

Reduce Risk by Eliminating Paper Chart Records

Overview

For decades, USDA and FDA regulated industries have relied upon paper charts as the definitive record for proof of manufacturing process quality. In many applications, quality assurance managers and auditors accept a pen trace against a trend grid on paper as the sole means of validating the temperature, pressure, and other process variables that are critical to the quality and safety of a product. The purpose of this paper is not to cast doubt on this proven and accepted technology, but to prove that an electronic records-based system can provide data with higher resolution, higher reliability, greater security, and far more convenience. These systems also reduce cost by eliminating consumables, routine maintenance, the risk of lost data, and by providing new insight and access to the process that can help improve efficiency.

Canning Industry Regulations

9 CFR 318.3, Subpart G is the federal regulation that calls out the requirements for the instruments and temperature/time recording devices for thermal processing systems used in canning operations. All references to a temperature/time recording device and “chart” imply the use of a paper chart recorder and the paper chart records produced by these instruments.

For the purposes of this paper, a thermal processing system will be considered a retort, and we will be concerned with how an electronic recording system can be used as the required temperature/time recording device, effectively replacing the functionality of the paper chart recorder. Is the replacement electronic recording system the same device as the paper chart recorder and subject to compliance with the requirements of Subpart G? From the perspective of functionality, capability, and performance, it is not, but we can prove that our subject product (to be introduced shortly) will meet and exceed all of the known requirements.

As a leading manufacturer of industrial paper chart recorders, Yokogawa has perfected the technology of accurate process signal measurement and trending the values against time on a chart printout. There is much art and science in play here, ranging from the design of the analog signal measurement circuit and servo pen drive, to the chemistry of the ink pens and the proprietary recipe used for the chart paper. The result is a beautifully printed trace on the chart paper, with some optional tabular information. It gets even easier from there.

The Problems: Access and Preservation

A paper chart allows operators to write comments about a batch or process and to personally sign the record to authenticate the data. Industry and regulatory agencies acknowledge these printed charts as trusted documents. There are however, numerous problems to overcome:

- I have to carefully guard this print-out. It's the only copy we have!
- How are we going to file all of these charts?
- What if someone spills their coffee on that one and only validation record?
- The auditor will be here in 30 minutes and all of the chart records he will want to see are in boxes in the warehouse somewhere.

By the mid-1990s, the use and support for electronic records (PC-based data files) became widely accepted in process automation, and the inherent advantages of this technology began the drive to replace paper chart recording. In short order, the FDA created 21CFR Part 11, the 1997 regulation defining the criteria for which electronic records and electronic signatures are the equivalent of their paper counterparts. Since that time “Part 11” has become the de-facto regulation used to gauge product compliance for electronic recording systems in all pharmaceutical and biotech FDA program applications. It is also used and accepted in the food and beverage industry in similar product quality related applications.

Now back to the original problems of access and preservation. The inherent pitfalls of singular paper chart records are well known, but what is the best countermeasure? For reasons of operator familiarity, adherence to established quality procedures, and form and fit installation criteria, an excellent solution is to use an electronic recording system that improves upon all of the old features in very possible way.

The latest electronic recording systems provide vastly superior data and the ability to interpret, archive, and retrieve that data than their paper chart counterparts.

Questions are still raised about regulatory compliance when replacing paper chart recorders. Do the requirements in a regulation that references chart recorders apply the same to a new paperless replacement model? How do we create a report that looks like a paper chart? This document will help you answer these questions.

The Product and What it Does

The Yokogawa SMARTDAC+ GX series is a fully integrated, panel-mount data acquisition and display station. That’s a fancy way of saying “paperless recorder” but it is more truthful because the GX far surpasses the capabilities of old paper technology.

Mostly in order of occurrence, here are the key things that the GX provides:

- High accuracy measurement of common process sensors for temperature, pressure, flow and more.
- High resolution real-time trending of process data on a color touchscreen with precise digital readout and alarm status indication. Digital, bar graph, and overview screens are also provided
- Immediate access to all trend history by touch and swipe action on the touchscreen
- Batch information and comprehensive text message input via the touchscreen, captured in the data record
- Secure data recording and automatic archiving to a PC server
- User login with electronic signature support via the GX or with PC software
- Searchable retrieval of saved data records on-screen and with PC software that is also used for reporting and printing
- Ethernet connectivity supporting a host of functions that includes real-time web browser data monitoring and email messaging



As an electronic recording system, the GX replaces printed paper charts with secure electronic records (PC data files). When the GX /AS Advanced Security option is specified, data records are saved in a binary encrypted file format. During record mode, data is saved in real-time to a file in non-volatile flash memory. When recording is stopped, the file is copied to SD removable media for transport to the PC. If connected to a plant network, the GX can automatically send a copy of the file to a network server using the FTP client function. At any point in time, there can be as many as three identical copies of the secure data file stored before any additional PC archiving steps are required. A security check is performed each time the file is copied to ensure they are identical copies.

These data files are intended to be reviewed, reported, and archived in the PC environment. The GX records the data in a proprietary binary file format, and Yokogawa provides free Viewer software that knows how to access these files. With this software, users can search for data using date, time, channel number, tag, batch, and electronic signature status criteria. Users can then examine the data, review statistics, and print trend and tabular data reports. Data can also be converted to Excel or ASCII (.txt) file formats to be used by other applications for additional study and reporting.

