

A person wearing a white lab coat is holding a silver stethoscope. The background is a blurred clinical setting.

DICKSON insights

Spring 2014 • CD277b



HOSPITAL FOCUS

5 Factors That Influence
Your JCAHO Compliance

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What I Learned

Talking with Dickson Customers.

MICHAEL K. MILLER • DICKSON INSIGHTS EDITOR-IN-CHIEF

Back in early March, Dickson attended and exhibited at PittCon, a Laboratory and Sciences Trade Show in Chicago. Now, this may seem like a long time ago, and sure, it was. If you attended, it's probably left your consciousness, and you are only vaguely thinking about how many apples you will eat at next year's show (for those that didn't attend, they had a lot of free fruit).

I attended the show, hanging out in our booth, enjoying the complimentary coffee and chatting with all of Dickson's fabulous customers. What struck me over the course of four days, was both how friendly you all are (aww) and how much Dickson's Replaceable Sensors can help you out.

At Dickson, we like saving our customers money. We also like proving that our products will improve your processes, and make you less angry at temperature monitoring. Because let's be honest, many times it's something you have to do, not what you want to do.

PittCon validated something that I've had a hunch about for quite some time: our Replaceable Sensors rock. Yup, they rock. Customers I talked to perked their ears up a little more when I asked, 'Do you calibrate?' And then followed up that question up with, 'Do you hate it?'

I received a lot of 'yups'. Calibration takes time, it's a hassle that shuts down your critical processes. Whether you do in-house calibrations for your temperature monitoring equipment, or send units back to the manufacturer for calibration, it is a headache, and more importantly, it costs you time and money.

Where am I going with this? What's the sales pitch? Well, at Dickson, we eliminated that headache, and created the Aspirin of calibration: **Replaceable Sensors**. Please, if you have to calibrate, give us a call about them. **Turn to page 6**. Email us. We promise it will be worth your time.



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How to Stay Up to Date on The Most Recent Regulation Changes.

1. Newsletters and Emails

Look, we're not here to argue that getting stuck on an email list is a great thing: waking up every morning and sifting through 30 emails for the one of actual importance from your boss, coworker, sales rep, grandma, etc. isn't fun. But, if there was ever a reason to sign up to receive annoying emails, it's when you are manufacturing a product and are in charge of quality. Sign up with the regulatory agencies who monitor you. It may sound obvious, but our first piece of advice to handling regulation changes? Actually receiving the regulation change.

2. RSS Feeds

Get familiar with these things. By using a website such as feedly and feedreader, you can organize the websites that you visit (or should be visiting) to check on a daily, or weekly basis.

3. Ask, "How will the changes affect my processes, and the processes around me?"

Don't forget this! Whoever you are producing for, or producing from, whether it's a farmer in Illinois or an airline in Australia, keep in mind how the change in your manufacturing process will ultimately affect the entire line of your process. While a large scale thought, it should help provide a balance to how you implement the regulatory changes.

4. Official Control Documents are your friends

When regulation changes occur, you need to implement them, and then prove that you implemented them. Generating an official control document (whether stored in a software suite, or as a hard copy) will increase your legal security, and help you be transparent with your employees, customers, and auditors to the changes that have been made to comply with new regulatory standards.

5. Good old-fashioned communication

This article is meant to help all manufacturing supervisors, which includes a diverse range of industries. One staple in every industry? Communication. Whether you are in paper, food, textile, electronic, or chemical manufacturing, communication is paramount.

Strategize how you communicate to your employees. Speak with your production crew, specifically those who the regulation changes will affect. But communication doesn't just mean speaking with the individuals on your production floor. It means with your fellow manufacturing supervisors, other departments, and regulatory agencies. A question unasked, is an audit failed.

DICKSONONE CLOUD AND MOBILE APP



DicksonOne Cloud When storing data in some place other than your own servers or on your own hard drive, the question of security can constantly nag in the back of your mind. DicksonOne stores your temperature and humidity data securely in the Cloud. As a 21CFR11 compliant system, and with bank level security via Amazon Web Services, DicksonOne can assure you of an unparalleled server infrastructure that gets you your data reliably. Backed up multiple times, our servers are better than file cabinets.



DicksonOne Mobile App for iPhone A great tool for existing DicksonOne customers. Browse all devices and locations. Detailed channel display for seeing current data. Graphs for viewing current trends and historical data.

Requirements: Compatible with iPhone 3GS, 4, 4S, 5, 5S, iPad, and iPod touch 3rd, 4th, and 5th generations. Required iOS 6.1 or later. This app is optimized for the iPhone.



Shipping Critical Products

2.5 Tools To Mean Kinetic Temperature

Mean Kinetic Temperature: used by many but understood by few.

For the food, and pharma industries, knowing the mean kinetic temperature (MKT) of a product or group of products during storage or shipment can be crucial to quality, safety, and falling in line with your auditing agency. Below we've outlined 2.5 tools (more on that .5 later) to help you calculate the MKT of your processes. But first, a brief explanation of what mean kinetic temperature actually is . . .

