

## The importance of real-time monitoring for high value biological samples

It is estimated that there are 400,000 frozen human embryos in the United States alone. Globally, many millions of high value cryopreserved samples exist, the vast majority of which are intended for assisted reproduction. With such volumes currently in storage, are we doing enough to protect this precious biological material ?

In an incident in 2012 a fertility clinic suffered a power failure with devastating effects. Samples were lost due to a refrigeration failure as the temperatures in storage vessels went up from -196 degrees centigrade to +20 degrees over a weekend. Liquid Nitrogen used to keep the temperature stable was 'no longer available' according to a spokesperson and around forty patients were affected by the incident. An alarm was triggered by the rising temperature inside the freezer where the embryos were stored - but the freezer was in a basement so was inaudible.

Planer plc provide solutions that can monitor equipment and the rooms in the labs; allow access to data from the Internet; alarm with audibles, phone calls, emails and SMS; and graph and log data. In 2010 they supplied a system to an infertility centre providing treatment including ovum donation, GIFT and ICSI. It undertakes ~500 to 800 IVF cycles a year but in common with many facilities, expansion and logistics are not easy because of space restrictions.

Initial observations showed that skilled staff were spending time taking daily manual readings on temperature and CO2 within incubators, refrigerated equipment; weekly readings on LN2 tanks; additionally they were on call out in the evenings and weekends. Additionally items had to be calibrated at least once a year. The customer needed a simple to use, reliable alarm and monitoring system for sample, equipment and safety which could monitor (or have the ability of monitoring) practically everything in the lab including dewars/tanks, large and bench-top incubators, workstations and room environments etc. A modular system was preferred so the users could expand it as their labs grew and additionally it would have to comply with all European regulations including compliance with 21 CFR Part 11.

The solution proposed allowed the user to automatically monitor all equipment using reliable and independent sensors and ones which would alarm via various methods if equipment was not performing as expected. Information could be accessed securely from any browser desktop and alerts – pre alarm conditions defined by the user - could be provided to unlimited users using different methods: text messages, phone calls emails and numerous visual/audible alarms. The solution proposed could: collect data from eg liquid nitrogen dewars, incubators, room oxygen/temp/humidity monitors and refrigerators; pass that data in real time to Planer's management equipment; process the data and inform users of condition and alarms in user defined ways.

The alerts and alarms would be able to 'cascade' in both their importance and their routing to individuals, depending on the equipment involved and severity of the problem. The opportunity was taken to integrate safety equipment and monitor Oxygen levels within areas containing liquid nitrogen to provide external sounding alarms. After a pre-site survey a plan was drawn up along with a project timetable, proposed options and various costs. Subsequent to installation the system was checked and bedded down over a period of a month or so. With client's permission some maintenance could be carried out remotely if and when needed.

The monitoring and alarm solutions have been designed with expansion in mind. The system installed could house a large amount of data and could cope with many thousands of readings per cycle, automatically backing-up data onto an independent drive. The cost was comparable to other systems that had initially appeared similar but the new system provided flexibility efficiencies, in addition to those of safety and compliance, and these could be offset. A system such as this above also shows the start of Risk Management and may satisfy many insurance companies who can instruct users that critical samples are to be appropriately managed regarding risk.

The growing trend to become parents later in life promises to create further demand for assisted reproduction techniques. Combined with the continued expansion of other biobanks and storage facilities for high value biological materials, effective, scalable and reliable monitoring systems become more important. Directives and legislation still have some way to go in ensuring adequate environmental monitoring. Leading suppliers have made significant progress in providing different systems for different requirements- but perhaps the investment in such systems is insignificant when compared to the cost of replacing the irreplaceable.