Quality and Project Plan (QPP). This document contains, in addition to all hardware and software that has to be provided, details about planning, project-team, obligations and documentation which is required or mandatory.

A qualification and documentation manual can contain the following chapters:

- Chapter 1: Document Guide
- Chapter 2: User Requirement Specification (drawn up in cooperation)
- Chapter 3: Quality and Project Plan
- Chapter 4: Functional Specification
- Chapter 5: Risk based analysis report
- Chapter 6: System Design Specification
- Chapter 7: Factory Acceptance Test
- Chapter 8: Site Acceptance Test
- Chapter 9: Installation Qualification Protocol
- Chapter 10: Operational Qualification Protocol
- Chapter 11: Performance Qualification
- Chapter 12: Project Review Report
- Chapter 13: Change Control Documents
- Chapter 14: Training Certificates
- Chapter 15: User manuals
- Chapter 16: Maintenance manual
- Chapter 17: Calibration reports
- Chapter 18: Service Level Agreement

After delivery of each monitoring system, both the administrators and users will be trained to maintain and use the system optimally. Training can always be repeated on request. Where necessary, the administrator can get support from Lighthouse through a SLA contract. Training can take place both on-site and at Lighthouse.
Cleanroom training and advice

Lighthouse Benelux offers a high-quality package of advanced measuring instruments and monitoring systems. To enable you to achieve optimal returns on investments, we offer various training and education opportunities. These can be provided at your location, in our own training center and in our cleanroom. This education focuses on informing your employees about the standards and requirements that a cleanroom or hospital must meet. Our training sessions are also aimed at learning the practical skills for the operation of our measuring instruments and monitoring systems.

Our training center offers you:
• Professional trainers with years of work experience
• Trainers with knowledge of current standards and regulations
• Facilities to execute validation training
• A fully equipped cleanroom where practical training can take place

Rental program

Lighthouse Benelux understands better than anyone that it is not always economically feasible for you to purchase cleanroom tools when you don’t use them frequently enough. For this reason, we offer the possibility to rent these instruments.

The rental program includes:
• Handheld airborne particle counters
• Portable airborne particle counters
• Liquid particle counters
• Surface particle counters
• Microbiological airsamplers
• Filter-test equipment
• ‘OK richtlijn 7’ validation set consisting of:
  Laptop with software configured for handheld particle counters with accessories, particle generator including necessary cabling
• Other cleanroom validation equipment such as:
  Airflow meters, humidity meters, temperature meters, flow meters, foggers and diluters

For a complete and up-to-date overview, please visit our website www.golighthouse.nl
Maintenance and Support

In addition to calibration, maintenance is also a defining factor for your optimal reliability. If maintenance and support is properly arranged Lighthouse Benelux can guarantee an uptime of 99.9% guarantee your monitoring systems and measuring instruments.

Preventive maintenance
During preventive maintenance your measuring instruments and monitoring systems are periodically checked for defects, impurities and wear and tear. This maintenance is normally combined with calibrations which means cost saving for you. This type of maintenance can be custom made specifically to your situation and can be recorded in a contract.

Support
If your business processes depend on the accurate functioning of your measurement instruments and monitoring systems, and downtime must be held to a minimum, a support contract is recommended. Support options are:
• Email support
• Telephone help desk
• Remote support
• On-site support
• System maintenance and analysis

Service Level Agreement
If you want to be assured that support can also be used outside of office hours and that an unexpected malfunction is also addressed and resolved within a predetermined period, then a Service Level Agreement is required for you. Lighthouse Benelux can provide a Service Level Agreement that can be customised to your specific situation.
All Lighthouse monitoring systems at a glance:

