

DRUG STORAGE CONDITION TEMPERATURE MONITORING DEVICES



Sales & Distribution by Health Care Logistics, Inc.

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Introduction to Drug Storage Condition Temperature Monitoring

The Pharmacist is responsible for the disposition (proper storage and handling) of all drug products in the hospital, institution or pharmacy. The storage temperature of a drug is determined by the drug manufacturer through a series of stability studies they have performed prior to the drug's approval. Specific directions are then stated in drug monographs, package inserts and labels with respect to the conditions that pharmaceuticals should be stored and distributed.

Temperature monitoring devices are essentially aids for the pharmacist to perform the necessary monitoring of the storage conditions of drug products. Regulatory bodies like State Boards of Pharmacy and accrediting bodies like the Joint Commission (JCAHO) require and review whether the proper storage conditions are being maintained for drugs stocked in the pharmacy and within the institution.

Health Care Logistics offers a range of temperature monitoring devices to allow the pharmacist to comply to drug storage regulations.

[Note that some monitoring devices included in this bulletin manage both temperature and humidity. For the purposes of this bulletin we will use the term "temperature monitoring device" in a generic sense and point out those particular products that monitor both "temperature and humidity" when and where available.]

A temperature-monitoring device can be as simple as a visual readout of the current and/or range of temperatures. These basic devices have audible alarms to sound out an alert when set limits are exceeded (either above or below a pre-set range).

More sophisticated temperature monitoring devices can also provide hard copy records of the temperature range a drug is subjected to over a period of time. Hard copy records can be in the form of a chart that continuously records temperature over a prescribed period (i.e., 24 hour period, 7 days, etc.). Another form of a hard copy record is a computer file in the form of a table or graph that can be saved and stored in a computer as a spreadsheet or word processing document.

In either case the hard copy printout or file provides the pharmacist with physical evidence which can be filed and provided as evidence of drug temperature monitoring to any regulatory body at the appropriate time.

This technical bulletin will attempt to describe each device in this range of temperature monitoring aids. Charts will be included to aid in the selection of the proper monitoring device for site specific needs.

Traceable Memory Monitoring Devices



The most basic drug storage condition monitoring device is the Traceable Memory Monitor. These come in two models:

- 1) Room monitoring and 2)
Refrigerator/Freezer monitoring. These are essentially used as adjuncts for the pharmacist to make sure that the temperature stays within the limits of pre-set temperature ranges. They provide both a visual (LED readout) and audio (alarm) prompt to alert for temperature variations from a pre-set range.

Both models essentially function similarly. The units only differ with the probe that is used to record the temperature. The Standard Room Temperature Memory Monitor employs a distal probe/external sensor that is placed or positioned in the area that needs to be monitored. The probe/external sensor can be mounted to a wall using a screw with the unit being mounted on an outside wall. The cable can be pulled through a window or door. The proximal end of the probe/external sensor cable is plugged into the unit.

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The Refrigerator/Freezer Traceable Memory Monitor employs a probe imbedded in bottle containing a non-toxic glycol solution. This glycol solution provides a medium that allows for a consistent measurement of temperature when used in a refrigerator or freezer and doesn't cause fluctuations when the door is opened during normal usage. The cord is pulled through the side of the refrigerator/freezer door with hinges and plugged into the unit. The unit can be mounted on the side of the refrigerator with velcro or double sided tape.

Temperature Memory Monitoring Thermometer Features:

Each unit features an LCD digital thermometer. The internal current temperature, max and min memory display at same time with ranges being: internal = 23°F to 122°F (-5°C to 50°C) external = -58°F to 158°F (-50°C to 70°C) in the standard room unit HCL #10367 and -58°F to 158°F (-50°C to 70°C) for the refrigerator/freezer unit HCL #10368.

Each unit has user selectable °C or °F temperature unit range settings and sampling cycles. The user selects the °C or °F temperature units by using the switch on the back. The unit must undergo a hard reset after any change to these temperature units.

Sampling cycles can be normal or fast and are user determined. The normal sampling cycle samples temperatures every 60 seconds. The fast sampling cycle samples temperatures every 10 seconds. The unit must undergo a hard reset after any change to the sampling rates.

There are two display modes on the LCD readout: 1. Normal Display and 2. Alarm Display.

In the Normal Display Mode the current temperature and both the minimum and maximum temperatures experienced are displayed. In the Alarm Display Mode the current temperature and the high and low settings which the user pre-selects and programs into the unit are displayed.

Each unit has a high/low alarm function. To set the unit to alarm the user has to switch to alarm mode. (Alarm mode has hi and low indicated on LCD. On back of unit press 'hi' button to set 'hi' temp and the 'lo' button to set the 'lo' temp. These units adjust in 1 degree increments. If held down for a short length of time it adjusts in 5 degree increments (faster).

Each unit sounds an alarm in both modes. Normal and Alarm. There is an on/off switch to turn off alarm. When the temperature reaches the 'hi' or 'lo' preset limits the alarm will sound for 1 minute. If left unattended, the alarm will stop automatically after 1 minute to conserve power and will issue a 3 second repeater beep every minute for up to 12 hours as a continued warning that the temperature has moved outside the limits that the user preset. Note that the alarm will sound even if the temperature goes back to the normal range you preset.