It's a number. That number is expressed in Celsius, Fahrenheit, or Kelvin, thus it is a number that expresses a temperature value. To expand a little further, MKT is a temperature value that attempts to simulate how a product was effected by temperature over a period of time. Think of it like this: you have a pharmaceutical drug recently manufactured en route to a storage facility. The temperature at the facility it was coming from was 43F, the truck it was shipped in was 27F, and the new storage facility is 38F. MKT simulates the effect of all those temperatures on your product.

1. The Formula Difficulty: **Annoying**

$$T_K = \frac{\frac{-\Delta H}{R}}{\ln\left(\frac{e^{-\Delta H/RT_1} + e^{-\Delta H/RT_2} + \dots + e^{-\Delta H/RT_n}}{n}\right)}$$

2. DicksonOne Difficulty: **Zero**

DicksonOne automatically calculates your MKT for you, appearing on screen next to your temperature and humidity values. For more information, turn to page 10, or give us a call. We'd love to chat.

2.5. Excel Sheet Calculator Difficulty: **Not Quite as Easy as DicksonOne**

Don't want a formula, but not quite ready for DicksonOne? Visit our blog at blog.dicksondata.com. There you'll find a downloadable Excel sheet that lets you simply put in your temperature values over the time you monitored, push a button, and boom, you've got your mean kinetic temperature. Also, it's absolutely free.

Probing Questions

Are You Using The Correct Probe?

Stay with me for a quick hypothetical:

You've been in your current position for only a short while. Let's say you are the QA Manager of a food manufacturer. As you go through the necessary learning curve, and get to know the environment you'll be working in, you notice that your monitoring products need calibrating, or are too few and far between, or aren't functioning at the level you'd like them to be functioning at.

You call up your company's purchasing agent, say you need another temperature data logger, and hang up the phone.

I'm not here to ask the lame rhetorical question, "does this sound like you?" This situation most likely has never happened to you, and you even less likely are dealing with it at the current time.

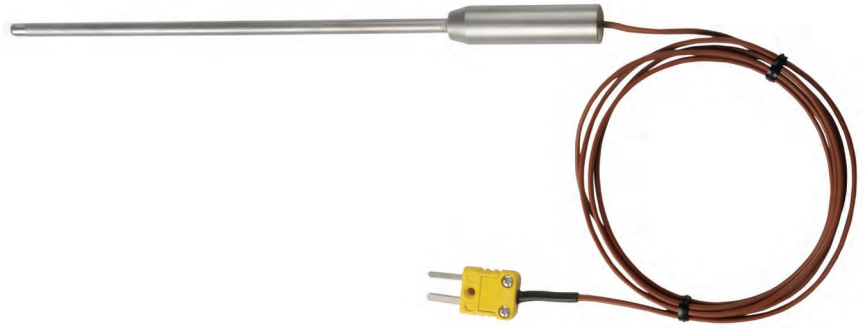
But, it's not invaluable. The above situation illustrates how quality can be sacrificed for convenience. It makes sense to call your purchasing agent when you need a new product, I'm not arguing that. I'm saying that maybe they are making the wrong purchase.

What you are measuring with is as important as what you are measuring. Probes, in our case temperature probes, are not all the same. (Probes/Sensors measure temperature, are connected to a data logger, which records the measured values).

Our question to you is a simple reiteration of our title: "Are you using the right probe?"

Another Quick Example:

If you're using a K-Thermocouple Probe to Monitor Vaccines, you're doing it all wrong. You need to be using a Thermistor or RTD probe, submerged in a Glycol Bottle, with an accuracy of 1.0F or .5C. When did this come around? Less than two years ago. If you're still using a



K-Thermocouple Probe to measure the temperature of your vaccines' environment, you are doing it wrong per the CDC. Reevaluation should happen consistently, if not on a yearly basis. Most of the time you'll be fine, you'll be using the correct probe. However, regulations change, and you need to change with them.

How To Figure It Out:

Step 1: Do you even need a probe?

If you are measuring the ambient temperature of a room, you might not. If you are measuring the ambient temperature of an environmental chamber and want your device on the outside of that environmental chamber, then you probably do. There are hundreds of reasons to use or not use a remote probe. The most basic? Do you want to measure the temperature of something but not submerge your device in the same environment? If so, you need a remote probe.

Step 2: Check your current specifications.

Temperature Accuracy and Range. The two most essential things to your probe. Find out what they are/were. This may seem easy, but if you are using a device made a long time ago, you may have to do a little digging. Start with any old spec sheets or manuals you may have kept, then move onto contacting the manufacturer.

Also be aware of:

- Response Time
- Corrosiveness
- Material type (i.e. HACCP & Stainless Steel)

Step 3: Look up what the people who could get you in trouble really want.

Who audits you? What standards do you have to comply to? Here are a couple of common regulatory agencies that our customers work with in environmental monitoring:

- FDA
- CDC
- USDA

Step 4: Compare.

