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NEWSLETTER

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To Alarm or Monitor?

A Cost-Benefit Analysis Comparing Laboratory Dial-Out Alarms and a Real-Time Monitoring System.

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INTRODUCTION

It is now generally accepted – if not actually a formal regulatory requirement – that ART laboratories must have a system installed that will alert personnel when a piece of critical equipment (e.g. incubator or cryotank) malfunctions or fails outside normal working hours. This is an inherent element of the laboratory's Quality Management System ("QMS") [Gianaroli *et al.*, 2000; Mortimer & Mortimer, 2005; Kennedy & Mortimer, 2007]. However, the means by which this is achieved range from simple dial-out alarm systems that merely report when an alarm condition is detected by the equipment itself, to more costly automated real-time monitoring systems that not only make, and log, independent measurements on critical functions of equipment, but can also perform the same tasks for the laboratory's environment.

Given the specific requirements of the QMS required by the Directive 2006/86/EC, the second Technical Directive subsequent to the European Union's Tissues and Cells Directive ("EUTCD", Directive 2004/23/EC) [European Union, 2006], these compliance costs, especially those relating to the laboratory's air handling system, constitute a major operating cost for the ART laboratory. This article explores the costs and benefits of these two approaches using example systems in three different size example installations.

COMPLIANCE COST OF MONITORING ART LABORATORY ENVIRONMENT AND EQUIPMENT

The QMS required for compliance with the EUTCD requires that all ART laboratories undertake the following activities routinely (text taken from Annex I of Directive 2006/86/EC):

C1. . . . Where equipment or materials affect critical processing or storage parameters (e.g. temperature, pressure, particle counts, microbial contamination levels), they must be identified and must be the subject of appropriate monitoring, alerts, alarms and corrective action, as required, to detect malfunctions and defects and to ensure that the critical parameters are maintained within acceptable limits at all times. . . .

D7. Critical parameters (e.g. temperature, humidity, air quality) must be controlled, monitored, and recorded to demonstrate compliance with the specified storage conditions.

However, no specifics are given for the frequency of this monitoring, resulting in the following basic structure for the monitoring scheme:

Installation qualification: Performed by certified engineers from the manufacturer or installation contractor when a piece of equipment (e.g. laminar flow cabinet) or physical plant (e.g. HVAC system) is first installed to ensure that it is operating in accordance with its design specifications.

Operational qualification: Performed by certified engineers on a regular basis to establish that the piece of equipment or physical plant is operating in accordance with its design specifications. Usually performed on an annual (sometimes bi-annual or biennial) basis, depending on the stability of the item in question.

Performance qualification: Performed by a member of staff using appropriate calibrated instruments to verify that the piece of equipment or physical plant continues to function within its required operational parameters (hence sometimes referred to as "operational verification"). Performed as often as the user considers is necessary in order to be confident that the item continues to function as per defined requirements.

Clearly an annual re-certification is not sufficient to be sure that the HVAC system continues to provide the desired background air quality (e.g. "Grade D" or ISO Class 8), and more frequent testing will be required – but cost will come into play here as external air quality testing (i.e. repeat operational qualifications) by external specialist companies is expensive. Consequently, more and more laboratories are buying hand-held particle and VOC analyzers, and sending settle and contact plates to a microbiology lab for culture. Nonetheless, there is significant hardware capital cost as well as ongoing staff costs and microbiology service costs associated with this activity, but such expenditures must now be accepted – at least by all ART laboratories within the EU – as necessary compliance costs.

Very many ART laboratories perform independent measurements of incubator temperature and CO_2 on a daily basis, again accepting the device purchase, recalibration and ongoing staff costs as a necessary component of proper quality management. On top of making the measurements there is also the staff cost for data entry and analysis, plotting graphs, and report preparation. Therefore, when comparing the cost of a real-time laboratory monitoring system to that of a basic laboratory equipment alarm system, we must also include *all* the other costs for laboratory equipment and environment monitoring, up to the stage of having reports available for review by the Clinic's Scientific or Laboratory Director and Quality Committee.