For long-term archiving, future access for reporting (like when an auditor wants data on short notice) all common PC tools and practices can be employed to safeguard the data files. For example, files can be automatically backed up to multiple servers to guard against loss of critical data. To satisfy an auditor's report request, the user can search the archive folder for the requested data and quickly produce a report. The benefits of electronic records over paper charts from the standpoint of data security and easy access to the data is reason enough to abandon paper charts!

Meeting Regulatory Requirements With the GX

Canning operations in the food industry must comply with Federal Regulation 9 CFR, Subpart G. Use of paper chart recorders is called out in numerous areas in Section 318.305 for trending temperature, pressure, and other variables against time.

The next section of this paper will look at the GX functions in detail that replace, and generally exceed, corresponding chart recorder functions. Although 9 CFR, Subpart G applies to paper chart recorders, and GX is an electronic recording system, we can say that GX meets the requirements of this regulation in all important aspects when it is used to replace paper chart recorders. The next few pages explain this. This is important from a data interpretation functional replacement point of view.

21CFR Part 11

Since the GX is an electronic recording system, it must meet the requirements of FDA Regulation 21CFR Part 11 when used in FDA or USDA program applications. This regulation calls out the requirements for which electronic records are deemed the equivalent of paper records, and the GX fits squarely into this category. To fully achieve compliance with 21CFR Part 11, the GX must be equipped with the /AS Advanced Security option. This option adds audit trail, advanced user login functions, and electronic signature functions to the GX.

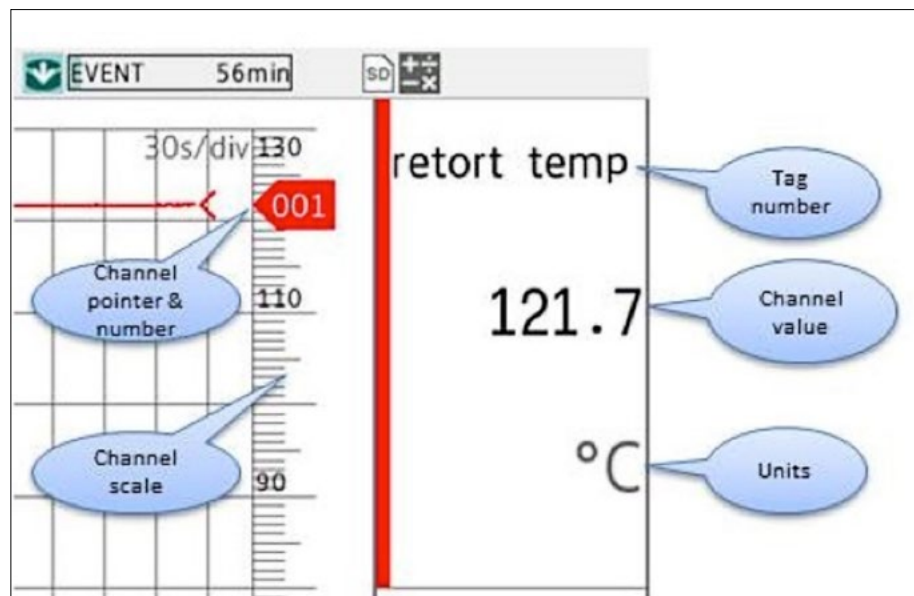
Proving Compliance Through Validation

Yokogawa provides a separate technical white paper for the GX that explains in detail how 21CFR Part 11 compliance is achieved. Ultimately, the end user must prove compliance in their application, and this is performed through validation. Yokogawa provides a detailed validation test protocol for the GX and the viewer software that greatly reduces the time required to perform complete installation and operational qualification testing of a new GX system.

Beyond a Paper Chart: Superior Trend Display, Trend History, and Reporting

GX Trend Display

The GX trend display identifies each input channel by the channel number and descriptive text tag number. Each input channel is color-coded to a channel pointer and digital display window. The channel pointer rides in a scale that uses the channel span range with divisions adjustable from 4-12 increments.



Detail of trend and digital data display

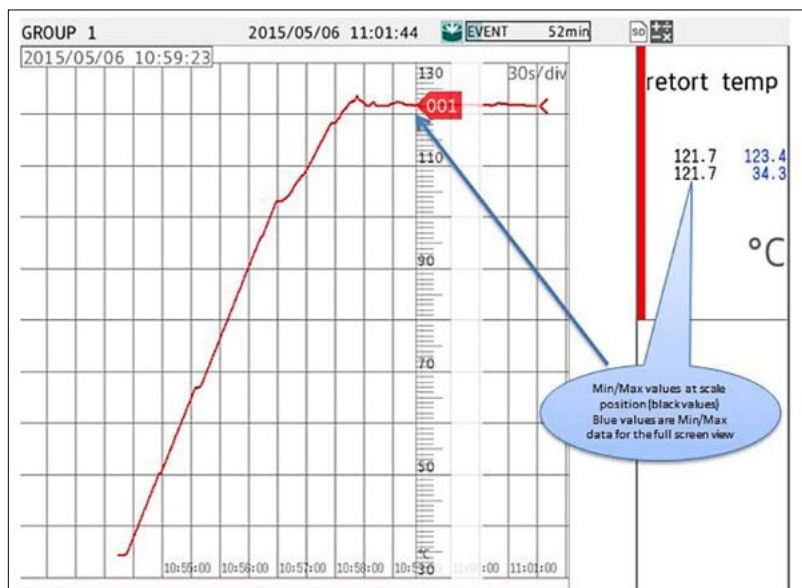
Channel colors can be freely assigned and the digital display can be disabled if desired to increase the visible trend area. The GX measurement functions are always ON and the real time channel values are always displayed regardless of the recording status. Operators always have intuitive and precise visibility of the actual channel values as well as the big picture trend of the entire process.



