Next Generation Quality Control in the IVF Laboratory
Using data loggers to monitor real time incubator temperature

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Introduction

Quality Control (QC) in the IVF laboratory plays an important role in the success of any IVF program. The role of QC procedures in the IVF laboratory is to fine tune existing protocols in order to more effectively help infertile patients in their quest to have a healthy baby. The three most important physical conditions in the IVF laboratory that can be controlled are temperature, pH and osmolality. Laboratories are required to document and monitor these physical conditions regularly as part of their ongoing QC/QA programs. Monitoring and documentation of temperatures inside incubators, refrigerators and freezers is an integral part of routine day to day QC in the IVF laboratory and is a prerequisite for accreditation by CAP, JCAHO or other agencies. In laboratories with multiple banks of incubators and freezers this is a time consuming and laborious process. In large volume laboratories this process can take up to 1 hour every day. Here, we find a new application for real time temperature logging by introducing this system into the IVF laboratory. Data loggers continuously transmit temperature of incubator, freezer and refrigerator interiors at set programmed intervals directly on to a PC. Maximum and minimum values over a period of 24 hours, high and low temperature alarm notification via phone and email were programmed into the system, documented directly and saved as files. We studied one such data logger from Marathon Products, San Leandro CA, the RF2 data logger with its accompanying MDAS-PRO software and adapted this to the IVF laboratory.

Materials and Methods

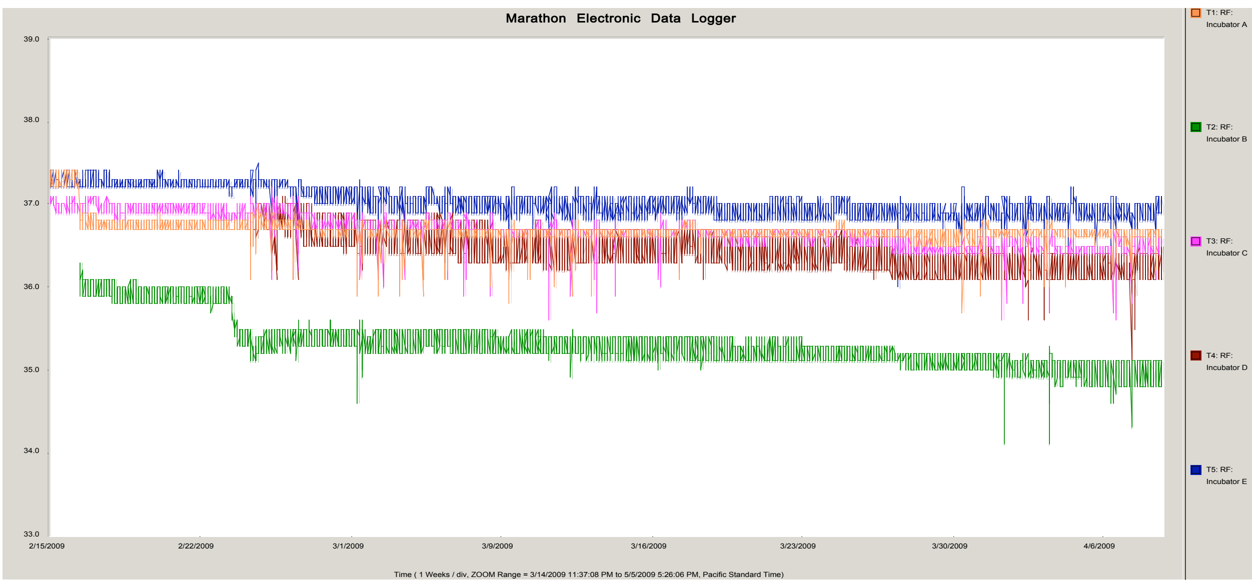
RF2 data loggers were purchased from Marathon products, San Leandro, CA along with the MDAS-PRO software program. Standard Forma water jacketed incubators, Fisher Scientific under counter refrigerators and freezers used in the IVF laboratory were fitted with the edl-RF2 temperature probes. The 1 meter long probes were fed through the port hole located at the back of the incubator. The probe was positioned on the side duct sheet of the incubator near the top shelf close to the rear wall. For the refrigerator and freezer the probes were fed through the door and secured to the back wall using surgical tape. The other end of the meter long probe was connected to the edl-RF2 which is an RF (radio frequency) transmitter with its standard power source. The antenna on the edl-RF2 was positioned for optimal transmission. A distance of 3 feet was maintained between each edl-RF2 to eliminate interference of the signals transmitted. An RF Base Station was connected to a PC to receive the signals from the edl-RF2. The PC was running the MDAS-PRO software and receiving the data transmitted simultaneously from the incubators, freezers and refrigerators. Data was collected over a period of 3 months. Transmission intervals between each reading were adjusted to be 4 minutes and 16 seconds or 4 minutes and 14 seconds apart. High temperature alarm trigger was set at 37.9 C and low temperature was set to 35.0 C for the incubators, 0 C and 8 C for the refrigerators and -30 C to -14 C for the freezer. Each morning the temperature graph profiles were checked and printed prior to opening the doors. Each, specific equipment was designated by a specific color on the graph. Every 15 days the temperature data was saved on a backup disc. edl- RF2 probe readings were compared to both NIST calibrated mercury thermometer readings and digital temperature displays on the incubators. Recovery times after door openings were calculated for all equipment. Drifts were used to recalibrate temperatures and spikes in temperature correlated with door openings. Approximately 25,000 measurements made over a period of 74 days were included in the study. 5 incubators in the embryology laboratory A,B,C,D,E were of the 3110 series while the Andrology top incubator was model 3193.