In the following example analyses we have included only those aspects of the real-time systems that can be performed "manually", on a routine basis, by laboratory personnel, alongside a basic equipment alarm system. Other capabilities of the real-time monitoring system (e.g. logging incubator door openings, LN2 usage trend analysis for cryotanks), as well as the trivial cost of more frequent measurements (e.g. hourly instead of just daily), constitute substantial added value of the system.

COST-BENEFIT ANALYSES

General Principles

- In all three examples that follow, it is assumed that the facility has a HVAC system to provide at least ISO Class 8 air, and that has integrated photocatalytic VOC removal capability [Lawrence *et al.*, 2007].
- Microbiology cultures (settle and contact plates) have not been included in the costings as they would be the same for either system.
- All costs are in Euros, and an exchange rate of GBP £1.00 to EUR €1.45 has been assumed.

Basic Equipment Alarm and Manual Monitoring System

All "mission critical" items of laboratory equipment, such as incubators and cryotanks, must be connected to a simple dial-out alarm system that will call the Lab Manager (and/or other designated staff members) if an alarm condition occurs outside normal working hours. This is not an intruder alarm or part of the Clinic's or building's security system. The *alarm unit* (auto-dialler) is located near the main entry into the ART laboratory, typically next to a *patch panel* that is connected to all the equipment *alarm connection points* around the laboratory suite. The auto-dialler unit itself needs mains power and a direct telephone line (i.e. one that will not fail should the Clinic's telephone system fail). The Phonetics *Sensaphone 1108* is a very cost-effective unit for this purpose (Fig.1); see www.sensaphone.com/sensaphone-1108-specs.html for more details. *Alarm connection points* are wired from the location of each piece of equipment around the laboratory suite, including the cryobank, to the patch panel. A common arrangement would be for each alarm connection point to comprise a recessed or surface electrical box with two or more connectors that is wired back to the patch panel using, ideally, Cat.5 (or the newer Cat.6) computer network cable as this could also serve for future expansion of the installation as a computer-based monitoring system. The patch panel allows any alarm connection point to be connected, or "patched", to any of the "zones" of the alarm auto-dialler (7 zones are available on a Sensaphone 1108). The example shown in Fig.1 uses RCA "phono" connectors, allowing the use of short audio cables as patch leads.

Fig. 1: Example of a small laboratory equipment alarm system based on the Sensaphone 1108 unit. Note the patch panel on the left, using RCA "phono" type connectors and short audio leads as patch cables.

The system is zero voltage as the equipment being monitored has only "dry" contact points (typically "normally open"). These contacts are built into equipment such as incubators, but special arrangements might be needed for the compressed gas autochange units and for cryotank sensors.

- A system monitor panel should be installed for the laboratory gases, including CO_2, N_2 if tri-gas incubators are used, "pre-mix" gas for use with incubators such as the Cook MINC, and compressed air for anti-vibration tables. While such a panel should display an "alert" when cylinders are successfully changed automatically, it must only trigger an "alarm" when a changeover fails – there is no point in the system calling the Lab Manager at 3am just to notify that a changeover occurred successfully!
- Cryotank monitors should combine low liquid nitrogen ("LN2") level and temperature sensors. Suitable devices are available from many manufacturers, e.g. Taylor-Wharton, Gordinier Electronics, MidAtlantic Diagnostics, etc.

The following estimated retail prices, including taxes, have been assumed in the calculations:

- 1 × Sensaphone 1108 per laboratory, €1000.
- Each alarm connection point (including cable & installation) at €100.
- Patch panels (including cable & installation) at €1000, €2000 or €3000 for the small, medium and large installations respectively.
- Combined low LN2 level and temperature probes at €1200 per cryotank.
- Hand-held electronic thermometer with immersion and surface probes,€3000.
- Small electronic thermometers with bottle-type probes for use in traditional incubators, refrigerators and freezers (e.g. VWR cat. # 620-0904) at €30 per unit.
- Certified reference thermometer, €1000.
- Hand-held *i.r.* CO_2 analyzer (Bacharach 2820 or equivalent), €2000.
- Particle monitoring using the *HandiLaz*® Mini (manufactured by Particle Measuring Systems, Boulder, CO, USA, and distributed in Europe by Research Instruments, Falmouth, UK), €5000.
- VOC monitoring using the *ppbRae Plus* (Rae Systems, San Jose, CA, USA) rather than the ppm *VOC Meter* (Research Instruments, Falmouth, UK; actually the *MiniRAE 2000* instrument) that is only capable of detecting down to the 0.1 ppm level, €8500.