Detail of trend and digital data display

GX Trend History

Users can review trend history directly on the GX at the same time real-time data recording is in progress. This is done by simply touching and swiping the trend display. Precise MIN/MAX values at any point in the trend history can be reviewed by sliding the pen scale across any area of interest on the trend display. This is shown in the screen image below.



Trend history using sliding pen scale to review MIN/MAX trend data

Trend history for all previously saved data records stored in the GX memory can be searched and recalled very quickly using the calendar search screen. Operators simply touch the day on the calendar that contains the desired data, followed by entry of the search time within that day. This method allows the user to review previously save data with the same precision and presentation as used on the real time trend display. Real time data recording continues to run with no interruption when these trend history functions are used.

Paper chart recorders could never provide the search and historical playback capabilities of this system.

GX Data Recording

As an electronic recording system, the GX is purpose-built to save data with the highest degree of security and reliability. To achieve this, data is recorded in real-time to non-volatile flash memory, which has the advantage of no moving parts and no requirement for a battery back-up circuit to retain data in the event of loss of power. Recorded data is retained indefinitely during power loss and recording automatically resumes when power is restored. When recording is completed (end of batch or stop action) the recorded data file is copied to the SD removable media which is considered the permanent archive. This allows the data file(s) to be readily transported to the PC environment for reporting. If the GX is equipped with the USB interface option, USB media can also be used to transfer the files, or they can be copied using FTP via a network connection.

The GX can save data files in a secure, proprietary binary file format, or easily accessible text format. For the purposes of this paper, the binary file format will be discussed since this is the required format to comply with 21CFR Part 11. In fact, when the Advanced Security option is present, this is the only supported file format.

Data can be recorded using two file types: display or event.

The display file is an archive of the trend display. It records MIN and MAX values at the trend update interval. The GX draws the trend on the screen by calculating the min and max channel values within the trend interval time period, and then illuminating pixels proportional to the MIN/MAX deviation relative to the channel scale. These MIN and MAX values are captured and stored in the display data file each time the trend is updated. This file type has the advantage of recording MIN and MAX channel values that are calculated at the measurement speed resolution, so it can capture transient data regardless of the trend update interval speed. In summary, each saved data set records the MIN and MAX channel values within the update interval period.

The event file is simply an archive of the channel values recorded at a fixed interval. For example, if the interval is set for one minute, the instantaneous channel values are captured and recorded every minute.

When the GX is used in a continuous recording application, the user can choose the file length, or saving interval, for both file types, as well as the time of day when a new file starts. For example, a new file can be automatically created every day at midnight.

◀ 2015 ▶ ◀ 8 ▶						
2014			2016	7		9
SUN	MON	TUE	WED	THU	FRI	SAT
26	27	28	29	30	31	1
2	3	4	5	6	7	8
9	10	11	12 EVENT	13 EVENT	14 DISP	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29

Reviewing and Reporting GX Data in the PC Environment

The primary mission of the GX is to produce an electronic record, or data file, containing the batch process data. This file is intended to be reviewed and permanently archived in the PC environment. The free Yokogawa Universal Viewer software is used to review, print, and convert the data in the file to Excel or ASCII file formats. This software can read the secure binary data files saved by the GX as well as the supplemental report files that can be produced when the GX math option is present. To ensure data security, a CRC authentication test is performed each time the viewer software accesses a data file to ensure the file is not damaged or corrupted.

Searching for Data

Over a time period and based on the frequency at which files are saved by the GX, a large number of data files can accumulate for reporting and archiving. When moving these files to the PC environment for archiving, it is advantageous to organize the files by keeping them in separate folders, each assigned to the GX that produced them. Subfolders can then be assigned to further segregate the data by year, month or other helpful criteria. The viewer software can then search for a file of interest within a root folder, across a date and time range using channel and batch information as the search criteria.

Files that hold data that matches the query criteria are presented in a table as shown here:

Search Open

Folder: C:\FTP\GX files

☒ Include Sub Folder

Search Condition: ☒ Date & Time: 2014 / 10 / 09 00 : 00 - 2015 / 08 / 13 15 : 22 (☐ Exclude specify time)

☒ Channel No.: 001

☐ Batch Name: - (Batch No. - Lot No.)

☐ Signin Status: 1No sig.

