



# REAL TIME LABORATORY MONITORING SYSTEM



## MONITORING

### LET XILTRIX® WATCH OVER YOUR LABORATORY!

20 years' experience and XiltriX expertise makes XiltriX the total monitoring solution for any laboratory. All day, every day, XiltriX will continuously check from one to thousands of monitor points, log the data securely and generate public or personal alarms when any parameter strays outside set limits. Fully detailed and customised reports are instantly available for auditing or diagnostics. The modular, network based design concept means that systems can be configured to meet every need, with expandability built in. XiltriX is not constrained by the physical structure of the laboratory either, as data transmission can be hard wired, wireless or a combination. Consultancy services from XiltriX ensure that the monitoring solution delivered will be the best and most cost-effective for your individual situation. Validation services from XiltriX mean that it will comply with all the appropriate quality standards like GMP, GLP, ISO and FDA 21 CFR part 11. By developing, programming, maintaining, calibrating and validating XiltriX is your partner in the search for your ideal monitoring system.

### WHAT IS MONITORING?

Quality standards in hospitals, blood banks, pharmaceutical industry etc. are becoming more and more stringent. In any professionally run laboratory, product storage, microbiological processes, and environmental conditions must all be critically controlled. It is impossible for a user to watch equipment all the time, so XiltriX International has developed a system that does it for you. 24 hours a day, 7 days a week, XiltriX watches a myriad vital parameters like temperature and pressure, and warns the user if any controlled parameter moves outside set limits.

### THE BENEFITS OF MONITORING

By closely monitoring all the vital control parameters, quality loss in your product or experiment will be prevented. Furthermore any equipment problems will usually be detected before total failure, allowing preventive actions. These and more benefits will improve your quality system and save money in the future: less products to be thrown away, and medicines, blood and cultures maintained under optimum conditions. XiltriX watches over the lab and notifies those responsible when something is wrong, even when no-one is around. XiltriX can also provide the audit trails, historical data and graphical information needed to provide quality assurance to your suppliers and customers.

### CO<sub>2</sub> AND O<sub>2</sub> MONITORING

Microbiological and IVF laboratories use CO<sub>2</sub> incubators or triple gas incubators (CO<sub>2</sub> and O<sub>2</sub>), and their internal atmospheres must be continuously monitored to maximise cell or culture viability. In the unique XiltriX system, atmosphere samples are taken from the incubator and dried. The true concentrations of CO<sub>2</sub> and O<sub>2</sub> are then measured at programmed time intervals using a system that is automatically calibrated against a standard gas mixture. This ensures consistency of results and prevents false alarms. Sensor systems are available that can monitor up to 16 incubators simultaneously, keeping the cost per incubator down.



### FLEXIBLE: SOLUTIONS FOR EVERY NEED

Every customer has unique needs and wishes, ranging from small systems to the monitoring of entire buildings. XiltriX can satisfy all these needs, offering convenient monitoring packages from 4 measuring points upwards. Each server can handle up to 2000 measurement points and it is possible to scale up to several servers when the demand is higher, for virtually unlimited capacity.



### PARTICLE COUNTING

Particle counting is important for clean rooms, pharmaceutical premises and wherever airborne particulates may be a problem. XiltriX laser-based counters are available to a number of specifications, but typically can monitor particles down to  $0.3\mu$  in diameter. Two size channels are counted simultaneously and the count transmitted digitally to XiltriX. Using digital communication means that there are no data losses due to signal transmission or conversion. XiltriX provides traceable, real-time data that will greatly assist compliance with GMP and similar quality protocols.

### IMMEDIATE INFORMATION ACCESS

XiltriX offers several alarm options – flashing lights, acoustic signals, pre-recorded telephone messages via an automatic dialler, e-mail or SMS text messages. Diagnostic information is always immediately available. For example, the SMS text module provides the location of the alarm and the value that triggered it. Bi-directional communication allows the user to interrogate the XiltriX system, so an alarm situation can be managed from a mobile phone. If more information is needed, the user can log in to XiltriX at home via an internet connection.

## XILTRIX – TOTAL, REAL TIME COMMUNICATION WITH YOUR LABORATORY

Monitoring systems have to be robust, yet flexible enough to adapt to every situation. Every building is different and customers may have to comply with different regulations. XiltriX has found a unique way to combine network, hard-wired and wireless communication in a complete real-time system.