Position of the edl-RF2 probe and thermistor inside incubator.

The edl-RF2 transmitter in position with its antenna.

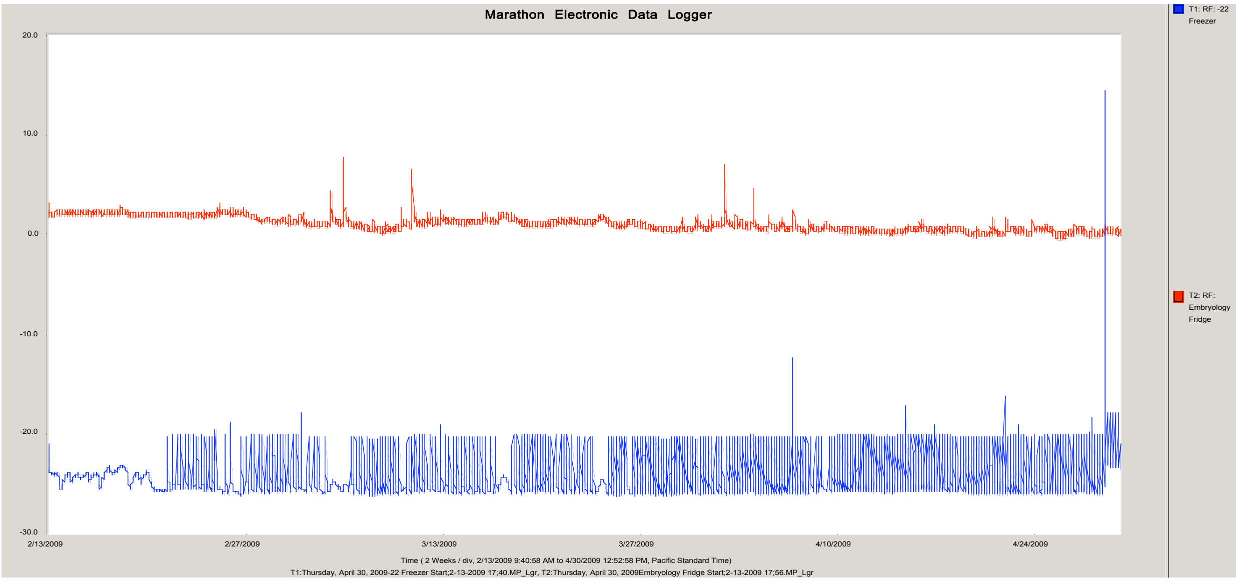
Results

Figure. 1 shows temperature of the interiors of the incubators as measured by the edl-RF2 probe. The different colors code for specific incubators. Downward spikes represent the times the door of the incubator was opened. Incubator B shows a downward drift of temperature even though the digital display on the incubator remained constant at 36.7 C.