File List

File Name	Device Type	Start Time	Stop Time	Batch Name
000148_150506_101610.GSE	GX20	2015/05/06 10:16:10.000	2015/05/06 10:36:16.000	-
000149_150506_104557.GSE	GX20	2015/05/06 10:45:57.000	2015/05/06 10:46:11.000	-
000150_150506_104735.GSE	GX20	2015/05/06 10:47:35.000	2015/05/06 10:47:59.000	-
000151_150506_105414.GSE	GX20	2015/05/06 10:54:14.000	2015/05/06 11:06:17.000	-
000152_150506_131821.GSE	GX20	2015/05/06 13:18:21.000	2015/05/06 13:22:09.000	-
000153_150526_114140.GSE	GX20	2015/05/26 11:41:40.000	2015/05/26 12:41:39.000	-
000154_150526_124140.GSE	GX20	2015/05/26 12:41:40.000	2015/05/26 13:09:11.000	-
000155_150526_132631.GSE	GX20	2015/05/26 13:26:31.000	2015/05/26 13:29:23.000	-
000156_150608_171227.GSE	GX20	2015/06/08 17:12:27.000	2015/06/08 18:12:26.000	-
000157_150608_181227.GSE	GX20	2015/06/08 18:12:27.000	2015/06/08 19:12:26.000	-
000158_150608_191227.GSE	GX20	2015/06/08 19:12:27.000	2015/06/08 20:12:26.000	-
000159_150608_201227.GSE	GX20	2015/06/08 20:12:27.000	2015/06/08 21:12:26.000	-
000160_150608_211227.GSE	GX20	2015/06/08 21:12:27.000	2015/06/08 22:12:26.000	-
000161_150608_221227.GSE	GX20	2015/06/08 22:12:27.000	2015/06/08 23:12:26.000	-
000162_150608_231227.GSE	GX20	2015/06/08 23:12:27.000	2015/06/09 00:12:26.000	-
000163_150609_001227.GSE	GX20	2015/06/09 00:12:27.000	2015/06/09 01:12:26.000	-

Viewing and Analyzing Data

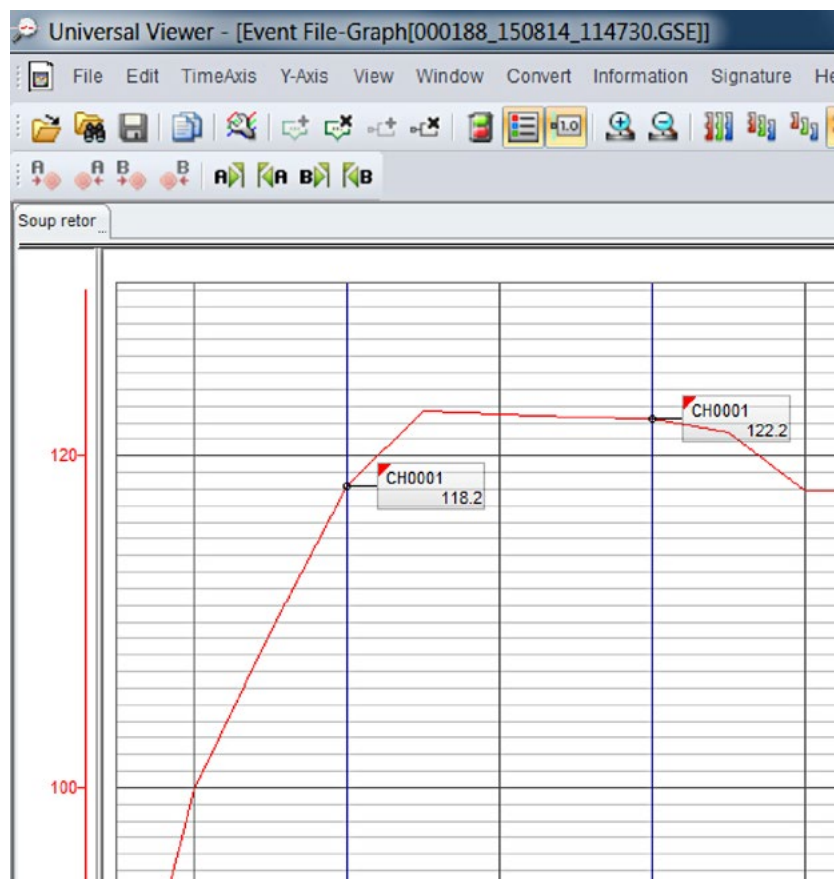
The Universal Viewer has a range of useful display and analysis functions, allowing the user to easily examine the data record, and then print a report or convert the file to Excel or ASCII format for additional study and reporting. When a GX file is opened with the viewer, all of the GX channel display and display group attributes are used as the default view by the software. This includes channel number, color, tag information, scale ranges, and display group assignments. This makes it easy to identify and study the data; by default it appears in the software the same way it did on the GX display screens.

Users can then enable/disable channels within each group, create new groups, change the scale ranges, and customize the overall view for the purposes of a report they may need. These attributes can then be saved and re-used to review subsequent data files.

Trend and Tabular Data

The primary display modes are the trend and tabular sheet views. Within each view, the user can select any portion of the saved data with cursor controls and review the statistical information within the selected range.

When a cursor is placed on an area of interest on the trend display, it will indicate the precise channel value on the cursor line. A second cursor can be placed on the screen to select the data range between cursors. This is shown on the trend display at right. For the temperature range shown in the example (0-130°C), the Y-axis grid lines can show 1°C resolution.