Do they match? If not, time to reevaluate your probe choice.



Dickson has a growing collection of great videos on:

- Product Introductions and Overviews
- Application Showcases
- How To's

www.youtube.com/dicksondata

Dickson Replaceable Sensors

Recalibration Made Easy

THE OLD WAY

1. Call or order a recalibration online.
2. Acquire a Return Authorization Code from a Dickson Representative.
3. Take unit and probe out of their environment.
4. Shut down production/storage area if necessary.
5. Box unit up.
6. Ship it to Dickson.
7. Dickson recalibrates the unit and ships it back.
8. Receive the unit.
9. Place unit back in your environment.

Total Down Time: 7-10 Days

THE NEW WAY

1. Call or order a Replaceable Sensor online.
2. Receive Replaceable Sensor.
3. Take old sensor off, put new sensor on.

Total Down Time: 0 Days



MODEL	PROBE TYPE	TEMPERATURE RANGES	ACCURACY	PRICE
TEMPERATURE/HUMIDITY				
R200	Digital Sensor	-40° to 185°F (-40° to 85°C)	±0.8°F, 20 to 120°F (±0.44°C, -6.67 to 48.89°C)	\$69
R250	Digital Straight Sensor	-40° to 185°F (-40° to 85°C)	±0.8°F, 20 to 120°F (±0.44°C, -6.67 to 48.89°C)	\$69
TEMPERATURE				
R300	Digital Sensor	-22° to 122°F (-30° to 50°C)	±0.8°F, 20 to 120°F (±0.44°C, -6.67 to 48.89°C)	\$49
R350	Digital Straight Sensor	-22° to 122°F (-30° to 50°C)	±0.8°F, 20 to 120°F (±0.44°C, -6.67 to 48.89°C)	\$49
R400	K-Thermocouple	300° to 2000°F (-184° to 1093°C)	±1.8°F, -22 to 122°F (±1°C, -30 to -50°C)	\$49
R500	Thermistor in Glycol Bottle	-58° to 158°F (-50° to 70°C)	±0.9°F, -58 to 68°F (±0.5°C, -50 to 20°C)	\$69
R525	Stainless Steel Thermistor	-40° to 300°F (-40° to 149°C)	±0.8°F, -20 to 176°F (±0.44°C, -28 to 80°C)	\$69
R600	Platinum RTD	-148° to 350°F (-100° to 176°C)	±0.5°F, -148 to 350°F (±0.3°C, -100 to 176°C)	\$199
R700	Dual K-Thermocouple	300° to 2000°F (-184° to 1093°C)	±1.8°F, -22 to 122°F (±1°C, -30 to -50°C)	\$99
R800	Dual Thermistor in Glycol Bottles	-58° to 158°F (-50° to 70°C)	±0.9°F, -58 to 68°F (±0.5°C, -50 to 20°C)	\$69

NEW PRODUCTS FOR 2014

1. Report Logger

We decided to make the best compact data logger on the market, our **RL200**. With a new outer case, user selectable logging times, and redesigned PC interface, it's exactly what you need.



59 \$



2. Touchscreen Handheld Indicator

TC700/TH700 Instant temperature or temperature/humidity data. No-slip silicone cover. Battery powered.

299 \$

3. Waterproof High Temperature Data Logger

HT300 Waterproof, High Temperature Data Logger. HACCP and FDA Compliant. USB Download. IP68 Rating. Temperature Range -40° to 257°F (-40° to 125°C).

349 \$



TOUCHSCREEN DATA LOGGERS

Full Control At Your Fingertips.

No running back to your PC to see data. Jumbo 4.9" x 6.4" touch-screens. Zoom and scroll with the touch of a finger. Audible/visual alarms. USB and FLASH card data download. Rechargeable Backup Battery. Optional Display Lock. Pre-Calibrated Sensor Compatible.



MODEL	REMOTE PROBE	PROBE TYPE	TEMPERATURE RANGES	ACCURACY	RELAYS	PRICE
TEMPERATURE/HUMIDITY						
FH625	Optional	Temp/RH PCS*	-40°F to 185°F (-40° to 85°C)	±0.8°F, ±0.45°C	▪	\$489
FH635	Optional	Temp/RH PCS*	-40°F to 185°F (-40° to 85°C)	±0.8°F, ±0.45°C		\$529
TEMPERATURE						
FT600	Optional	Temp PCS*	0 to 122°F (-17° to 50°C)	±0.8°F, ±0.45°C	▪	\$399
FT620	1	KT/C	-300°F to 2000°F (-184° to 1093°C)	±1.8°F, ±1°C		\$449
FT630	2	KT/C	-300°F to 2000°F (-184° to 1093°C)	±1.8°F, ±1°C		\$499
FT625	▪	Thermistor	-40°F to 300°F (-40° to 148°C)	±0.8°F, ±0.45°C		\$449
FT640	1	Thermistor/Glycol	-40°F to 158°F (-40° to 70°C)	±0.9°F, ±0.5°C		\$469
FT645	2	Thermistor/Glycol	-40°F to 158°F (-40° to 70°C)	±0.9°F, ±0.5°C		\$489
FT660	▪	RTD	-148°F to 350°F (-100° to 176°C)	±0.5°F, ±0.28°C		\$549

*Pre-Calibrated Sensor

Temperature and Temperature/Humidity Data Logging Solutions

Data loggers are cost effective solutions for monitoring any required area. With solutions for the food, pharma, manufacturing and dozens of other industries, Dickson's data loggers get you your data how you want it.