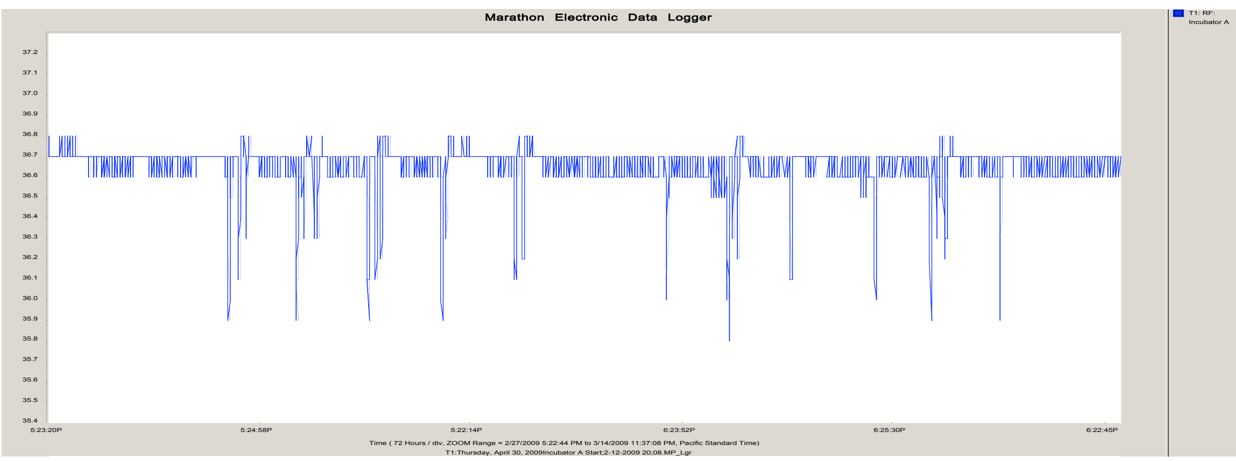
Internal temperatures of incubators measured every 4.25 minutes by edl-RF2.

Figure. 2. Freezer and embryology refrigerator interior temperatures over a period of 2.5 months as measured by the edl-RF2 probes. Upward spikes represent door opening of the refrigerator. Temperatures in the refrigerator were maintained between 1.2-8 C. The freezer temperatures show fluctuations between -25 to -20 C. The upward spikes represent door openings.



Internal temperatures of embryology refrigerator and freezer measured by edl-RF2

Figure 3. Incubator A showed a 0.8 to 1.2 degree C drop from set temperature during door opening and a recovery time of 64 minutes.

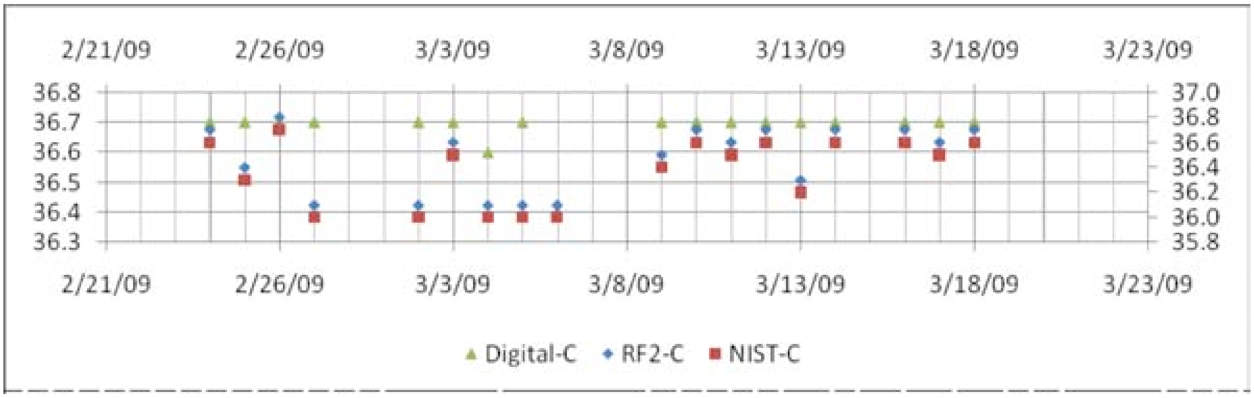


Incubator A showing temperature drops when the door was opened.