Statistics[000188_150814_114730.GSE:Soup retort 1A]					
Section 3 - 7		2015/08/14 11:49:00.000 - 2015/08/14 11:51:00.000			
Channel	MIN	MAX	P-P	Mean	RMS
CH0001[°C]	118.2	122.7	4.5	121.6	121.6

When the Statistics window is selected, the MIN, MAX, Peak to Peak, Mean and RMS channel values within the selected range can be viewed as shown below. These tools allow the user to quickly and easily examine any range of data within the file, for any desired channels, with a high degree of precision. This is impossible to do on a paper chart recorder!

The tabular digital display screen can be used to view the same data in digital tabular column form, like a spreadsheet. The date, time and data count for each data set appears in the left column, with the channel columns to the right. The selected data range is highlighted; this can be selected by clicking and dragging with the mouse, or by using the cursors on the trend display.

The statistics window can also be used in conjunction with the tabular view.

Universal Viewer - [Event File-Sheet[000188_150814_114730.GSE:Soup retort 1A]]	
File Edit Time View Window Convert Information	
Soup retort ...	
Absolute Time[No.]	retort 1A temp [°C]
2015/08/14 11:47:30.000[00000000]	81.9
2015/08/14 11:48:00.000[00000001]	99.9
2015/08/14 11:48:30.000[00000002]	109.4
2015/08/14 11:49:00.000[00000003]	118.2
2015/08/14 11:49:30.000[00000004]	122.7
2015/08/14 11:50:00.000[00000005]	122.5
2015/08/14 11:50:30.000[00000006]	122.3
2015/08/14 11:51:00.000[00000007]	122.2
2015/08/14 11:51:30.000[00000008]	121.4
2015/08/14 11:52:00.000[00000009]	117.9
2015/08/14 11:52:30.000[00000010]	117.9
2015/08/14 11:53:00.000[00000011]	117.9
2015/08/14 11:53:30.000[00000012]	117.9
2015/08/14 11:54:00.000[00000013]	117.9
2015/08/14 11:54:30.000[00000014]	117.9
2015/08/14 11:55:00.000[00000015]	117.9
2015/08/14 11:55:30.000[00000016]	117.9

File Name	: 000148_150506_101610.GSE	1/25
File Message		
Process Type	: Batch	
Device Type	: GX20	
Serial No.	: SSN908467	
Time Correct	: None	
Starting Cond.	: Manual	
Dividing Cond.	: Manual	
Meas Ch.	: 26	
Data Count	: 1207	
Calibration Corrected Ch.	: None	
Print Group	: GROUP 1	
Print Range	: 2015/05/06 10:16:10.000 - 2015/05/06 10:36:16.000	
Comment		

Absolute Time[No.]	CH0001 [°C]
2015/05/06 10:16:10.000[000000]	36.4
2015/05/06 10:16:11.000[000001]	36.4
2015/05/06 10:16:12.000[000002]	36.4
2015/05/06 10:16:13.000[000003]	36.4
2015/05/06 10:16:14.000[000004]	36.4
2015/05/06 10:16:15.000[000005]	36.4
2015/05/06 10:16:16.000[000006]	36.4
2015/05/06 10:16:17.000[000007]	36.5
2015/05/06 10:16:18.000[000008]	36.5
2015/05/06 10:16:19.000[000009]	36.9
2015/05/06 10:16:20.000[000010]	37.4
2015/05/06 10:16:21.000[000011]	37.8
2015/05/06 10:16:22.000[000012]	38.2
2015/05/06 10:16:23.000[000013]	38.7
2015/05/06 10:16:24.000[000014]	39.2
2015/05/06 10:16:25.000[000015]	39.7
2015/05/06 10:16:26.000[000016]	40.1
2015/05/06 10:16:27.000[000017]	40.6
2015/05/06 10:16:28.000[000018]	41.1
2015/05/06 10:16:29.000[000019]	41.6
2015/05/06 10:16:30.000[000020]	41.9
2015/05/06 10:16:31.000[000021]	42.4
2015/05/06 10:16:32.000[000022]	42.9
2015/05/06 10:16:33.000[000023]	43.4
2015/05/06 10:16:34.000[000024]	43.8
2015/05/06 10:16:35.000[000025]	44.3
2015/05/06 10:16:36.000[000026]	44.8
2015/05/06 10:16:37.000[000027]	45.3
2015/05/06 10:16:38.000[000028]	45.7
2015/05/06 10:16:39.000[000029]	46.1
2015/05/06 10:16:40.000[000030]	46.6
2015/05/06 10:16:41.000[000031]	47.1
2015/05/06 10:16:42.000[000032]	47.2
2015/05/06 10:16:43.000[000033]	47.1
2015/05/06 10:16:44.000[000034]	47.2
2015/05/06 10:16:45.000[000035]	47.3
2015/05/06 10:16:46.000[000036]	47.2
2015/05/06 10:16:47.000[000037]	47.6
2015/05/06 10:16:48.000[000038]	48.1
2015/05/06 10:16:49.000[000039]	48.6
2015/05/06 10:16:50.000[000040]	49.1
2015/05/06 10:16:51.000[000041]	49.5
2015/05/06 10:16:52.000[000042]	49.9
2015/05/06 10:16:53.000[000043]	50.4
2015/05/06 10:16:54.000[000044]	50.9
2015/05/06 10:16:55.000[000045]	51.3
2015/05/06 10:16:56.000[000046]	51.6
2015/05/06 10:16:57.000[000047]	52.3
2015/05/06 10:16:58.000[000048]	52.8

Printing Reports

Any of the available display modes in the viewer can be output directly to a printed report. A range of descriptive information about the data file can be included in the report and these information fields can be enabled/disabled as needed by the user.