If the unit is in the Normal mode, the temperature either 'hi' or 'lo' that went out will flash. The alarm can be deactivated permanently by switching the alarm off – on the on/off button. The alarm can be deactivated temporarily by pressing the 'hi' or 'lo' button.

There is a built in low battery signal indication on these units. All °C or °F digits will flash when the battery is low.

Pressing the memory clear button resets the both the min/max temperatures at the same time. Pressing the min or max button on the back of unit resets that particular temperature.

A hard reset is accomplished when by using a pointed object (like a paper clip) which must be pushed into the reset hole on the back of unit to reset the unit.

These units are wall mountable using a screw; velcro or magnet with self-stick backing. Each unit has a built in stand.

A Practical Example for Using the Traceable Memory Monitoring Thermometer

A practical example for using this device is when a hospital pharmacist wants to monitor the temperature of a refrigerator.

The USP designation for a refrigerator is - "a refrigerator is a cold place in which the temperature is maintained thermostatically between 2°C and 8°C (36°F and 46°F)."

Using the Traceable Memory Monitoring Refrigerator/Freezer Thermometer one needs to pre-set it with those temperatures. (One can set the device in either degrees C or degrees F).

There are two modes: 1) the normal display mode and 2) the alarm display mode.

The alarm display mode is set for the range of temperature one wants to monitor. In the case of a refrigerator the "lo" would be set at 36°F and the "hi" would be set at 46°F.

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The probe (green glycol solution imbedded) is placed in the refrigerator. The cable is channeled out through the side of the refrigerator/freezer hinged door and is plugged into the unit. The unit can be mounted on the side of the refrigerator with velcro or double sided tape.

When the unit is switched to the normal display mode one will see three readings registered on the LED: 1) the current temperature of the refrigerator and 2) the minimum temperature experienced in that environment and 3) the maximum temperature experienced by that environment. If one exceeds or goes below the set range the corresponding "min" or "max" will flash on the LED and one can determine if the temperature exceeded the range set or went below the set range. One will also see the range (i.e., what the lowest temperature that was recorded in that environment and the highest temperature recorded in that environment).

When the temperature falls out of the range set the alarm will beep. First for 1 continuous minute. Then for 3 seconds every minute thereafter for the next 12 hours until the alarm is switched off.

A monitoring program utilizing these traceable memory monitoring devices necessitates that a pharmacy designee needs to visually inspect each recording device in the pharmacy and around the hospital or healthcare institution. This designee would have to hand record the monitoring information from each unit to a logbook on a regular basis as prescribed by the site specific drug storage condition monitoring protocol developed for that institution.

Temperature Recorders are available from HCL in two sizes: 1) compact and 2) standard. Also available are additional accessories (i.e., charts and pens).

Temperature Recorder Kits & Charts: Compact & Standard Models

As one progresses up the range of sophistication of drug storage condition monitoring devices the next in line is the Temperature Recorder. Temperature recorders are essentially adjuncts for the pharmacist to check or monitor that the temperature stays within the limits of the required temperature ranges. The added benefit of the temperature recorder is that they provide hard copy or physical evidence in the form of completed charts as to the conditions experienced in the areas that are being monitored.

The pharmacist using a temperature recorder can provide actual hard copy evidence (in the form of a chart) to prove that they are complying to the prescribed drug storage requirements. Usually a recording book or file is kept. The file would name the area being monitored and would hold the finished and dated charts that recorded the temperature variations during the time period monitored. This file or book is then the document that is maintained by the pharmacist and provide to the regulatory body reviewer verify that proper storage conditions were maintained.

When purchasing a temperature recorder It is important to understand the intended use in order to determine which model will provide the most appropriate service. The below chart is an attempt to simplify the process.

Note that there are 7-day recorders and one 24-hour recorder. They are available in either Fahrenheit and Centigrade. Digital or non-digital. Regular sized or compact. The operating range of temperatures of these devices allow it to fit and function inside a freezer, refrigerator or discreetly on a shelf at room temperature.

Replacement charts and pens are available for all models. Tamper seals are available for the compact model.

More detailed Technical Bulletins are available for both the standard and compact models.

Note that other temperature ranged models are available through the Health Care Logistics Resource Department.

HCL#	Description	Description	F (0 to 100)	C (-30 to +50)	F (+4 to +50) or C (-15 to +10)	F (+50 to 96) or C (+10 to +35)	Replacement Charts	Replacement Pens	Tamper Seals
8251	Temperature Recorder Kit-7 Day	Non-Digital	X				8206	8203	
8252	Temperature Recorder Kit-7 Day	Digital	X				8206	8203	
8248	Temperature Recorder Kit-7 Day	Non-Digital		X			8272	8203	
8249	Temperature Recorder Kit-7 Day	Digital		X			8272	8203	
8263	Temperature Recorder Kit-24 Hour	Digital		X			8273	8203	
8258	Compact Temperature Recorder-7 Day	Non-Digital			X		8260F/8270C	8203	8262
8259	Compact Temperature Recorder-7 Day	Non-Digital				X	8261F/8271C	8203	8262

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1. Compact Temperature Recorder - #8258 and #8259



The compact temperature recorder begins functioning as soon as a standard "AA" battery is inserted. The battery drives are designed to run for approximately two years.