1



2



3



4

- 1 **SM300 \$249** Temperature Logger. Range -4 to 158°F, -20 to 70°C. Accuracy $\pm 0.8^\circ\text{F}$, $\pm 0.44^\circ\text{C}$.
SM320* \$299 Temperature Logger. Remote Probe. Range with Probe -300 to 2000°F, -184 to 1093°C. Accuracy $\pm 1.8^\circ\text{F}$, $\pm 1.0^\circ\text{C}$.
SM325* \$399 Temperature and Humidity Logger. Two Remote Probes. Range with Probe -300 to 2000°F, -184 to 1093°C. Accuracy $\pm 1.8^\circ\text{F}$, $\pm 1.0^\circ\text{C}$.
SM420 \$499 Temperature Logger. Remote Probe. Range with Probe -50 to 350°F, -45 to 176°C. Accuracy $\pm 0.5^\circ\text{F}$, $\pm 0.28^\circ\text{C}$.
TM320 \$299 Temperature and Humidity Logger. Range -4 to 158°F, -20 to 70°C. Accuracy $\pm 0.8^\circ\text{F}$.
TM325 \$399 Temperature and Humidity Logger. Remote Probe. Range -40 to 185°F, -40 to 85°C. Accuracy $\pm 0.8^\circ\text{F}$.
- 2 **SP125 \$119** Temperature Logger. Accuracy $\pm 1.2^\circ\text{F}$, $\pm 0.67^\circ\text{C}$. Range -10 to 176°F, -23 to 80°C.
SP175 \$229 Temperature Logger with Thermo-couple Probe. Accuracy $\pm 1.8^\circ\text{F}$, $\pm 0.1^\circ\text{C}$. Range -300 to 2000°F, -30 to 50°C. A203 Probe required for +500°F.
TP125 \$199 Temperature and Humidity Logger. Accuracy $\pm 0.8^\circ\text{F}$, $\pm 0.45^\circ\text{C}$. Range -10 to 176°F, -23 to 80°C.
- 3 **SP425 \$159** Temperature Logger. Digital Display. Accuracy $\pm 1.2^\circ\text{F}$, $\pm 0.67^\circ\text{C}$. Range -4 to 158°F, -20 to 70°C.
TP425 \$249 Temperature and Humidity Logger. Digital Display. Accuracy $\pm 0.8^\circ\text{F}$, $\pm 0.45^\circ\text{C}$. Range -4 to 158°F, -20 to 70°C.
- 4 **SK550 \$699** Temperature. Pack of twelve. Accuracy $\pm 1.8^\circ\text{F}$, $\pm 1^\circ\text{C}$. Range -4 to 158°F, -20 to 70°C.
TK550 \$999 Temperature & Humidity. Pack of twelve. Accuracy $\pm 1.8^\circ\text{F}$, $\pm 1^\circ\text{C}$. Ranges -4 to +158°F, -20 to +70°C.

Software required and sold separately. For software and other accessories, visit Page 15, call **630.543.3747** or go to www.DicksonData.com.

Connect With Us

Dickson Social Media Accounts



@DicksonData



Channel:
DicksonData



Search
"Dickson"



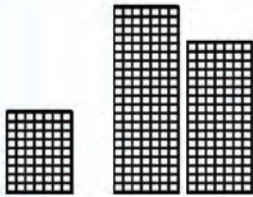
Search
"Dickson Data Loggers"

DicksonOne



Temperature and Humidity Monitoring. Re-imagined.

DicksonOne is a wireless temperature and humidity monitoring system that automatically collects your data and delivers it to wherever you are. No more changing charts, no more downloading data.



MULTI-LOCATION How many points will you be monitoring? 1, 5, 100, 1000? From small cheese factories to multi-location healthcare distributors, DicksonOne is up for the task. Monitoring an additional location is as simple as buying another logger.



ALARMS When temperatures get too hot or cold, your power goes out, or your probe is unplugged, DicksonOne can call, text, or email you to alert you of the mishap. Throw away less products, and ensure the safety of your environment, even when you're not there.



INFINITE STORAGE We don't run out of space, and you never have to worry about hard drives or file folders. We've got you covered.

WHY DID WE MAKE IT?

DicksonOne is the direct result of customer feedback like this:

1. We want to monitor **multiple locations** with one system.
2. We're spending too many **personnel** hours changing charts and pens.
3. We want an **easier way** to share our data.
4. We need **more robust** alarming capabilities.
5. I need to view **my data** from anywhere.