Trend screens can be printed on a single page or across multiple pages, showing the complete data record or a selected portion of the data record. The tabular digital display prints as many pages as necessary to accommodate the data range.



Converting Data

The secure binary GX data files can be converted to Excel or ASCII file formats. Users can then incorporate this data into Excel reports or use other applications that can work with ASCII data.

All of the data contained in the file can be converted, or just a range of data; specified by channel and date and time range.

The Convert Data window shown above produced the Excel file shown below where a simple line chart was produced from the specified data set.

Convert Data

Start:

0

2015/08/14 11:47:30.000

End:

16

2015/08/14 11:55:30.000

Step:

1

☒ Group

1 - 1

☐ Channel

retort 1A temp -

Additional Information:

None

File Type:

Excel 97-2003 Workbook (*.xls)

File Partition:

65536

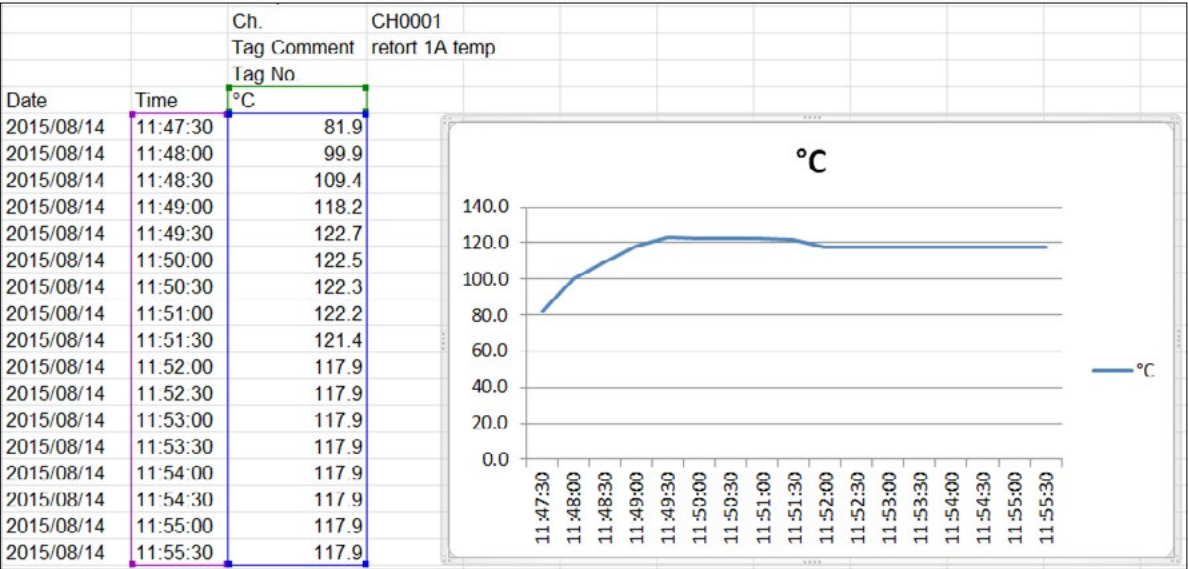
File:

C:\FTP\GX_files\000188_150814_114730.GSE.xls

...

OK

Cancel



9 CFR Ch. III (1–1–10 Edition) Subpart G — Canning and Canned Products	Yokogawa GX Series Compliance
§318.305 Equipment and Procedures for Heat Processing Systems	
318.305 (a) <i>Instruments and controls common to different thermal processing systems—(1) Indicating temperature devices</i> Each retort shall be equipped with at least one indicating temperature device that measures the actual temperature within the retort. The indicating temperature device, not the temperature/time recording device, shall be used as the reference instrument for indicating the process temperature.	GX shall NOT be used as the reference temperature indicating instrument.
318.305 (a) (2) <i>Temperature/time recording devices</i> Each thermal processing system shall be equipped with at least one temperature/time recording device to provide a permanent record of temperatures within the thermal processing system. This recording device may be combined with the steam controller and may be a recording/controlling instrument. When compared to the known accurate indicating temperature device, the recording accuracy shall be equal to or better than 1F° (or 0.5C°) at the process temperature. The temperature recording chart should be adjusted to agree with, but shall never be higher than, the known accurate indicating temperature device. A means of preventing unauthorized changes in the adjustment shall be provided. For example, a lock or a notice from management posted at or near the recording device warning that only authorized persons are permitted to make adjustments, are satisfactory means for preventing unauthorized changes. Air-operated temperature controllers shall have adequate filter systems to ensure a supply of clean, dry air. The recorder timing mechanism shall be accurate.	Complies: GX meets all requirements for temperature/time recording and temperature sensor measurement accuracy in °C and °F temperature units. GX does not perform steam control; a separate controller must be used. GX can interface to the controller via serial Modbus RTU or Ethernet Modbus TCP to receive, display and record the process value from the controller.
318.305 (a) (2) (i) <i>Chart-type devices</i> Devices using charts shall be used only with the correct chart. Each chart shall have a working scale of not more than 55F°/ inch (or 12C°/cm) within a range of 20F ° (or 11C°) of the process temperature. Chart graduations shall not exceed 2F degrees (or 1C degree) within a range of 10F degrees (or 5C degrees) of the process temperature. Multipoint plotting chart-type devices shall print temperature readings at intervals that will assure that the parameters of the process time and process temperature have been met. The frequency of recording should not exceed 1-minute intervals.	Complies: GX presents real-time trend data on a high resolution color touch screen display. Focus of 2 degree lines is on Viewer printout. GX provides separate, high resolution channel pointer scales that can be displayed and configured independently for each input channel on the trend display. Scale resolution of 2°F or 1°C is supported based on span settings. The background grid divisions on the trend display can be set from 4 to 12 major divisions; there are no minor divisions. Historical data can be precisely viewed by sliding the scale to the left across the trend screen. The precise digital value is color coded to the pen pointer and displayed on the same screen. Complies: GX saves precise digital channel values at the user-specified interval.