1. The device is opened by pressing simultaneously on the bars on opposite sides of the faceplate.
2. The chart disk is affixed to the device, carefully positioning the chart to correspond to the correct day of the week and time of day. This is done by inserting a coin in the "pen adjust screw/chart hub" in the center of the device. A "time index clip" directly to the right of and below the pen tip should be used as a reference point to position the chart in the correct position.
3. The pen tip cartridge is then affixed on the pen arm by carefully lifting and then sliding the pen tip cartridge on until it is firmly seated.
4. Once seated, the pen cap, can be taken off and stored on the pen cap holder on the face of the device.
5. The faceplate is then snapped back on the device. The device can then be placed into the area which is to be monitored.

[Care should be taken to locate the recorder in a clean environment – free of dust and corrosive fumes. It should be kept vertical and level. It can be mounted on a wall.]

A Tamper Seal is available for the compact temperature recorder. It has pre-printed spaces to record the date, time, lot number, and a signature. It is affixed around the recorder and sealed on to itself. This assures that the device is not tampered with during the period it is recording.

The compact recorder is perfect for monitoring goods during transportation.

2. Standard Size Temperature Recorder



The standard sized temperature recorder functions in much the same way as the compact recorder. This size comes with two options: non-digital and digital. The digital recorder has an LED monitor that displays the current temperature. It is more expensive – but well worth the extra expense because you can very easily visualize the current temperature – large and legible.

This standard sized temperature recorder has a door that swings open for easy access for chart and pen replacement.

This model has a separate "pen adjust screw" for correct placement of the pen on the chart. It also has a "chart guide clip" that helps secure the chart on the face-plate.

This model also runs with a standard "AA" battery, but has an "on/off" switch to start and stop the recorder. Battery life estimated to be up to 3 years.

This model also has a feature that allows a "tie-down" cable to secure the device in the area being monitored.

Both models can be surface or wall mounted. These models are used primarily in warehouses, store rooms, hospitals and other storage areas to monitor storage conditions for drugs, food, chemicals, computer equipment or archival materials. They can also be used to document conditions in laboratories, drug compounding rooms and clean rooms. These units are usually wall mounted or fastened to an eye level shelf.

Example:

A practical example for using this device is when a hospital pharmacist wants to monitor the temperature of a drug storeroom.

If the storage conditions are to be at "controlled room temperature" we know that the temperature must be maintained thermostatically and it encompasses the usual and customary working environment of 20°C to 25°C (68°F to 77°F). It allows for excursions between 15°C and 30°C (59°F and 86°F) that are experienced in pharmacies, hospitals and warehouses.

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One could use either of the following standard or compact temperature recorders:
#8251; #8252; #8248; #8249, #8259

Choice is dependent on whether a adjunct digital readout is also desired and whether the size of the monitoring device is important.

Temperature & Temperature/Humidity Data Loggers

The most sophisticated drug condition monitoring devices are the Temperature & Temperature/Humidity Data Loggers. These are similar to the above drug condition monitoring devices in that they accomplish the same task of monitoring the environment and providing evidence of that monitoring.

The added benefit of the "Data Logger" is that software is available to allow for downloading the captured drug monitoring information.

This provides the pharmacist with physical evidence in two forms:

1. Computer file and 2. Printed hard copy generated from the computer file. The computer file (table and/or graph) can be saved to the computer like one would save a spreadsheet or word processing document and hard copy reports can be generated from them.

These saved files (table and/or graph) serve as the evidence of the pharmacist monitoring the conditions where drugs are stored. Usually a drug monitoring record book or file is kept. The contents being the areas monitored along with dates, times and actual data as to the temperature variations during the time periods monitored. This file or book can be used for review by the regulatory body to verify that proper storage conditions were met and maintained for the corresponding recording periods and prove that the hospital, institution or pharmacy is complying to the prescribed drug storage requirements.

It is important to again determine ones needs for a monitoring device to best select which model and accessories is best for the intended use. The above chart is an attempt to simplify the process.

If one has a unique monitoring application need (i.e., range of temperatures/humidity; etc) and the above units do not serve that need - other temperature ranged models are available through the Resource Department at HCL.