### Alarms and reporting

If a monitored parameter goes out of limits, XiltriX can alert the user in many different ways. Local alarms such as sirens or flashing lights can be located centrally or in the laboratory itself. Automatic SMS messages can be sent direct to the user's mobile telephone, which can then be used to interrogate the system to identify the failure. E-mail messages can be generated automatically, direct to the user's personal computer, in the laboratory or at home, which can then be used to view the status of the entire system. Detailed reports, statistics and historical data are available at all times.

### Webservers and the internet

The XiltriX communication network acts as a living entity, with the webserver at its heart. This robust industrial hardware is built to run 24/7 for years on end. The webserver can be installed in the lab for small systems, or in the IT server room for bigger systems. XiltriX is available via its network interface from any authorised computer, in house or remotely from home. The XiltriX software continuously communicates with the sensor network and checks whether all its processes, modems, substations and sensors are present and working correctly. XiltriX can correct minor system problems itself and will only alert the user if a serious problem needs addressing. This means there is no need to routinely check the system, as the user is alerted only when intervention is needed.

### Flexible communication options

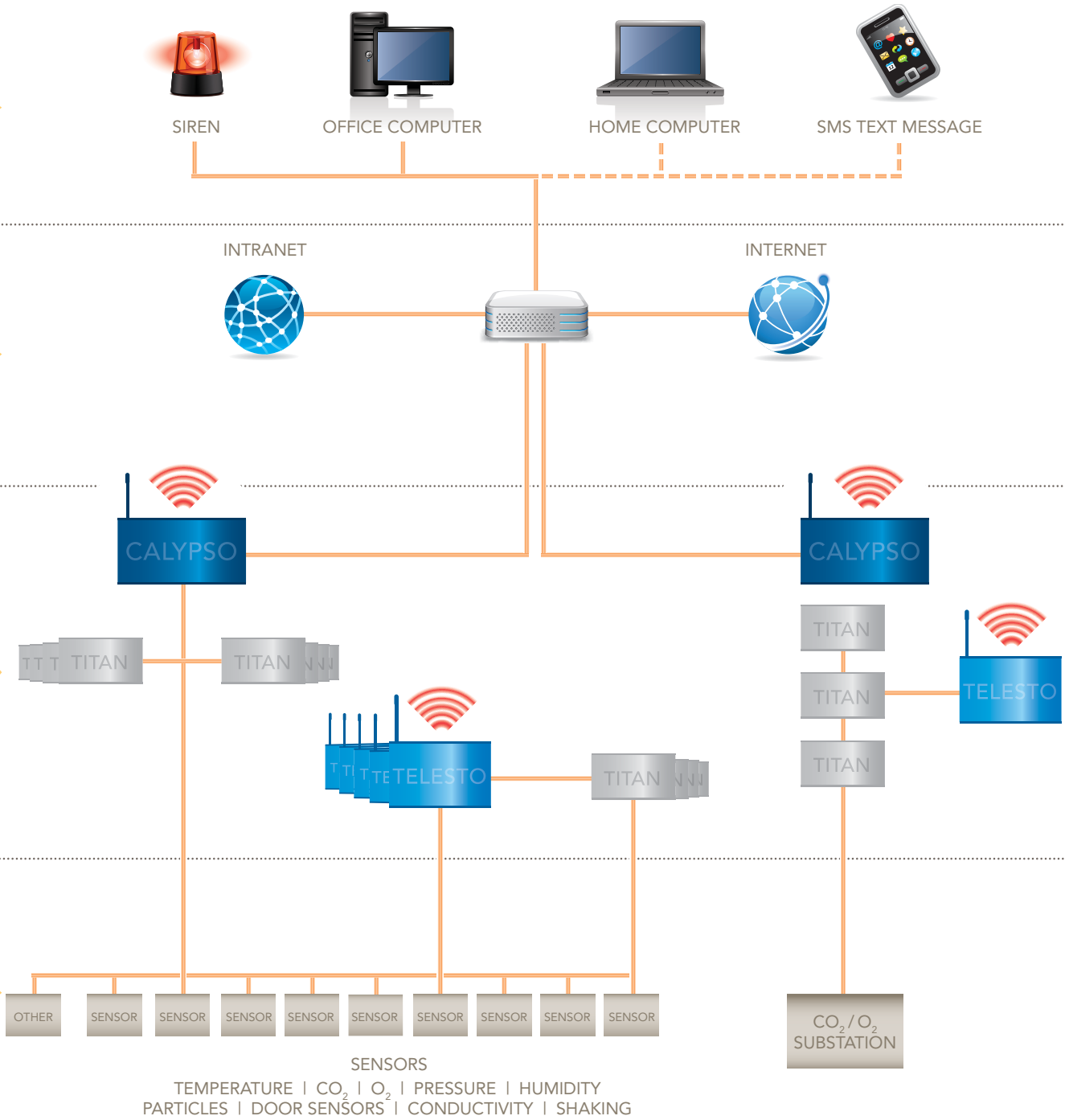
The webserver communicates with the sensor network via XiltriX multi-functional Calypso modems. These in turn communicate with the sensors using either hard-wired Titan or wireless Telesto modems, each of which can handle several sensor inputs. The ability to choose between wired or wireless configuration gives infinite flexibility and expandability and the most cost-effective installation – there is no difference in measuring speed between hard-wired or wireless communication. Telestos can even be used as a wireless communication bridge between a local hard-wired Titan network and Calypso. The 434 MHz frequency band gives good signal penetration through walls, even in "difficult" buildings. Calypso also has digital local alarm outputs and a built in watchdog for added security. Built-in backup batteries and power failure monitors alert the user of local or building-wide power issues while monitoring and alarming keeps on going.