DICKSONONE HARDWARE

DicksonOne Data Loggers are robust and reliable. With battery backup, your choice of Ethernet or Wi-Fi communication, and a digital display, these loggers provide the security and convenience your application needs.



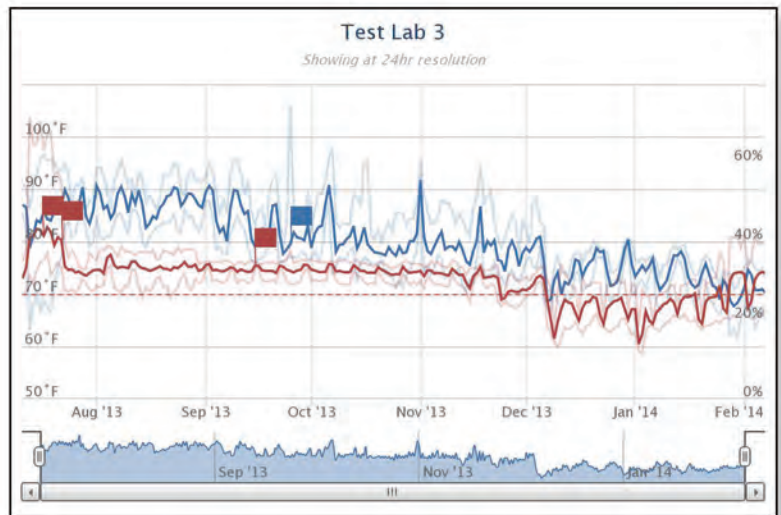
DICKSONONE SOFTWARE

DicksonOne is a SaaS (Software as a Service) platform that automatically stores your data and makes it accessible anywhere.

The software is the real key to DicksonOne. We believe it rises above the competition in usability, security, and scalability. The interface is easy to navigate for everybody, from your IT team to the end-user working with the product you're trying to keep safe. DicksonOne is 21CFR11 compliant, and all data is backed up redundantly, perfect for showing an audit trail. We've had a jump on all other environmental monitoring systems for over a year, and we've kept it that way. We continually improve the system and add new features based on customer feedback. Seriously, someone is working to make it better right now.

The list of features in DicksonOne is endless. Instead of listing them all, we invite you to see for yourself.

Start your free trial at www.DicksonOne.com



DicksonOne Hardware Pricing

MODEL	REMOTE PROBE	PRICE
WFH20/ENH20	Digital Temperature and Humidity Replaceable Sensor	\$499
WFT20/ENT20	Digital Temperature Sensor	\$499
WFT21/ENT21	Thermistor Temperature Sensor with Glycol Bottle	\$479
WFT23/ENT23	K-Thermocouple Temperature Sensor	\$479
WFT25/ENT25	Platinum RTD Temperature Sensor	\$599

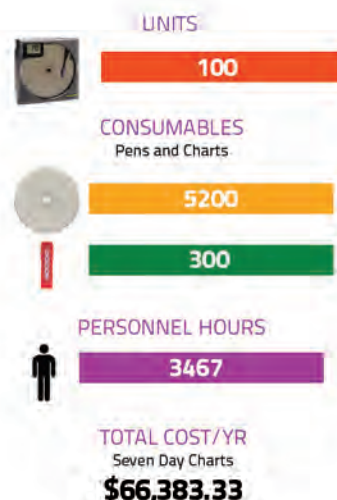


DicksonOne Software Pricing

PLAN	DEVICES	FEATURES	PRICE
Basic	Unlimited	Data Stored for 30 days, 1 hour sample rate	\$0
Starter	1 to 5	Unlimited Data, Multiple Sample Rates, API Access	\$119/year
Regular	6 to 20	Unlimited Data, Multiple Sample Rates, API Access	\$359/year
Plus	21 to 50	Unlimited Data, Multiple Sample Rates, API Access	\$1199/year
Enterprise	51 +	Unlimited Data, Multiple Sample Rates, API Access	Call for Quote

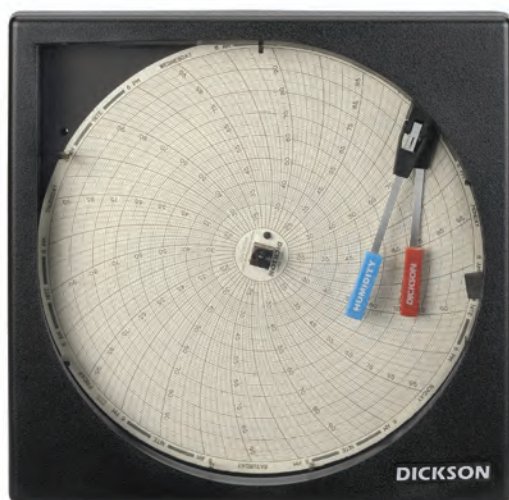


Consider The Cost Of That Old Chart Recorder...