318.305 (b) (3) (vi) Retort speed timing The rotational speed of the retort shall be specified in the process schedule. The speed shall be adjusted as specified, and recorded by the establishment when the retort is started, and checked and recorded at intervals not to exceed 4 hours to ensure that the correct retort speed is maintained. Alternatively, a recording tachometer may be used to provide a continuous record of the speed.	Note: The GX can accept a proportional DCV or mA output from the speed sensor. The speed can be trended and recorded with the other data.
318.305 (b) (4) (i) Hydrostatic retorts The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a) (1) and (2) of this section.	Complies: As above for paragraph (a) (2); (a)(1) does not apply to GX.
318.305 (b) (4) (vi) Conveyor speed A recording device may be used to provide a continuous record of the conveyor speed. When a recording device is used, the speed shall be manually checked against an accurate stopwatch at least once per shift by the establishment.	Note: The GX can accept a proportional DCV or mA output from the speed sensor. The speed can be trended and recorded with the other data.
318.305 (c) (1) (ii) Pressure recording device Each retort shall be equipped with a pressure recording device which may be combined with a pressure controller.	Note: The GX can accept a proportional DCV or mA output from a pressure transmitter. The pressure value can be trended and recorded with the other data. GX does not perform pressure control; a separate controller must be used. GX can interface to the controller via serial Modbus RTU or Ethernet Modbus TCP to receive, display and record the process value from the controller.
318.305 (d) (1) Pressure processing with steam/air mixtures in batch retorts The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a) (1) and (2) of this section.	Complies: As above for paragraph (a) (2); (a)(1) does not apply to GX
318.305 (d) (3) Recording pressure controller A recording pressure controller shall be used to control the air inlet and the steam/air mixture outlet.	Note: The GX can accept a proportional DCV or mA output from a pressure transmitter. The pressure value can be trended and recorded with the other data. GX does not perform pressure control; a separate controller must be used. GX can interface to the controller via serial Modbus RTU or Ethernet Modbus TCP to receive, display and record the process value from the controller.
318.305 (e) (1) Atmospheric cookers— Temperature/ time recording device Each atmospheric cooker (e.g., hot water bath) shall be equipped with at least one temperature/time recording device in accordance with the basic requirements described in paragraph (a)(2) of this section.	Complies: As above for paragraph (a) (2).

318.306 Processing and production records	
318.306 (a) Processing in steam—(1) Batch still retorts. For each retort batch, record the retort number or other designation, the approximate number of containers or the number of retort crates per retort load, product initial temperature, time steam on, the time and temperature vent closed, the start of process timing, time steam off, and the actual processing time. The indicating temperature device and the temperature recorder shall be read at the same time at least once during process timing and the observed temperatures recorded.	GX can capture applicable text data in batch text fields. Digital inputs (DI) can capture date and time stamped process timing and status information as well as temperature data and other measured process values in the batch record. DI status, temperature data, and other measured process values can be digitally transferred to a control system via Modbus or EtherNet/IP.
318.306 (2) Batch agitating retorts. In addition to recording the information required for batch, still steam retorts in paragraph (a)(1) of this section, record the functioning of the condensate bleeder (s) and the retort or reel speed. 318.306 (3) Continuous rotary retorts. Record the retort system number, the approximate total number of containers retorted, product initial temperature, time steam on, the time and temperature vent closed, time process temperature reached, the time the first can enters and the time the last can exits the retort. The retort or reel speed shall be determined and recorded at intervals not to exceed 4 hours. Readings of the indicating temperature device(s) and temperature recorder(s) shall be made and recorded at the time the first container enters the retort and thereafter with sufficient frequency to ensure compliance with the process schedule. These observations should be made and recorded at intervals not exceeding 30 minutes of continuous retort operation. Functioning of the condensate bleeder(s) shall be observed and recorded at the time the first container enters the retort and thereafter as specified in § 318.305(b)(3)(v).	GX can capture applicable text data in batch text fields. Digital inputs (DI) can capture date and time stamped process timing and status information as well as temperature data and other measured process values in the batch record. DI status, temperature data, and other measured process values can be digitally transferred to a control system via Modbus or EtherNet/IP.