### Sensors and equipment

XiltriX sensors are available for a wide range of parameters, and several can be connected to each Titan or Telesto network modem, which also act as the sensor power supplies. Sensors often need to be installed inside equipment such as incubators, and incubators from XiltriX have optional built-in sensor ports for ease of installation. The unique XiltriX multi-channel CO<sub>2</sub> and O<sub>2</sub> substations can each monitor up to 16 incubators using an automatic gas sampling system that also includes automatic calibration. Sensors are also available for ambient air monitoring for clean rooms, etc., including particle counting.



## Schematic of XiltriX installation with communication options





## EQUIPMENT

### EQUIPMENT FOR EVERY MONITORING NEED

#### SENSORS:

- › Temperature: a range of Pt100 sensors covering temperatures down to -200°C and up to +250°C. Different models for culture vessels, incubators, refrigerators, freezers and surfaces such as microscope heated plates
- › CO<sub>2</sub> and O<sub>2</sub>: vital for IVF and other applications of CO<sub>2</sub> and triple gas incubators. Single sensors or the unique XiltriX 16-channel CO<sub>2</sub> and O<sub>2</sub> substations with automatic sampling and calibration
- › Pressure: differential pressure transmitters to monitor ambient pressure in clean rooms etc.
- › Humidity: to measure Relative Humidity in CO<sub>2</sub> incubators or clean rooms
- › Particles: particle counters for clean rooms or biosafety areas
- › Door sensors: in case the incubator or refrigerator is left open
- › Conductivity: for water purity
- › Shaking: to monitor thrombocyte shakers etc.
- › Special sensors on request

#### DATA TRANSMITTERS:

The building blocks of the XiltriX system, these compact, unobtrusive and stylish units provide totally flexible, wired or wireless connection options between sensors and central server:

- ›› **Calypso**: multifunctional communications between the sensor network and the system server via wireless (434 MHz) or wired (RS485) connections
- ›› **Titan**: wired (RS485) communications interface between sensors and Calypso
- ›› **Telesto**: wireless (434 MHz) or wired (RS485) communications between the sensor network and Calypso
- ›› **Tethys**: Network (RJ45 100 MBit) communications interface between sensors and server

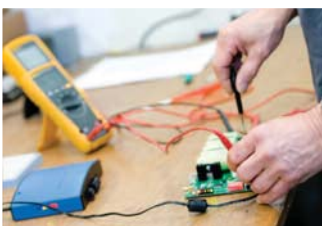
**Physical, virtual and cloud servers**, with XiltriX software with full reporting facilities including:

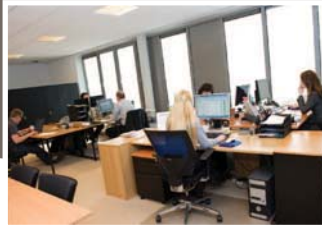
- ›› Historical reports generated in seconds
- ›› Graphs, numerical values and statistical information from any sensor at any time
- ›› Up to 8 parameters displayed simultaneously for easy comparison and trend analysis
- ›› Export of all numerical and statistical data to MS Excel™ compatible files
- ›› Statistics including all commonly used values e.g. MKT (Mean Kinetic Temperature)

#### ALARM OPTIONS:

Home or away, immediate notification of equipment failure or imminent breakdown:

- ›› Warning lights or sirens for local alarms
- ›› SMS alarm package, with accurate event description and receipt acknowledgement
- ›› E-mail package including accurate event description
- ›› Telephone dialler with pre-recorded messages





## CONSULTANCY

Specifying and implementing an effective laboratory monitoring system can be a complex process, with impacts on many functions and disciplines. Each case needs individual attention, not just to the technical requirements but also to the needs of other stakeholders such as the local IT department or financial management. Local and international regulations and norms may need to be taken into account. The layout and construction of the laboratory building will almost certainly have implications for the design and installation of the system. XiltriX International has an in-depth appreciation of the needs, priorities and risks involved and can advise on all these aspects and at all levels. XiltriX' aim is not just to sell equipment, but to provide the guidance and advice needed to implement a comprehensive, cost-effective and technically sound solution in every case.

XiltriX can identify the critical information that has to be accumulated prior to purchase, to ensure that what is purchased fully satisfies the need and to make certain that the proposed XiltriX monitoring solution will integrate fully into the laboratory and quality environment. This includes system integration with other suppliers' equipment if that is the most appropriate solution. XiltriX will guide the customer through the entire purchasing process, from defining the real needs to separating the complex process of decision making into clear steps that produce practical solutions. Properly trained staff are essential to the smooth operation of any laboratory monitoring system, and XiltriX can help here too, with comprehensive training on-site or at the XiltriX headquarters in Rosmalen. Following installation and commissioning, full after-sales support and advice are always available. The XiltriX Consultancy Service has unrivalled specialist knowledge and a unique skill set to put at the service of the market place.



## VALIDATION

Many XiltriX installations are in laboratories operating in regulated environments, where validation is an essential part of the implementation of the system. Validation is a multi-step process, and XiltriX International can assist at all stages.

On request XiltriX will provide the necessary URS (User Requirement Specification) and functional specification documentation to get the validation process kick-started. These documents will be compared to the need and requirements of the customer to see if they match. The results of this exercise will be reported in a review document which is the first step of the validation process. Any subsequent changes will be recorded in the change request documents provided. This part of the process is sometimes known as DQ (Design Qualification).

After installation IQ (Installation Qualification) documents will be completed that record in detail all necessary product information: part numbers, serial numbers, delivery dates, version numbers etc. The way the XiltriX installation was performed is also recorded in great detail. The finished IQ documents provide a blueprint of how the complete system is built up, and with what components. The IQ documents are the second part of the validation report.

The next step is to prepare the OQ (Operational Qualification) template, to confirm that the system does what it is supposed to do according to the functional specifications. This describes all necessary tests, and provides printed proof that the whole of the installation performs to optimum specifications. The finished OQ is recorded in a review document that is also part of the validation report.

Finally the customer will need to perform a regular PQ (Performance Qualification) exercise in order to prove that XiltriX continues to perform correctly, on a daily basis under normal working conditions. XiltriX International can provide documents and procedures to facilitate and largely automate the PQ, and any test results are archived by the XiltriX system. The complete validation report will contain all of the above documents and the printed proof to show auditors that XiltriX complies with appropriate accreditation regulation.

**CONTACT DETAILS:**

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**XILTRIX INTERNATIONAL**

XiltriX International is a growing, innovative company from the Netherlands, specialising in integrated real-time monitoring solutions in clinical, biotechnology, pharmaceutical and microbiology laboratories world-wide. The company delivers integrated, total laboratory solutions ranging from monitoring, consultancy, calibration and validation services. Contact XiltriX on [sales@xiltrix.com](mailto:sales@xiltrix.com) or visit our website: [www.xiltrix.com](http://www.xiltrix.com) (International)