Staff costs, including overheads, have been calculated at €40/hr (equivalent to a salary of about €60,000 *p.a.*).

Real-Time Monitoring Systems

These systems are appearing in increasing numbers of ART laboratories, especially in jurisdictions where the regulatory authority requires more comprehensive monitoring of equipment and/or the working environment. Depending on the sensors installed, they can offer far more than a simple equipment alarm system.

For the purpose of this analysis, the ***Assure24seven*** system from Planer (Sunbury, UK; see www.assure24seven.com) has been used, with the following installed capabilities:

- ***Monitoring:***
  - incubators: sensors for temperature, CO_2 and O_2 concentrations and relative humidity;
  - refrigerators and freezers: temperature sensors;
  - cryotanks: sensors for low LN2 level and temperature; and
  - ambient air: sensors for particulates and volatile organic compounds (VOCs).
- ***Logging:*** maintaining a constant record of all measurements, along with details of any alerts, alarms, operator actions, etc.
- ***Alerting*** when problems occur, by conventional visual and audible annunciators, as well as "direct" options including telephone messages, e-mail, text (SMS) messages.
- ***Reporting:*** via graphical and written reports for easy visualization of data, events and trends.
- ***Accessibility:*** since the system has a web-based interface it can be accessed remotely from anywhere via the Internet.
- ***Security*** of the system's operation and integrity via "all's-well" messages.
- Being computer network-based, the system has inherent ***expansion*** capability (e.g. additional sensors to monitor incubator door openings, or cryotank lid openings).

Example Laboratories (see Figure 2)

Small IVF Laboratory: A small IVF laboratory (no real diagnostic andrology activity), performing about 150 oocyte retrievals per year, that operates using Cook MINC incubators with pre-mixed gas for all embryo culture.

Mid-Size ART Laboratory: A medium-sized ART laboratory, performing around 750 oocyte retrievals per year, that operates using Cook MINC incubators with pre-mixed gas for all embryo culture.

Large ART Laboratory: A large ART laboratory designed to perform 2000 oocyte retrievals per year, to operate using a combination of traditional tri-gas incubators as well as Cook MINC incubators with pre-mixed gas for embryo culture.

Cost Calculations

The calculations of the costs for the two alternative monitoring approaches for the three example laboratories are presented in Tables 1 and 2, and summarized in Table 3.

Table 1: Cost model for the use of alarms and "human" monitoring of equipment and laboratory air quality.