HCL#	Description	Description	Temp Range Humidity Range	Temp Accuracy Spec	Humidity Accuracy Spec @ 73°F	Software & Cable
8278	Temperature/Humidity Data Logger	Economy - Temp/Humidity Basic storage and transportation evaluation	- 40 to +176°F 25% to 95%	± 2.25°F > 14°F	±5%	HCL 8307
8279	Temperature Data Logger	Economy - Temp/Humidity Basic storage and transportation evaluation	-40 to +176°F	± 2.25°F > 14°F		HCL 8307
11667	Temperature/Humidity Data Logger	Provides Current, Min/Max Readings at a push of a button LED Readout	+14 to +158°F 0 to 95%	±1.8°F from +14 to +158°F	±2%	HCL8307
11668	Temperature Data Logger	Provides Current, Min/Max Readings at a push of a button LED Readout	+14 to +158°F	±1.8°F from +14 to +158°F		HCL8307
8307	Software & CableDigital	Use with all loggers				
8309	Water Resistant Pouch	used to contain logger in condensing environments				
8314	Temperature/Humidity Data Logger Kit	Includes Software and Cable	same as 8278	same as 8278	same as 8278	
8315	Temperature Data Logger Kit	Includes Software and Cable	same as 8279	same as 8279	same as 8279	

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1. Non-Digital Version Data Loggers



HCL # 8278 Temperature/Humidity & HCL # 8279 Temperature Data Loggers are economy versions useful for basic storage and transportation evaluation monitoring. Information is recorded directly into the monitor and is easily downloaded to a computer utilizing Windows compatible software. This software allows for easy access to the data in the form of both a table and graph. Recorded data can be saved to a computer file for accurate documentation and record keeping. The only way one can utilize these loggers is through the use of the software. [Note: the software will be described further on in this document p. 8-9]. These Loggers operate on an easily replaceable lithium cell battery with a battery life of 1 year.

Recording times can be programmed into the device to record sample points from 10 second to 24 hour intervals in 10 second increments. These loggers can store up to 7,680 sample points.

The sampling parameters can be easily changed utilizing the software.

These loggers are recommended for non-condensing areas. It is recommended that if the environment creates condensation, to try and place the unit (temperature models only) in a small sealed plastic bag to protect it from condensation.

HCL sells an optional water resistant pouch which is recommended for use in condensing areas such as a refrigerator - HCL #8309. These loggers are sold separately or can be purchased as a kit that includes the software and cable.

One software package is all that is needed if the customer purchases multiple loggers.

2. Digital Version Data Loggers



HCL# 11667 Temperature/Humidity & HCL #11668 Temperature are upgraded versions of data loggers which allow the user both a real time visual monitor and a computer file logging capability.

The visual prompt shows the current temperature (and humidity depending on the model being used) as well as both the minimum and maximum temperatures (and humidity depending on the model being used) the logger was exposed to during its monitoring cycle. This is accomplished by pushing the button on the front of the logger. An LED screen indicates the appropriate temperature and/or humidity as well as the min/max.

Again the monitoring information is recorded directly into the logger and is easily downloaded to a computer utilizing Windows compatible software. This software allows for easy access to the data in the form of both a table and graph.

Recorded data can be saved to a computer file for accurate documentation and record keeping. The only way one can utilize these loggers is through the use of the software. [Note: the software will be described further on in this document p. 8-9].

These Loggers operate for 1.5 years at room temperature with an easily replaceable battery. Operation of any of these loggers at extreme temperatures or in real-time mode for prolonged periods can reduce battery life.

Recording times can be programmed into the device to record sample points from 10 second to 24 hour intervals in 10 second increments. These loggers operate for longer monitoring periods and can store up to 32,512 sample points.

The sampling parameters can be easily changed utilizing the software.

These loggers are recommended for non-condensing areas. They recommend that if the environment creates condensation, to try and place the unit (temperature models only) in a small sealed plastic bag to protect it from condensation. HCL sells an optional water-resistant pouch which is recommended for use in condensing areas such as a refrigerator – HCL #8309.

One software package is all that is needed if the customer purchases multiple loggers.

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3. Software Description -

DicksonWare



The brains of all of these "data loggers" is the software package. One must utilize this software in order to use these data loggers. It allows one to verify the performance of the loggers & systems quickly. It allows one to modify, view, graph, store files and print the recorded data.

The software package includes a cable that plugs into a serial port on a computer and allows for easy downloading of the recorded data so that it can be monitored and stored in a data file. Data is displayed in two formats:

1) table and 2) graph which can be integrated into documents, spreadsheets & powerpoint presentations.

Downloaded Data - Monday May 5, 2003

Date/Time	(TR320) Temp/°F	(TR320) RH/%	Index
Minimum Value	72.7	0.9	
AverageValue	74.3	40.3	
Maximum Value	78.4	91.5	
1/7/03 10:15:00 AM	73.7	4.9	0
1/7/03 10:16:00 AM	73.7	4.6	1
1/7/03 10:17:00 AM	73.7	4.2	2
1/7/03 10:18:00 AM	73.7	3.8	3
1/7/03 10:19:00 AM	73.7	3.5	4
1/7/03 10:20:00 AM	73.7	3.3	5
1/7/03 10:21:00 AM	73.7	3.1	6

table

The software is Windows based. Compatible with Windows 95, 98, 2000 and NT. PC must have a 386 or better microprocessor, 4MB of RAM, 1 free COM (serial port) and a CD drive.