Table 1. Recovery times of internal temperatures after doors have been opened for 30 seconds.

- Andrology top Incubator: 75 min
- Incubator A: 64 min
- Incubator B: 43 min
- Incubator C: 43 min
- Incubator D: 51 min
- Incubator E: 55 min
- Embryology Refrigerator: 32 min
- Freezer: 30 min

Figure 4. shows temperatures recorded using 3 different methods. The NIST certified thermometers, the edl-RF2 probes and the digital display on the incubators.



Comparison of the precision and accuracy of the edl-RF2 probes, NIST thermometers and digital display on the incubators.

Table 2 shows high, low, median and average temperatures recorded over a period of 3 months. Incubators ABCD and E were the Forma 3110 series while the Andrology incubator was a Model 3193.

	Andrology Top Inc	Inc A	Inc B	Inc C	Inc D	Inc E
Sample Interval	4 min 16sec	4 min 14sec	4 min 16sec	4 min 14sec	4 min 14sec	4 min 14sec
Number of Measurements	24,631	26,135	24,274	32,643	21,785	25,834
Highest Temperature _C	38.4	37.5	36.3	37.3	37.1	37.5
Lowest Temperature _C	35.6	35.7	33.5	35.1	35.1	36.0
Median Temperature _C	36.9	36.7	35.1	36.4	36.3	37.0
Average Temperature _C	36.9	36.7	35.1	36.5	36.4	37.0
Mean Kinetic Temperature _C	36.9	36.7	35.1	36.3	36.4	37.0

Incubator measurements and sampling statistics.

Conclusions

Temperature is one of the most important physical conditions in the IVF laboratory that requires close attention. Temperature fluctuations have been known to disrupt spindle and chromosomal organization of human oocytes. and cause chromosomal abnormalities of embryos developing from these oocytes. (Almeida and Bolton, 1995).Figure 1 shows temperature data from Embryology and Andrology incubators. All incubators maintained temperature within normal ranges with downward spikes representing door openings except incubator B. Here we see temperatures slowly drifting below set temperatures of 37 C. We were able to pinpoint this drift very early on and exclude this incubator from routine use. Further investigation showed a malfunctioning fan that was not circulating the air inside the incubator optimally creating temperatures gradients in the incubator. The digital display on the incubator remained at 36.7 C throughout this period of drift. Tracking interior temperatures in real time allowed us to be more aware of door openings. Recovery time for incubator temperatures depend on the time the door was left open. A 30 second door opening caused 1.2 degree C fall from set temperatures in the forma 3110 series incubators. Recovery times varied from 43 to 64 minutes. Recovery times were higher around 75 minutes for the Forma 3193 series. Opening the doors of refrigerator and freezers caused temperatures to spike up by 4-6 degrees but still maintain between the normal ranges. Maximum and minimum temperatures were recorded for each incubator and printed daily for QC record keeping. We found the edl-RF2 probes corresponded closely with NIST certified mercury thermometer in both precision and accuracy while the digital displays were found to be inaccurate. Discrepancies between actual readings and the digital display of Forma 3110 incubators have been reported previously (Mortimer, 2004).

In human IVF laboratories there is considerable awareness that the environment of the laboratory itself can alter the quality of the embryos produced and the industry as a whole is moving towards implementation of auditable quality management systems (Lane et al, 2007). Continuous recording of interior temperatures using the edl-RF2 over a period of months allowed for closer monitoring of environment in which the embryos were being cultured and prompt trouble shooting when drifts from the norm occurred.

We conclude that data logging provides such an auditable quality management system and easy, hands off approach to quality control in the IVF laboratory that is a time saving reliable and convenient.

Literature cited

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For further information

More information on temperature data logging can be obtained contacting Lakshmi Sharma at Lakshmi_Sharma@rush.edu or calling (312)- 563-2570; or contact Marathon Products, Inc. 510-562-6450, www.marathonproducts.com.