ITEM	Time	Unit cost	Small Lab		Medium Lab		Large Lab	
	(h)		Qty	Cost	Qty	Cost	Qty	Cost
CAPITAL COSTS								
Sensaphone 1108 alarm		€ 1,000	1	€ 1,000	1	€ 1,000	1	€ 1,000
Patch panel		€ 1,000	1	€ 1,000	2	€ 2,000	3	€ 3,000
Alarm connection points		€ 100	12	€ 1,200	17	€ 1,700	36	€ 3,600
LN2 level/temp probes		€ 1,200	3	€ 3,600	5	€ 6,000	25	€ 30,000
Certified reference thermometer		€ 1,000	1	€ 1,000	1	€ 1,000	1	€ 1,000
Hand-held thermometer		€ 2,000	1	€ 2,000	2	€ 4,000	3	€ 6,000
Small thermometers + bottle probes		€ 30	5	€ 150	17	€ 510	25	€ 750
Hand-held CO2 analyzer		€ 2,000	1	€ 2,000	2	€ 4,000	2	€ 4,000
Hand-held particle monitor		€ 4,000	1	€ 4,000	1	€ 4,000	1	€ 4,000
Hand-held ppb VOC analyzer		€ 6,600	1	€ 6,600	1	€ 6,600	1	€ 6,600
+ calibration gas regulator		€ 200	1	€ 200	1	€ 200	1	€ 200
Sub-total				***€ 22,750***		***€ 31,010***		***€ 60,150***
RECURRENT COSTS								
Materials costs								
CO2 analyzer humidity traps	annually	€ 125	1	€ 125	2	€ 250	2	€ 250
Particle analyzer zero count filters	quarterly	€ 180	4	€ 720	4	€ 720	4	€ 720
VOC analyzer calibration gas	quarterly	€ 100	4	€ 400	4	€ 400	4	€ 400
Sub-total				***€ 1,245***		***€ 1,370***		***€ 1,370***
Staff costs	per hour:	**€ 40**						
Annually:								
Thermometer calibration	0.20		6	€ 48	19	€ 152	28	€ 224
Annually sub-total				*€ 48*		*€ 152*		*€ 224*
Daily:								
Workstation temperature check	0.05		1	€ 2	2	€ 4	9	€ 18
Workstation CO2 check	0.10		1	€ 4	2	€ 8	6	€ 24
Incubator temperature check	0.05		4	€ 8	19	€ 38	39	€ 78
Incubator CO2 check	0.10		1	€ 4	4	€ 16	8	€ 32
Waterbath temperature check	0.05		1	€ 2	2	€ 4	2	€ 4
Tube warmer temperature check	0.05		1	€ 2	2	€ 4	3	€ 6
Microscope stage temperature check	0.05		2	€ 4	5	€ 10	8	€ 16
Fridge/freezer temperature check	0.05		1	€ 2	4	€ 8	5	€ 10
Gas cylinder level check (per gas)	0.05		3	€ 6	3	€ 6	4	€ 8
Daily sub-total				*€ 34*		*€ 98*		*€ 196*
Weekly:								
LN2 tank level check	0.10		3	€ 12	5	€ 20	25	€ 100
Workstation particle testing	0.10		3	€ 12	5	€ 20	12	€ 48
Lab particle testing (sites/week)	0.10		1	€ 4	2	€ 8	6	€ 24
Lab VOC testing (sites/week)	0.15		1	€ 6	2	€ 12	6	€ 36
Weekly sub-total				*€ 34*		*€ 60*		*€ 208*
Weeks per year			48		50		52	
Sub-total				€ 13,104		€ 37,452		€ 82,384
Total recurrent costs				**€ 14,349**		**€ 38,822**		**€ 83,754**
TOTAL COSTS OVER 3 YEARS	(3% inflation in years 2 & 3)			**€ 65,797**		**€ 147,476**		**€ 311,412**

Fig. 2: See next page. Overview layouts of the three example laboratories. The small laboratory is a generic design by DM; the medium-sized ART laboratory was designed by DM and Dr Sharon Mortimer for the Pacific Centre for Reproductive Medicine (Burnaby, BC, Canada); and the large ART laboratory is the new facility being built for the Mount Sinai Hospital Reproductive Biology Unit (Toronto, ON, Canada), designed by the authors.

EXAMPLE LABORATORIES

Small IVF Laboratory (below)

Medium-sized ART Laboratory (right)

5 m

Large ART Laboratory (below)