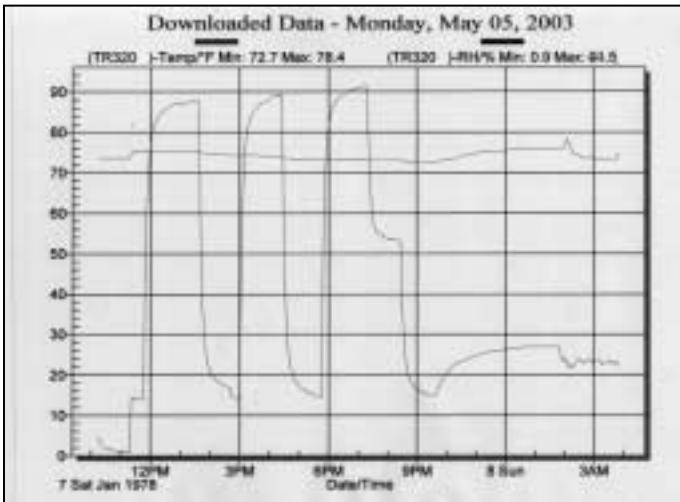
Once loaded onto a computer the Initial Screen – logger Program Main Form comes up.

From this screen the loggers can be set-up with many user configurable features.

One can configure the following:

- Set logger identification – name the logger for recording purposes (i.e., pharmacy storage area, nursing unit storage area, satellite pharmacy storage area, etc)
- Sample intervals – from 10 seconds to 24 hours
- Stop or Wrap when full – feature which stops the recording of data when full or keeps the recorder going when full by recording over the earlier first readings (First In First Out) sliding window which ensures that one always has the latest readings
- Channel Settings (Temperature Channel and Humidity Channel in appropriate model loggers)
- Switch between Fahrenheit and Celsius
- Monitor the battery charge
- Download the recorded data
- Modify the look of the data – change graphics
- Clear Logger Readings – reset loggers
- Set Sample Start Delay – used to insure that multiple loggers start monitoring at the same time
- View data in real-time
- Monitor multiple monitors (MP 100 Multiport Monitor)

graph



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4. Common Data Logger Usage Tips

Unless one needs to view data in real-time the data logger is only connected to the computer when one wants to view/retrieve data.

Data storage is expressed as Sample Point storage. HCL's model #'s 8278 & 8279 can store up to 7,680 sample points and the #'s 11667 & 11668 can store up to 32,512 sample points. The user sets how often a sample point is "logged" from 10 seconds to 24 hours in 10-second intervals.

(For example a temperature logger with storage of 32,512 samples set at 30-second intervals would record for 11.25 days.)

After one downloads the data from a logger - one "clears" the logger and it is again ready to record more data.

Data loggers have two user selectable modes. Stop and Wrap. In Stop mode, they will quit logging data when the memory is full. In Wrap mode, the Logger will begin to overwrite the oldest data in its memory.

Depending on the model used, these data loggers can be used just about anywhere – particularly if used with the optional water resistant bag they can also be used in condensing areas such as refrigerators.

Data loggers gather data just like the chart recorders listed above but the data is logged onto a microchip for PC downloading rather than traced on a paper chart.

The biggest advantage of data loggers is that the data is "logged", stored on a microchip inside the data logger. Data in electronic memory takes advantage of the power of the PC and software. One can:

- Store more data as you would save any document on a PC
- Retrieve archived data as easily as opening a file on a PC
- Share data as you would any PC file, email, copy, and paste.

Data can be imported into spreadsheets and word processing documents.

About the size of a pager, a data logger can be wall mounted with Velcro or simply set anywhere one has a monitoring need.

Drug Storage Condition Monitoring Programs and Device Calibration

Drug Storage Condition Monitoring in this situation is defined as a planned sequence of observations or measurements to assess whether one is functioning under control and to produce an accurate record for use in verification of the monitoring procedure.

As such, this monitoring serves three main purposes:

1. it facilitates tracking of the operation
2. it serves to determine when there is loss of control and allows for the corrective action to be taken to bring the process back into control before a deviation from a critical limit occurs
3. it provides written or hard copy documentation for use in verification

An unsafe drug may result if a process is not properly controlled and a significant deviation occurs. Therefore, monitoring procedures must be effective. Ideally, monitoring should be continuous.

For example, the temperature and time for a critical biotech drug stored under refrigeration is recorded continuously with a data logger that allows the data to be downloaded to a computer file. If the temperature rises above the required temperature range limits for a prescribed length of time this signifies loss of control of the system.

The viability of the product is in question and a decision to discard the product should be made and a corrective action needs to be taken to bring the process back into control. In this case, the refrigeration device needs to be repaired/replaced.

Ideally, the monitoring program should be set up such that as a system goes awry and before critical temperature/time limits are exceeded corrective action can be taken to avoid having to discard product.

Development of a well-documented and administered drug monitoring program in the pharmacy is an important task. An important consideration in this program is the assignment of the responsibility for monitoring and the proper training of personnel in monitoring technique for which they are responsible. It is critical that they fully understand the purpose and importance of monitoring, be unbiased in the process and reporting, and accurately report the results of monitoring.