Temperature and Temperature/Humidity Chart Recorders

Want a physical readout right where you are monitoring? Our Chart Recorders have you covered. For ninety years we've built the best chart recorders in the business. Check out our models below.



8 and 6 Inch Models

Eight and Six Inch Chart Recorders to see detailed temperature and humidity values.

MODELS AND FEATURES

KT6	6 Inch Temperature	Starting at \$369
KT8	8 Inch Temperature	Starting at \$419
TH6	6 Inch Temperature and Humidity	Starting at \$489
TH8P	6 Inch Temperature and Humidity	Starting at \$489



4 and 3 Inch Models

Four and Three Inch Temperature Chart Recorders designed to fit any application.

MODELS AND FEATURES

SL4350	4 Inch	\$239
SL4100	4 Inch	\$239
SC3 Series	3 Inch	\$239

Charts sold separately. For charts and accessories, visit Page 15, call **630.543.3747** or go to www.DicksonData.com.

PRESSURE DATA LOGGERS



Pressure Data Logger One second sampling rate. User replaceable battery. Optional delayed start. USB connectivity. Pressure sensor includes built-in diaphragm seal.

PR125	\$499	0-100 PSI
PR325	\$499	0-300 PSI
PR525	\$599	0-500 PSI



Rugged Utility Pressure Data Logger Water resistant case. 3 year battery. Unobtrusive design. Fits easily in a toolbox. USB Connection.

PR150	\$499	0-100 PSI
PR350	\$499	0-300 PSI

PRESSURE CHART RECORDERS



4 and 8 Inch Models

Four and Eight Inch Chart Recorders to meet your needs.
Single AA battery powered. Rugged low-maintenance design features.
7-day or 24-hour recording times. 1/4 inch NPT Connector.

MODELS AND FEATURES

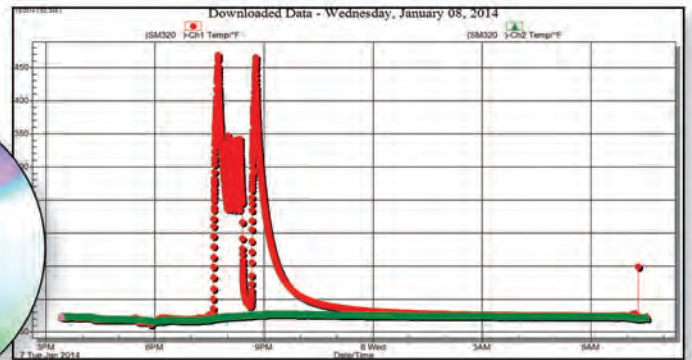
0-100 PSI	PW860/1 \$629	PW470 \$449
0-200 PSI	PW864/5 \$629	PW474 \$449
0-300 PSI	PW866/7 \$629	PW476 \$449
0-500 PSI		PW479 \$629
0-1000 PSI	PW875 \$749	

Charts sold separately. For charts and accessories, visit Page 15, call 630.543.3747 or go to www.DicksonData.com.

DicksonWare

DicksonWare Software was designed with you in mind.
Easy installation. Painless logger setup and data downloads.
Data visualization through populated graphs
and tables.

Learn more at www.DicksonData.com



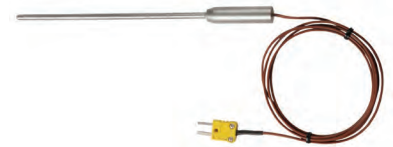
PROBE ACCESSORIES



D617 \$52 10' K-TC Straight Extension Cable



D605 \$79 4" Piercing Probe

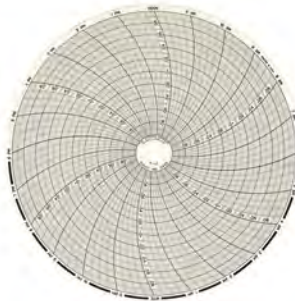


A203 \$125 6" High Temperature Immersion Probe

CHARTS AND PENS

We make reordering charts and pens a cinch.

Only authentic Dickson charts and pens guarantee the accuracy of your temperature, humidity, and pressure data. Fortunately we've made the process of reordering charts and pens fast and easy. Simply go to www.DicksonData.com, click 'Charts and Pens' at the top, choose your device, and easily reorder to the exact specifications you desire. Or give us a call.



Go to DicksonData.com
Or call **630-543-3747**



Dickson Test:

How Hot Does A Dishwasher Get?

Many of our tests begin with an office argument about how hot or cold something is. In this case, an internet rumor sparked our interest.

We have been told that you should run your toothbrushes, potatoes, garden tools, lunch boxes, and sponges through your dishwasher, as it is the only thing that gets hot enough (and doesn't fry them) to sterilize and kill bacteria. Well we wanted to see how hot a dishwasher actually got. So we tested it.

What We Used:

Dickson's HT300 Data Logger. (Page 7) This data logger is extraordinary in monitoring high temperatures. With a range of -40 to 257F, we figured these loggers could handle whatever temperatures a dishwasher threw at them.