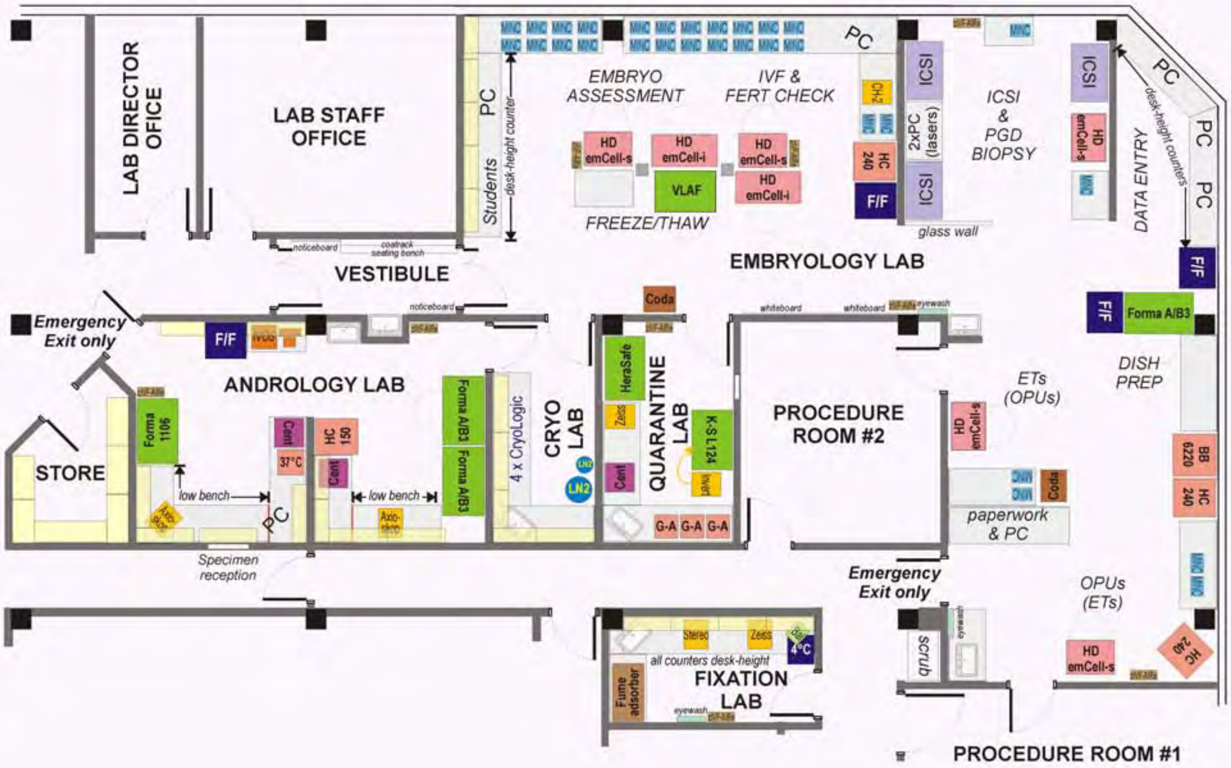

Table 2: Model for the use of an automated real-time system for monitoring equipment and laboratory air quality (based on the Planer *Assure24seven* system).

SYSTEM COMPONENTS	Monitoring requirement(s)	Unit	Small Lab		Medium Lab		Large Lab	
		£	Qty	£	Qty	£	Qty	£
BASIC SYSTEM								
1 each KryoAdmin, Watchdog & Autodialler modules				2,650		2,650		2,650
LAN connection modules				2,400		7,200		16,800
Installation cost (estimate)				6,100		11,200		21,100
EQUIPMENT								
Class II cabinet	Air particulates	£2,353	1	2,353	1	2,353	4	7,045
Vertical laminar flow cabinet	Air particulates	£2,353	1	2,353	2	3,918	3	5,483
IVF Chamber workstation	Air particulates, temp, %CO_2, humidity	£3,944	1	3,944	2	7,100	6	19,718
Incubator, air	Temperature	£80	1	80	3	240	3	240
Incubator, CO2 (traditional)	Temperature, %CO_2, humidity	£1,591	1	1,591	4	6,364		0
Incubator, tri-gas (traditional)	Temperature, %CO_2, %O_2, humidity	£3,091			.		8	24,728
Incubator, MINC-type (pre-mix gas)	Temperature	£150	2	300	12	1,800	28	4,200
ICSI workstation	Stage temperature	£150	1	150	2	300	3	450
Compound microscope	Stage temperature	£150	1	150	3	450	4	600
Waterbath	Temperature	£80	1	80	2	160	2	160
Fridge/freezer	Tempv x 2 (+4°C, -20°C)	£160	1	160	4	640	4	640
Refrigerator	Temperature (+4°C)	£80					1	80
LN2 cryotank (standard type)	LN2 level & temperature	£365	3	1,095	5	1,825	25	9,125
Compressed gas autochange	Alarm condition if fails	£1,175	3	3,525	3	3,525	4	4,700
FACILITY								
Lab air quality (locations)	Particulates		1	2,353	2	3,918	6	10,172
	VOCs	£3,766	1	3,766	2	7,532	6	22,596
Sub-Totals				***£33,050***		***£61,175***		***£150,487***
+ VAT		17.5%		5,784		10,706		26,335
TOTALS (£)				**£38,834**		**£71,881**		**£176,822**
TOTAL SYSTEM COSTS (EUR, €)		**1.45**		**€ 56,309**		**€ 104,227**		**€ 256,392**

Table 3: Summary comparison of the costs of using either alarms with "human" equipment monitoring or automated real-time monitoring systems (see Tables 1 and 2 for details).