To assure that the process remains under control it is equally important to develop procedures to follow when there is a trend towards loss of control so that adjustments can be made in a timely manner.

All records and documents associated with drug monitoring should be dated and signed or initialed by the person doing the monitoring.

NIST= National Institute of Standards and Technology

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When feasible, continuous monitoring is always preferred. Also, it is important that one use calibrated instruments when monitoring drug storage conditions and also have proof that they are calibrated to provide to the regulatory bodies.

When it is not possible to monitor on a continuous basis, it is necessary to establish a monitoring frequency and procedure that will be reliable enough to indicate that the system is under control.

Temperature measurement is only as accurate as the device used. Regular calibration of these devices is an important practice that should be included in any drug storage condition monitoring program.

In a well run drug storage monitoring program it is always recommended that one order additional monitoring devices at staggered intervals to have for use as necessary back-ups and temporary replacements in areas where devices need to be switched out for recalibration.

Usually, under normal operating conditions it is recommended to return the monitoring units to the original manufacturer every year for recalibration. In unusually harsh environments, or where required by special quality programs, recalibration may be required every 6 months.

All of Health Care Logistics drug storage condition monitoring devices are available with either a Serial Numbered Certificate of Calibration or Initial Calibration Certificate. These are included to indicate traceability to standards provided by the National Institute of Standards and Technology (NIST). It is important that one use calibrated instruments when monitoring drug storage conditions and also have proof that they are calibrated to provide to the regulatory bodies if requested.

(see page 12-14 for samples of these certificates and associated devices)

Recalibration is the responsibility of the purchaser and subsequent recalibration costs are a basic cost of conducting a proper drug storage condition monitoring program. Health Care Logistics recommends that the purchaser deal directly with the manufacturer in the recalibration process. Health Care Logistics will provide its customers with the information necessary to obtain recalibration certificates on these devices.

Use of Temperature Monitoring Devices in Food Service and Laboratory

This technical bulletin has been focused primarily on the monitoring of drug storage conditions. However, it should be noted that the temperature monitoring devices in this bulletin have numerous uses in a health care institution beyond the pharmacy.

Food service departments need to monitor the storage, refrigeration/freezing and transportation conditions in the handling of food with standards and guidelines being set by State Departments of Public Health or the FDA's Hazard Analysis Critical Control Points.

Laboratories have the need to monitor blood bank conditions as well as specimens, some purchased consumables and test items. Here, the standards and guidelines are set by FDA (Food & Drug Administration), manufacturers and various lab related organizations such as NCCLS (National Committee for Clinical Laboratory Standards), ASM (American Society for Microbiology) , AABB (American Association for Blood Banks) or AACC (American Association for Clinical Chemistry).

Essentially, these temperature recorders can also be used in the following situations:

- Monitoring storage conditions:
 - for food
 - chemicals
 - computer equipment
 - archival materials
- Document conditions:
 - in clean rooms
 - in laboratories
 - in warehouses

Summary

Drug storage condition monitoring is a regulatory requirement and responsibility of the pharmacy and pharmacist. Health Care Logistics offers a selection of drug storage condition monitoring devices that provide a range of sophistication in terms of data collection and reporting. This Technical Bulletin attempted to describe this range of monitoring devices and provide a basis for the selection of the appropriate device for the given monitoring situation. It also provides a recommendation for the development of a well run drug storage condition monitoring program complete with the means to seamlessly include recalibration of the devices to assure that the optimal storage conditions are met and monitored.

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Appendix I

Temperature Range Definitions Review

The following are temperature storage conditions specified by USP 26, pages 9-10, General Notices, Storage Temperature

Freezer: a place in which the temperature is maintained thermostatically between -25°C and -10° C (-13°F and 14°F).

Cold: any temperature not exceeding 8°C (46°F). A refrigerator is a cold place in which the temperature is maintained thermostatically between 2°C and 8°C (36°F and 46°F).

Cool: Any temperature between 8°C and 15°C (46°F and 59°F). An article for which storage in a cool place is directed may, alternatively, be stored and distributed in a refrigerator, unless otherwise specified by the individual monograph.

Room Temperature: the temperature prevailing in a working area.

Protection from Freezing: Where, in addition to the risk of breakage of the container, freezing subjects an article to loss of strength or potency, or to destructive alteration of its characteristics, the container label bears an appropriate instruction to protect the article from freezing.

Warm: any temperature between 30°C and 40°C (86°F and 104°F).

Excessive Heat: Any temperature above 40°C (104°F).

Controlled Room Temperature:

a temperature maintained thermostatically that encompass the usual and customary working environment of 20°C to 25°C (68°F to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°C; and that allows for excursions between 15°C and 30°C (59°F and 86°F) that are experienced in pharmacies, hospitals and warehouses. Provided the mean kinetic temperature remains in the allowed range, transient spikes up to 40°C are permitted as long as they do not exceed 24 hours. Spikes above 40°C may be permitted if the manufacturer so instructs. Articles may be labeled for storage as "controlled room temperature" or at "up to 25°C", or other wording based on the same mean kinetic temperature. The mean kinetic temperature is a calculated value that may be used as an isothermal storage temperature that simulates the nonisothermal effects of storage temperature variations.