The Experiment:

We started our first test way back on October 4, 2013, in one of our em-

ployee's home dishwashers. His dishwasher was compact, and had a multitude of settings, including sani-rinse and high temperature wash. We ran the test a few dozen times in his apartment over the course of a couple of days, trying these different settings, and placing multiple HT300 loggers on both the top and bottom racks of the dishwashers. We used multiple sample rates as well.

In this one series of tests, we found that at their peak, temperatures inside his dishwasher climbed to 170.3F, or about 76.8C. The USDA explains the "Bacteria Danger Zone" as a range of temperatures in which bacteria grows the most rapidly, from 40 to 140F. The National Sanitation Foundation has stated that a dishwasher must reach 150F during the final rinse cycle to be "certified" in being able to kill 99.99% of bacteria. It looks like our team member's dishwasher did that.

For the complete test, and all of our findings, visit our blog at blog.dicksondata.com.

Five Factors From Five Standards That Could Influence Your JCAHO (TJC) Compliance

1. Leadership

Standard LD.02.03.01 "Hospital establishes time frames for the discussion of issues that affect the hospital and the population it serves."

Poor communication between hospital leaders on issues of safety and quality is a problem which The Joint Commission (TJC or JCAHO) realizes, and looks for during auditing. You must prove that the means of communication are present, and that communication on quality and safety is regularly happening in an organized fashion. How? By creating time frames to discuss issues that the hospital has come across.

2. Life Safety

Standard LS.03.01.70 "The hospital prohibits all combustible decorations that are not flame retardant."

Everyone likes to get into the holiday spirit, but be sure you don't buy flammable decorations, or put them in problem spots, such as near space heaters or fuel-fired heaters.

3. Medication Management

Standard MM.03.01.01, Part 18 "The hospital periodically inspects all medication storage areas."

This is about managing medicine safely. Document every time you check storage areas. You want hard evidence. To use data loggers as an example, you should get a device that stores data over time, and allows you to present that data to TJC inspectors, or the QA Manager of the medication at any time.

4. National and Patient Safety Goals

Goal 6, NPSG.06.01.01 "Improve the safety of clinical alarm systems."

What the TJC offers for advice is this: "Develop a systematic, coordinated approach." They stress the significance of managing scrupulously those alarm systems that are in most direct contact with patients, or have the largest effect on them.

5. Patient Care, Treatment, and Services

Standard PC.01.02.13 "The hospital assess the needs of patients who receive treatment for emotional and behavioral disorders."

Standards differ for those patients who are being treated for emotional disorders and behavioral disorders, and expectations can be in depth. PC-12. Take a look at it and make sure you've taken all the necessary measures when it comes to patient mental health.

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10 Key Takeaways

European Union Good Distribution Practices

Below are 10 key takeaways from the EU's "2013 Good Distribution Practices for medicinal products." Why 10? Well, there are 10 main chapters to the European Commission's publication, so we outlined one point you should definitely know from each.

Chapter 1: Quality Management

Takeaway: "The quality system should ensure that records are made contemporaneously."

The EU simply wants to make sure you record what is happening in your quality system, while it is happening. Continuous environmental monitoring, documentation of the validation and verification processes, and regularly updated safety policies help ensure your medicinal products are of the highest quality.

Chapter 2: Personnel

Takeaway: "The Responsible Person."

This person is essential to wholesale distributors of pharmaceutical and medicinal products. The EU lists their responsibilities on Page 3 of the Good Distribution Practice Guidelines, and also talks about the desired qualifications of the responsible person. Namely, this person should:

- have a degree in pharmacy
- be continuously contractible
- delegate duties (not responsibilities)
- have defined authority

Chapter 3: Premises and Equipment

Takeaway: "Calibration of equipment should be traceable to a national or international measurement standard. Appropriate alarm systems should be in place to provide alerts when there are excursions from predefined storage conditions."

Be sure all of your equipment used for the distribution of medicinal products has been properly calibrated, and has all the necessary alarms. 2 A.M wake up calls aren't fun, but they are important to safety.

Chapter 4: Documentation

Takeaway: "Documentation should be retained for the period stated in national legislation but at least five years."

The processes you document should be retained for 5 years. While that may seem like a

long time, hard drives and cloud computing allow less file cabinet space to be used, and less worry about accidentally throwing away documentation about an antibiotic drug an auditor will want 2 years from now. Keep things safe, secure, and easily accessible. Those three pillars for security are hard to come by, so explore different options before committing to one or many means of storage.

Chapter 5: Operations

Takeaway: Qualify your customers

For many, the checking in and out of vendors who supply the medical supplies sold to customers is a daily process. When you sell a pharmaceutical product to a customer, you obviously ask for certain information, more than just their name and favorite color. This information helps qualify them as a customer. It works similarly to when you distribute to new and existing customers. Get signatures, constantly re-check customer authorization to buy medicinal products, and be sure to monitor all your transactions. You don't want to sell something to somebody you shouldn't be selling to them.