**Customers with LMS Pharma Monitoring**

- Abbott Nederland, Olst
- Alcon Novartis, Puurs (Belgium)
- Alfasan Diergeneesmiddelen, Woerden
- Amival, Turnhout (Belgium)
- Apotheek Haagse Ziekenhuizen, Den Haag
- Astra Zeneca, Mölndal (Sweden)
- Bactimm, Nijmegen
- Basic Pharma, Geleen
- Behr Systems, Blaichach (Germany)
- BetaPlus Pharma, Brussel (Belgium)
- Bilthoven Biologicals, Bilthoven
- Biocrates, Mechelen (Belgium)
- Biotech Training Facility, Leiden
- BioTRADING, Mijdrecht
- Brocacef, Venray
- BV Cyclotron VU, Amsterdam
- Catalent, Swindon (Engeland)
- Ceban, Breda
- Curium Pharma (IBA Molecular), Fleurus (Belgium)
- Curium Pharma (Mallincrodt Medical/Covidien), Petten
- Datwyler Pharma Packaging, Alken (Belgium)
- DORC, Zuidland
- EMC, Mijnbogen
- Eppendorf, Namur (Belgium)
- Fagron Compounding, Bornem (Belgium)
- Fagron De Bereiders, Hoogeveen
- Fagron Pharma Assist, Hoogeveen
- Fresenius Hemocare, Emmert-Compascuum
- GE Healthcare, Eindhoven
- Hal Allergy, Leiden
- Hammersmith Medicines Research, London (Engeland)
- HMS Blistique, Heereneven
- Initial, Veldhoven
- Janssen Pharmaceutica, Beerse (Belgium)
- Janssen Vaccines & Prevention (Crucell), Leiden
- JSR Micro, Leuven (Belgium)
- Kuros Biosciences, Bilthoven
- Lelypharma, Lelystad
- Lonza (Pharmacell), Geleen
- MDS-Nordion, Fleurus (Belgium)
- Mediline, Angleur (Belgium)
- Medimmune, Nijmegen
- Micronclean, Bolsward
- MSD, Haarlem
- MSD Biotech, Burgwedel (Germany)
- Nelipak, Venray
- Pfizer, Puurs (Belgium)
- Pharmacell, Geleen
- Pharmaline, Oldenzaal
- Produlab Pharma, Raamsdonkveer
- Promethera, Brussel (Belgium)
- Proxy Laboratories, Leiden
- QPS, Groningen
- Qualipharm, Bornem (Belgium)
- Rentex Floron, Bolsward
- RomPharm, Boekarest (Romania)
- Sanico, Turnhout (Belgium)
- Sanofi Pasteur, Brussel (Belgium)
- Sanquin, Amsterdam
- Scheldezoom Farmacie, Goes
- Sharp Packaging Solutions, Halmont-Achel (Belgium)
- Sonoco, Berkel en Rodenrijs
- Stichting Apotheek Haarlemse ziekenhuizen, Haarlem
- Synthon, Nijmegen
- Tiofarma Collegiale Bereiding, Oldenzaal
- Tiofarma, Oud-Beijerland
- Verenigde apotheek Limburg, Maastricht
- Von Gahlen Hot cells, Zevenaar

**Customers with LMS Hospital Monitoring**

- Academisch ziekenhuis Maastricht, Maastricht
- Albert Schweitzer ziekenhuis, Dordrecht
- Alexander Monroe ziekenhuis, Bilthoven
- Amstelland ziekenhuis, Amstelveen
- azVesalius, Tongeren (Belgium)
- Bergman Kliniek, Bilthoven
- BovenIj ziekenhuis, Amsterdam
- Bronovo ziekenhuis, Den Haag
- Canisius-Wilhelmina ziekenhuis, Nijmegen
- Catharina ziekenhuis, Eindhoven
- Centrum Oosterwal, Alkmaar
- Elkerliek ziekenhuis, Helmond
- Equipe Zorgbedrijven, Eindhoven
- Equipe Zorgbedrijven, Enschede
- Equipe Zorgbedrijven, Hilversum
- Equipe Zorgbedrijven, Rotterdam
- Equipe Zorgbedrijven, Velp
- Equipe Zorgbedrijven, Zeist
- Gelderse Vallei ziekenhuis, Ede
- Isala Klinieken, Zwolle
- Máxima Medisch Centrum, Eindhoven
- Meander Medisch Centrum, Amersfoort
- Medisch Centrum Leeuwarden, Harlingen
- Medisch Centrum Leeuwarden, Leeuwarden
- Medisch Spectrum Twente (MST), Enschede
- Noordwest Ziekenhugroep, Alkmaar
- OLVG Oost (Onze Lieve Vrouwe Gasthuis), Amsterdam
- OLVG West (St. Lucas Andreas Ziekenhuis), Amsterdam
- Ommelander ziekenhuis groep, Delzicht Delfzijl
- Ommelander ziekenhuis groep, Lucas Wenschoten
- Oogheelkunde Rijswijk, Rijswijk
All Lighthouse monitoring systems at a glance:

Oogheelkunde Warmond, Warmond
Oogziekenhuis Rotterdam, Rotterdam
Park Medisch Centrum, Rotterdam
Rode Kruis ziekenhuis Beverwijk
Slingeland ziekenhuis, Doetinchem
Slotervaart ziekenhuis, Amsterdam
Spaarne ziekenhuis, Heemstede
Spaarne ziekenhuis, Hoofddorp
Tergooi ziekenhuis, Blaricum
Tergooi ziekenhuis, Hilversum
Tjongerschans ziekenhuis, Heerenveen
Tjongerschans ziekenhuis (locatie Sportstad), Heerenveen
Treant Groep Bethesda ziekenhuis, Hoogeveen
Treant Groep Refaja ziekenhuis, Stadskanaal
Treant Zorggroep Schepen ziekenhuis, Emmen
UMC Radboud, Nijmegen
UMC Utrecht, Utrecht
UMCG, Groningen
Universitair Ziekenhuis Antwerpen, Antwerpen (Belgium)
Viecuri, Venlo
VU Depotheek, Amsterdam
VU Medisch Centrum, Amsterdam
Waterland ziekenhuis, Purmerend
Zaans Medisch Centrum, Zaandam
Zorgsaam locatie Antonius ziekenhuis, Oostburg
Zorgsaam locatie De Honte ziekenhuis, Terneuzen

Customers with LMS Professional Monitoring
ASML, Veldhoven
Boers & Co, Schiedam
Bosch Transmission Technology, Tilburg
FEI, Eindhoven
Frencken, Eindhoven
Liquavista, Eindhoven
NAMSA, (Luxembourg)
NTS-Group, Eindhoven
Shell, Amsterdam
TNO Nano, Delft
Vistec, Best
Wennekes Welding Support, Mill
Xycarb Ceramics, Helmond

Customers with LMS Wireless Monitoring
ACE Pharmaceuticals, Zeewolde
Antonius ziekenhuis, Sneek
Avery Dennison, Turnhout (Belgium)
Certe (LabNoord), Groningen
Certe (Laboratorium voor Infectieziekten), Groningen
DHL Medical Warehousing, Nijmegen
DHL Medical Warehousing, Schiphol
DHL Pharma Logistics, Mechelen (Belgium)
Elbo Technics, Groningen
FutureChemistry Holding, Nijmegen
HCM Medical, Nijmegen
Izore Centrum Infectieziekten Friesland, Groningen
Medical Expert Group, Gorinchem
Mediq Apotheek De Esch, Losser
Mediq Apotheek Teylers, Losser
Movianto Healthcare Logistics, Aalst (Belgium)
Movianto Healthcare Logistics, Oss
Nestlé, Nunspeet
Ofichem, Ter Apel
Pall Medistad, Medemblik
Pharming-Broekman Instituut, Schaijk
Pharming-Broekman Instituut, Someren
Polytemp, Bolsward
Polyviation, Groningen
Sandoz, Almere
Steris SynergyHealth, Ede
Steris SynergyHealth, Etten-Leur
Vicentra, Utrecht
Vitreq, Vierpolders
Winclove, Amsterdam

Contact details:

Lighthouse Worldwide Solutions Benelux BV
Van Heemstraweg 19A
NL-6657 KD Boven-Leeuwen The Netherlands

Tel.: +31 (0)487 56 08 11
www.golighthouse.nl

Sales / Training / Rental program: benelux@golighthouse.com
Calibration / Maintenance / Support: csbenelux@golighthouse.com