An article for which storage at Controlled room temperature is directed may, alternatively, be stored and distributed in a cool place, unless otherwise specified in the individual monograph or on the label.

Initial Calibration Certificate

Included with #8258, #8259, #8278, #8279, #11667, and #11668.

Additional calibration certificates are available through our Resource Department.

Dickson Certificate of Instrument's Initial Calibration

Re-calibration instructions below

Dickson Models: TX120, SX100, SX120

Calibration Procedure: The customer instrument was compared to the calibration standard. Drifts and faults were determined, and any necessary mechanical or electronic adjustments were taken. The Dickson calibration system conforms to the requirements of MIL-STD-45662A and ANSI/NCSL Z540-1-1994 as appropriate.

Calibration Standards: (The Dickson Calibration Standards are traceable through NIST and are re-certified annually)

- General Eastern Chilled mirrors and RTD ($\pm .4\text{RH}$, $\pm .4^\circ\text{F}$)
- Azonix A1011 PRTD ($\pm .2^\circ\text{F}$)
- Ectron 1120 ($\pm .4^\circ\text{F}$)

Accuracy Specifications:

- TX120 RH: $\pm 5\%\text{RH}$ from 25 to 95%RH AT 77°F
- TX120 Temperature: $\pm 2.25^\circ\text{F}$ from $+14$ to $+176^\circ\text{F}$, $+7.65$ (-2.25°F) from -40 to $+14^\circ\text{F}$
- SX100/SX120 Internal: $\pm 2.25^\circ\text{F}$ from $+14$ to $+176^\circ\text{F}$, $+7.65$ (-2.25°F) from -40 to $+14^\circ\text{F}$
- SP120 External (thermistor): $\pm 5.4^\circ\text{F}$

For Your Next Calibration

This is a precision instrument that requires re-calibration. We recommend every 6-12 months.

Just send this completed form along with your instrument to Dickson, labeling the outside of the box with "CCM"...it's that simple!

A) Purchase Order #:

Name: _____ Phone: _____
Model Serial #: _____

B) (Select One)

- 1-Point NIST Calibration \$149.00
- 3-Point NIST Calibration \$199.00
- 3-Point A2LA Accredited 3-pt. Calibration \$299.00 (includes incoming readings)
- N995 - User selectable NIST Temperature points \$50.00 each
(to be selected in addition to one of the above calibration options)

Prices are subject to change

C) Please Return:

- Ground Freight*
- 2nd Day Air*
- Next Day*

D) Ship to:

Bill to: _____

*Charges added at factory

Let Dickson remind you the next time your unit is due for calibration. Join Calibration Club and receive calibration reminders free on all of instruments, including all non-Dickson brands of instrumentation. Learn more and register on-line at www.dicksonweb.com

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Phone: 630-543-3747 Fax: 630-543-0498
www.dicksonweb.com

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Calibration Certificate

Included with #8248, #8249, #8251, and #8252. Additional calibration certificates are available through our Resource Department.