Chapter 6: Complaints, Returns, Suspected Falsified Medicinal Products and Medicinal Product Recalls

Takeaway: "Stolen products that have been recovered cannot be returned to saleable stock and sold to customers."

Leaving returned stolen goods lying around your distribution center, waiting to be documented, and lurking for someone to accidentally put back on the shelf with the rest of the products equals bad news for your quality department. Mistakes happen, but these kind of mistakes can be avoided. If you receive a stolen medical product, document exactly what happened (preferably while it was happening) and then follow the procedure your local regulating authority has outlined for such instances.

Chapter 7: Outsourced Activities

Takeaway: "The contract acceptor must forward any information that can influence the quality of the products to the contractor . . ."

If you hire somebody on the outside, be sure the communication pipeline between you and them is effective. Besides asking for in-

ternal audit information, auditing them yourself, documenting every step of the way, and understanding exactly the limitations of this contract acceptor, the contract giver should receive any and all product quality information. That falls on both the distributor of medicinal products, and the person that they hire.

Chapter 8: Self-Inspections

Takeaway: "Self-inspections may be divided into several individual inspections of limited scope."

When planning a self-inspection, don't try to take on the whole world at once. Splice it up. It will allow you more time for documentation, process adjustment, and thorough changes to company policy.

Chapter 9: Transportation

Takeaway: "It is the responsibility of the wholesale distributor to ensure that vehicles and equipment used to distribute, store or handle medicinal products are suitable for their use and appropriately equipped to prevent exposure of the products to conditions that could affect their quality and packaging integrity."

Demonstrate that your stage in the supply chain of medicinal products demonstrates a lack of exposure. That means both setting standards for controlling environmental conditions and then proving those standards were enforced.

Chapter 10: Specific Provisions for Brokers

Takeaway: "[Brokers] must notify the competent authority of any changes to [address, contact, registration] details without unnecessary delay."

Who are brokers? People who work in the medical distribution process without actually handling the product. They negotiate independently on behalf of another person. While regulations are a little less intense for them, they do have to follow Directive 2001/83/EC rules (other than rules pertaining to product contact).

TEMPERATURE AFFECTS STROKE RISK

What We Can Do About It

Per a study presented at the American Stroke Association Meeting Report by Judith H. Lichtman, Ph.D., MPH., and Associate Professor in Epidemiology at the Yale School of Public Health, Lichtman and fellow researchers found that *the colder the temperature, the larger the daily temperature changes, and the higher the average dew point—the greater the risk of an ischemic stroke.*

The study used a sample of 134,510 adults (age 18 and older) admitted to hospitals from 2009-2010 for ischemic stroke. They then cross referenced those names with temperature and dew point data from that time.

What they found is a little staggering. Stroke risk fell 3% with every 5F increase in temperature. Additionally, they found that large temperature fluctuations and increased dew point (related to humidity) were tied to stroke hospitalization increases.

The next question is a little obvious: what do we do with this data? While no direct relationship between temperature changes/dew point and stroke risk has been established, the inklings of an association are present: blood vessels constrict in colder weather, causing blood pressure to rise. Large temperature fluctuations cause stress on the body, and as humidity increases, so does dehydration.

A temporary solution for those at-risk for stroke should focus on risk-aversion and temperature/humidity control, not only the latter. What if you could see trends in temperature and dew point over time, including when a large temperature fluctuation may be increasing your risk of stroke, and it's probably better to stay warm or cool indoors? Yes, this "solution" would allow for you to check The Weather Channel less, but it would also allow healthcare professionals and their patients to better monitor the surrounding environment, and thus help eliminate one cause of stroke.



Dr. Lichtman's study should illuminate for the healthcare industry a table full of possibilities. At one place setting is further research, and at another is stroke prevention through temperature monitoring. Strokes kill approximately 130,000 Americans each year, which according to the CDC is about one American every four minutes. That's an average. More Americans die in the winter than the summer. Let's help those struggling to stay warm a bit. Data Loggers with alerts are a tangible solution for hospitals, patients, and research labs.

If a temperature fluctuation of 5F increases stroke risks by 3%, then when the temperature drops one night from 40F to 10F, that's an 18% increase in someone's risk for stroke. Shouldn't high-risk individuals be alerted of that?

DicksonOne is a wireless temperature and humidity monitoring system and is a solution for the problem Lichtman's research uncovers. If every hospital bed with a stroke patient, and every at-risk stroke patient currently in their home had two temperature and humidity monitors, one for inside and one for out, strokes could be prevented. Turning up your thermostat does not alert you to the tempera-

ture in your bedroom at 2AM, and it doesn't alert you to a door being left open, and it probably hasn't been calibrated.

With the onset of wireless remotes, Nest Labs, and wireless in-home control, the ability to get real-time updates of the environment around us isn't the stuff of sci-fi movies anymore. With the touch a finger, with the plugging in of a data logger, those at-risk for strokes could be better helped.

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