318.306 (4) Hydrostatic retorts. Record the retort system number, the approximate total number of containers re-torted, product initial temperature, time steam on, the time and temperature vent(s) closed, time process temperature reached, time first containers enter the retort, time last containers exit the retort, and, if specified in the process schedule, measurements of temperatures in the hydrostatic water legs. Readings of the temperature indicating device, which is located in the steam/water interface, and the temperature recording device shall be observed and the temperatures recorded at the time the first containers enter the steam dome. Thereafter, these instruments shall be read and the temperatures recorded with sufficient frequency to ensure compliance with the temperature specified in the process schedule and should be made at least every hour of continuous retort operation. Container conveyor speed, and for agitating hydrostatic retorts, the rotative chain speed, shall be determined and recorded at intervals of sufficient frequency to ensure compliance with the process schedule and should be performed at least every 4 hours. 318.306 (b) Processing in water—(1) Batch still retorts. For each retort batch, record the retort number or other designation, the approximate number of containers or number of retort crates per retort load, product initial temperature, time steam on, the start of process timing, water level, water recirculation rate (if critical), overriding pressure maintained, time steam off, and actual processing time. The indicating temperature device and the temperature recorder shall be read at the same time at least once during process timing and the observed temperatures recorded. (2) Batch agitating retorts. In addition to recording the information required in paragraph (b)(1) of this section, record the retort or reel speed.	GX can capture applicable text data in batch text fields. Digital inputs (DI) can capture date and time stamped process timing and status information as well as temperature data and other measured process values in batch the record. DI status, temperature data, and other measured process values can be digitally transferred to a control system via Modbus or EtherNet/IP.
318.306 (c) Processing in steam/air mixtures. For each retort batch, record the retort number or other designation, the approximate number of containers or number of retort crates per retort load, product initial temperature, time steam on, venting procedure, if applicable, the start of process timing, maintenance of circulation of the steam/air mixture, air flow rate or forced recirculation flow rate (if critical), overriding pressure maintained, time steam off, and actual processing time. The indicating temperature device and the temperature recorder shall be read at the same time at least once during process timing and the observed temperatures recorded.	GX can capture applicable text data in batch text fields. Digital inputs (DI) can capture date and time stamped process timing and status information as well as temperature data and other measured process values in batch the record. DI status, temperature data, and other measured process values can be digitally transferred to a control system via Modbus or EtherNet/IP.
318.306 (d) Atmospheric cookers—(1) Batch-type systems. For each cooker batch, record the cooker number or other designation and the approximate number of containers. In addition, record all critical factors of the process schedule such as cooker temperature, initial temperature, the time the thermal process cycle begins and ends, hold time, and the final internal product temperature.	GX can capture applicable text data in batch text fields. Digital inputs (DI) can capture date and time stamped process timing and status information as well as temperature data and other measured process values in batch the record. DI status, temperature data, and other measured process values can be digitally transferred to a control system via Modbus or EtherNet/IP.
318.306 (2) Continuous-type systems. Record the cooker number or other designation, the time the first containers enter and the last containers exit a cooker, and the approximate total number of containers processed. In addition, record all critical factors of the process schedule such as the initial temperature, cooker speed, and final internal product temperature.	GX can capture applicable text data in batch text fields. Digital inputs (DI) can capture date and time stamped process timing and status information as well as temperature data and other measured process values in batch the record. DI status, temperature data, and other measured process values can be digitally transferred to a control system via Modbus or EtherNet/IP.
318.307 Record review and maintenance	

318.307 (a) Process records. Charts from temperature/time recording devices shall be identified by production date, container code, processing vessel number or other designation, and other data as necessary to enable correlation with the records required in § 318.306. Each entry on a record shall be made at the time the specific event occurs, and the recording individual shall sign or initial each record form. No later than 1 working day after the actual process, the establishment shall review all processing and production records to ensure completeness and to determine if all product received the process schedule. All records, including the temperature/time recorder charts and critical factor control records, shall be signed or initialed and dated by the person conducting the review. All processing and production records required in this subpart shall be made available to program employees for review.	GX can capture applicable text data in batch text fields. Digital inputs (DI) can capture date and time stamped process timing and status information as well as temperature data and other measured process values in batch the record. DI status, temperature data, and other measured process values can be digitally transferred to a control system via Modbus or EtherNet/IP. GX can also capture descriptive date and time stamped message text entered by operators. <u>Up to 3 separate date and time stamped electronic signatures with approval comments can also be input to the GX.</u>
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Conclusion

In summary, the GX is a highly capable, electronic recording system that greatly out-performs paper chart recorders in every meaningful way. Users can see real-time data more clearly, with greater resolution and accuracy, and on their choice of display screens. In addition, historical trend data can be recalled by simply touching and swiping the screen and also with a calendar search mode, allowing the user to review past data without disturbing real-time recording. Data is saved with far greater security than a paper recorder, and back-up copies of the data records are easily produced and archived.

Data records created by the GX can be reviewed with free PC viewing software and reports can be printed or saved to PDF file format. Data can also be exported to Excel for custom reporting. Pre-formatted reports can also be generated by the GX and automatically output to PDF format or printed to a network printer. Optional software is available to fully automate report printing and report file generation when FTP functions are used.

When equipped with the /AS Advanced Security option, the GX fully meets the requirements of FDA regulation 21CFR Part 11.

As an electronic recording system with a high resolution trend display and PC viewing software capable of displaying trend gridlines in 2° F increments, the GX also meets the intended specifications of 9CFR Subpart G for paper temperature recorders.

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