

Building thermal “Best Practices” at a pharmaceutical manufacturer

Application Note

Testing Functions Case Study



Tools: Fluke Ti10 Thermal Imager, Fluke 771 Milliamp Process Clamp Meter, Fluke 43B Power Quality Analyzer

Operator: Jeff Fleming, manager of engineering operations, CMC ICOS Biologics Inc.

Measurements: Motor, tank, and steam line surface temperatures, 4 mA to 20 mA readings, power spikes

The Food and Drug Administration (FDA) establishes current Good Manufacturing Practice or cGMP for pharmaceuticals. These specified procedures have the force of law and require that manufacturers, processors, and packagers be proactive in ensuring that their products are safe and effective. As a contract manufacturer of pharmaceuticals, CMC ICOS Biologics Inc. of Seattle must comply with cGMP, and it's personnel, including Jeff Fleming, the company's manager of engineering operations, use a variety of monitoring strategies to keep the company in compliance. These strategies include thermography, but Fleming and his co-workers use several other monitoring tools in addition to their thermal camera for troubleshooting equipment and process problems.

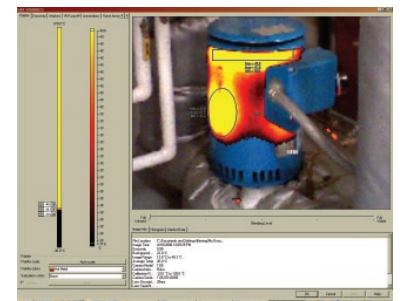
Thermography at this pharmaceutical company

Until very recently, CMC ICOS used an outside contractor to do thermography at the facility. The contractor's work provided baselines on critical equipment so that if, today, monitoring shows that a piece of equipment is trending toward failure, the company can take action.

The reason the company moved away from contract thermography is that it acquired a Fluke Ti10 Thermal Imager. That instrument not only produces thermal images that reveal the surface temperature of objects, it links each infrared (IR) image to a full visible light image, which, in turn, allows for various viewing modes in addition to full IR and full visible light. For example, a user can place a visible light picture as a frame of reference around a thermal image. Or the user can blend the visible and IR image in any ratio to create a single image with enhanced details. Finally, the user can create an “alarm mode” image, Fleming's favorite, in which only temperatures that fall above, below or within a specified range appear in IR while the rest of the scene is full visible light.

The accompanying image of a motor is an example of Fleming's use of the alarm or limit function. “I use the limit function a lot to isolate exactly where the hot areas are,” he says. “It just makes it easier when the diagnostic tool can get rid of all the non-critical values.”

Fleming's original thermal image of a problematic motor is shown above. The image below shows the fine-tuning he achieved using his thermal software to adjust the alarms, add more temperature data, and zero in on the heat location.





During a motor scan, Fleming noted abnormal temperatures on this unit.

Asked about his use of the other modes, Fleming replies, “I use the software a lot. It’s powerful to be able to see what you are looking at (in a full visible light image) but still see the IR image.”

Fleming uses the Ti10 for various troubleshooting tasks. He specifically mentions the following:

Motors have a normal thermal pattern. Fleming’s background in electrical and mechanical systems makes him familiar with these normal patterns and underscores a point to be noted in all preventive maintenance using thermography. That is, familiarity with the equipment being inspected makes diagnosis easier and more exact. For example, in the accompanying motor photo, enhanced by Fleming at his computer using the alarm mode, it was clear to him that the problem was a bad winding and not something else, e.g., inadequate airflow, unbalanced voltage, an overload, a failing bearing, insulation failure or shaft misalignment.

Electrical panels, in which loose or corroded connections increase resistance at the connection and show up as hot spots that require attention before failures occur.

Electrical services at the company, which include main distribution elements: switch gear, transformers, transfer switches, etc. “We are looking for change,” Fleming says, “because we have a good baseline from our previous thermography contractor.”

Steam traps, in which a high inlet temperature and a lower outlet temperature indicate the trap that is functioning correctly. Otherwise, the trap has probably failed, and further investigation into a root cause will be required.

The cold room is a special facility where product is stored near freezing but must not freeze. Sensors mounted throughout the room monitor it, but Fleming nonetheless, uses his IR camera to scan it, too. “We were concerned about the floor freezing as well as the product,” he says, “so we went through with the camera and got a complete picture.” Referring to the

accompanying image, Fleming says, “We’re looking at the air coil. All the blue is below freezing.” The thermal view was very useful for quality control (QC) and for ongoing evaluation. “We also used the thermals as a baseline on how the room was operating.”