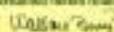
Certificate of Instrument Calibration and Testing														
Calibration report shall not be reproduced, except in full, without written authorization from Dicksen.														
Customer Instrument	Calibration Standards													
Dicksen Model Number: SL4359C7	Loops Model # A1001 Serial # T2489-0014													
Serial Number: 03011296	Probe Serial # 4961081822904													
Calibration Technician: Kitty McReynold	Accuracy: ± 2 °F Certified February, 2002													
Calibration Date: 02/17/2003	Cole Parmer Model # MC-11-49 Serial #: 00115801 Certified October, 2001 0000478 Certified October, 2002 0000475 Certified October, 2002													
Accuracy: ± 4 °F The calibration standards are traceable through the National Institute of Standards and Technology.														
Calibration Procedure P1130														
The customer instrument was compared to the reference standard. Delta's and limits were determined, and any necessary mechanical or electronic adjustments were taken. The Dicksen calibration system conforms to the requirements of IEC, OTCB-FN42CA, ANSI/NFCC, CSA, ISA-IEC guides 13, and ISO 17025 as appropriate. Recalibration of the customer instrument is recommended within 6 months after the unit is placed into service. A2A Certificate Number - 1011-81.														
Dicksen Chart Recorder accuracy specifications are very valid with the use of standard 300mm broad chart and pens. The specifications for chart printing, dot setting, and paper absorption rates and the complementary bleed rate specifications of pens are all critical factors in determining system accuracy.														
Environmental Condition 72 °F 41 %RH														
<table border="1"> <thead> <tr> <th>Calibration Standard Reading</th> <th>Customer Instrument Reading</th> <th>Unit Specification</th> </tr> </thead> <tbody> <tr> <td>Temperature: °C</td> <td>Temperature: °C</td> <td>Temperature</td> </tr> <tr> <td>25.7</td> <td>25</td> <td>±2% F%</td> </tr> </tbody> </table>			Calibration Standard Reading	Customer Instrument Reading	Unit Specification	Temperature: °C	Temperature: °C	Temperature	25.7	25	±2% F%			
Calibration Standard Reading	Customer Instrument Reading	Unit Specification												
Temperature: °C	Temperature: °C	Temperature												
25.7	25	±2% F%												
FOR YOUR NEXT CALIBRATION NO PHONE CALLS REQUIRED Fill out and send this form along with your instrument to Dicksen. Label the outside of the box with "CCP" - that is your R&R#. That's all there is to it!														
1. Purchase Order #: _____ Name: _____ Phone: _____ Model #: SL4359C7 Serial #: 03011296 That's all there is to it! 3. Please return via: <input type="checkbox"/> Ground Freight* <input type="checkbox"/> 2nd Day Air* <input type="checkbox"/> Next Day Air* *Charges added at factory														
2. 1-Pint Dicksen NIST Calibration \$149.00 <input type="checkbox"/> 3-Pint Dicksen NIST Calibration \$199.00 <input type="checkbox"/> 3-Pint Dicksen A2LA NIST \$299.00 (with increasing mailing) <input type="checkbox"/> NIST - Untraceable NIST Temperature points \$10.00 each (to be selected in addition to one of the above calibration options) <input type="checkbox"/> NIST - Next Day Service \$50.00 (Not available for UL/CSA service) Bill To: _____ 4. Skip To: _____														
Charge Plus Order now and receive items with your calibration unit <table border="1"> <thead> <tr> <th>Order No.</th> <th>Qty</th> <th>Price Ea.</th> </tr> </thead> <tbody> <tr> <td>1 Red Pen</td> <td>1</td> <td>\$0.50</td> </tr> <tr> <td>1 Red/3 Blue Pens</td> <td>1</td> <td>\$0.50</td> </tr> <tr> <td>1 Black* (6 per box)</td> <td>1</td> <td>\$12.00</td> </tr> </tbody> </table> *Pen 10 is the standard number. For a listing of available choices go to www.dicksen.com call or "broken pencil" and enter the product code, "Pen - Accessories". Prices are subject to change.			Order No.	Qty	Price Ea.	1 Red Pen	1	\$0.50	1 Red/3 Blue Pens	1	\$0.50	1 Black* (6 per box)	1	\$12.00
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Last Dicksen received you the next time you will be due for calibration. Register for our FREE Calibration Club now at: www.dicksenweb.com D Health Care Logistics, Inc. vices Register from Call Free 1-800-848-1633 Fax Free 1-800-447-2923 (305)342-4418														

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Included with #10367 and #10368.

Calibration complies with ISO 17025				
 (C)				
Cert. No. 4048; 260152				
Traceable® Certificate of Calibration for Digital Thermometer				
Instrument Identification				
Model No. 4048		S/N 221306221		Manufacture/Control Company
Standards/Equipment Used		Model	Serial No.	Recall Date
THERMOMETRICS TEMP PROBE		ES225	128	6/10/2003
HART SCIENTIFIC 2563 MODULE		2563	A27129	7/11/2003
HART PRECISION BATH		7011	93139	
Certificate Information				
As Found: New Instrument				Cal Date: 11/20/2002
As Left: In Tolerance				Due Date: 11/19/2004
Procedure: CAL-03				Technician: 68
Test Conditions: 23.0°C 47.0 RH 30 in Hg				
Calibration Data (As Left)				
Standard	Reading	Units	Condition	
0.001	1	°C	In Tolerance	
49.999	49	°C	In Tolerance	
Accuracy: ±1°C = 1.8°F, DISPLAYS AS 2°F				Test Uncertainty Ratio = 1.7
Expanded Measurement Uncertainty at k=2: ± 0.58°C				
<small>This Digital Thermometer was calibrated against National Institute of Standards and Technology Traceable Instruments. A Test Uncertainty Ratio-of-1 (k=1) is maintained unless otherwise stated and is calculated using the expanded measurement uncertainty. Uncertainty evaluation includes the instrument under test and is calculated in accordance with the ISO "Guide to the Expression of Uncertainty in Measurement" (GUM). The uncertainty represents an expanded uncertainty using a coverage factor k=2 to approximate a 95% confidence level. In tolerance conditions are based on test results falling within specified limits without reduction by the uncertainty of the measurement. The results contained herein relate only to the item calibrated. This certificate shall not be reproduced except in full.</small>				
 <small>Wallace Berry, Technical Manager</small>				
Maintaining Accuracy <small>In our opinion, once calibrated your Digital Thermometer should remain 96% accurate. There is no easy way to determine how long calibration will be maintained. Digital Thermometers change little, if any at all, but can be affected by aging, temperature, shock, and contamination.</small>				
Recalibration <small>For factory calibration and re-certification traceable to National Institute of Standards and Technology contact Control Company.</small>				
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<small>Control Company is an ISO 17025 Accredited Calibration Laboratory. (A2LA) American Association for Laboratory Accreditation Certificate No. 1150.01. Control Company is an ISO 9001 Accredited Company. (DNV) Det Norske Veritas Certificate No. CERT-01065-AQ-HCL-RAB.</small>				



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