System	**Small Lab**	**Medium Lab**	**Large Lab**
Alarms & manual monitoring, Year 1	€14,349	€38,822	€83,754
add Years 2 & 3 (inc. 3% inflation)	€65,797	€147,476	€311,412
Automated real-time system	€56,309	€104,227	€256,392
Savings by the end of Year 3	***€9,488***	***€43,249***	***€55,020***

DISCUSSION

Obviously the initial capital and installation costs for an automated real-time monitoring system are substantially higher than the annual cost of operating using alarms with manual monitoring. However, when the real costs of "human" monitoring is considered over a period of only 3 years, the substantial human resources cost of manual monitoring means that automated real-time monitoring systems provide a clear cost-benefit. Clinics can expect to see overall savings from somewhere between late in the second year of operation (Medium Lab) to mid-way through Year 3 (Small and Large Labs). Given the worldwide shortage of trained clinical embryologists, this should make automated monitoring systems both financially and operationally attractive. Automated monitoring systems also exemplify the fundamental management principle of well-run modern ART laboratories to "work smarter, not harder".

Additional features can be incorporated into the automated systems that will provide functionality beyond what is possible using “human” monitoring, for example:

- Calculating LN2 usage for autofill-capable cryotanks and using trend analysis to identify tanks whose performance is degrading.
- Monitoring the frequency and duration of incubator door openings can add a further dimension to the range of Key Performance Indicators (KPIs) that can be analyzed when monitoring culture system performance.

It should also be noted that the hardware cost for monitoring incubators that use pre-mixed gas (such as the Cook MINC mini-incubator) is substantially lower than that required for traditional “big-box” tri-gas incubators. Since CO_2, O_2 and humidity sensors are not required with compact incubators using pre-mixed gas, the approximate sensor hardware costs per unit are €100 *c.f.* €2100 (not including installation costs). This €2000 cost difference is in addition to the US $1500 per year (*ca.* €1000), per incubator, saving on gas supplies when using a MINC incubator (pre-mix gas) compared to a traditional tri-gas incubator (CO_2 and N_2) [Wiemer, 2006].

Finally, it should be noted that quality-focussed ART laboratories that install automated monitoring systems will very likely still want to have the in-house capability to independently verify at least temperature and %CO_2 for many items of equipment, as well as perform ongoing performance qualifications of their air system (i.e. be able to measure airborne particulates and VOCs). This will entail an extra capital outlay of about €16,000 plus human resource costs, additional factors that must be incorporated into each laboratory’s own cost-benefit analysis of which approach to employ.

CONCLUSION

Although real-time automated monitoring systems do have a significant up-front capital cost, rather than giving the “knee-jerk” response of declaring them “too expensive”, each laboratory should perform a thorough cost-benefit analysis of the ongoing costs of human-based monitoring and consider the total cost of monitoring the laboratory equipment and air quality over at least a 3-year period. From our analysis models it is clear that, even for a small laboratory, an automated system can represent not just increased functionality, but a modest saving within three years. For larger laboratories the savings are more substantial, and could be extremely important from a management perspective when trained embryologists are in short supply.

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It also monitors for deviations in the fiscal P&T transmitters, GC performance problems (response factors and alarms), and flow computer calculation discrepancies (actual volume, compressibility, corrected volume and energy). This is accomplished by incorporating a redundant P&T transmitter for each meter run. By comparing the CBMS pressure and temperature readings with the fiscal flow computerâ€™s values, deviations can be quickly and easily identified.Â Providing a system that does more than just monitor a USM metering station performance is now more practical then ever. Through the use of web-based systems like the AT&T cloud, more automation is being achieved today in order to lower meter station uncertainty.