Tank insulation on the company’s tanks is difficult to monitor, because the tanks are stainless steel. Of the three kinds of energy that can be emitted from an object—reflected, transmitted and emitted—only emitted infrared energy indicates the object’s surface temperature. Of course, the energy reflected from a shiny stainless steel tank, when recorded by an IR camera, does not represent the surface temperature of the tank. To compensate, personnel at CMC ICOS Biologics place paper tape in a lattice pattern on tanks to monitor the soundness of the interior insulation. The tape quickly reaches the temperature of the surface beneath, and then a valid reading can be made.

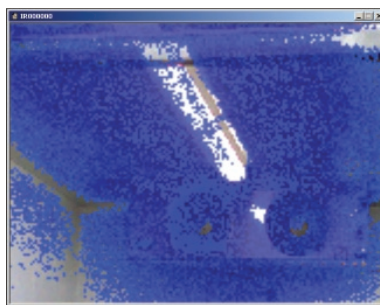
Thermography—looking ahead

The contract thermographer who established the company’s baselines on electrical panels and equipment also used an imager to perform steam trap inspections semi-annually, and Fleming plans to continue that practice. To systematize the inspection procedures, Fleming plans to establish his own inspection routes, take baselines, and regularly conduct inspections.

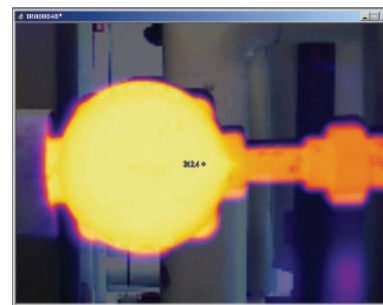
When Fleming’s monitoring program is completely implemented, Icos technicians with established skill sets in electrical, electronics, mechanics and other specialties will traverse pre-set inspection routes with descriptions of exactly where to stop and record thermal data. Fleming can use the described imager/software combination to plan the inspection routes and to analyze the thermal images his team collects.



Checking conductivity meter on an A/B control box. Using the 771 mA Clamp to verify the 4–20 mA signal from the unit to chart recorder, and the using the 43B Power Quality Analyzer to check power quality into the system, looking for fluctuations.



Using temperature alarms in the cold room to trace the freezing threshold.



If there's not a difference in temperature between the steam trap and the pipe, there might be a problem.

Other monitoring at the company

Fleming and his colleagues use several other instruments for maintenance and QC monitoring. Following are descriptions of just some of the instruments and practices performed to keep the company in compliance:

The Fluke 771 Milliamp Process Clamp Meter, recently acquired by the company, is used by Eric Simon and his calibration/metrology group to check 4 mA to 20 mA loops. His operation is more a QC effort than maintenance, but when a faulty mA control loop is found, there are, of course, both maintenance and compliance issues.

Fleming describes use of the 771 Clamp this way, "It's a very good tool to check to see if your 4 mA to 20 mA readings are accurate. While it's not a calibration instrument, it is a good tool for troubleshooting."

Fleming further explains, "Let's say that you have a 4 mA to 20 mA signal that's powering a display. Using the 771, you can clip on the wire quickly and get a ballpark figure that's within one percent of being accurate. So, we use it for doing system checks, but we are aware that it won't give us the full 4 to 20 scale the way a traceable meter would. But it does give us a quick check without breaking the wiring." If the Fluke 771 Milliamp Process Clamp Meter reveals a big problem, then they break out a calibrated instrument per the company's established cGMP procedures.

"Since we are a third-party contract manufacturing company making pharmaceuticals for other companies," Fleming notes, "they audit us and check what we're doing. They look at what our systems are doing. They look at our maintenance records. They want to see that we are running a facility per the cGMP guidelines. Eric (Simon) provides much of the audit support."

The Fluke 43B Power Quality Analyzer got added to the company's maintenance and QC arsenal when there was a problem with a failing autoclave. "The autoclave had an intermittent electrical problem that we could not find, and that's the reason I bought the 43B," Fleming explains. "It has the capability of logging." So, he put the power quality analyzer on line, and collected data for 14 days, at which point the autoclave failed due to a power spike.

Fleming says, "We were able to see the power spike (recorded) on the meter and then determine what caused it. With the suspect circuit identified, we went out to each component and looked for something that could have created the spike."

In this context, as with the earlier case of the motor with faulty windings, Fleming emphasizes that his familiarity with the systems and the equipment under his care is as big a tool as any of the instruments at his disposal. "My big thing with all test equipment is that you have to know what you are working on and with," he says. "You have to have a clear understanding of

what you are doing before you can start looking for problems."

While on the subject of his maintenance philosophy, Fleming emphasizes that he believes that baselines should be established for all new equipment from the time it's put into service. "It gives us a benchmark," he says. "We try to do baselines on all of our equipment, and that allows us to do risk analysis."

Asked whether this risk analysis is part of the cGMP or simply something the company is doing on its own, Fleming replies, "It's kind of a little bit of both. As we become ready for FDA audits, we're pushed more towards risk assessments. Auditors want to know that you've thought about all your possible failure modes."

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