



**EUROTHERM**

CONTROLS  
PROCESS AUTOMATION  
RECORDERS

# Process Data

**Acquire it. Display it. Manage it.**

**The Eurotherm 5000 Series  
Data Management System provides  
unsurpassed local and network  
access to your process data**

Technical innovation and design excellence *means*  
peerless data acquisition from Eurotherm



ETHERNET

	Screen Size	Input Channels	Relay Outputs	Removable Data Storage	Ethernet Network Connection
<b>5180V</b>	12.1 inch	6 to 36	3 to 24	PC Card or Floppy Disk	Standard
<b>5100V</b>	5.5 inch	6 or 12	3 to 9	PC Card or Floppy Disk	Standard
<b>5100e</b>	5 inch	6	1	Floppy Disk	Standard

# 5000 Series – data acquisition, display – a complete data management system

Constant focus on technical innovation and design excellence gives Eurotherm a world-beating product range.

Eurotherm products are specifically designed to satisfy the needs of individual applications. This market sensitivity has helped to establish Eurotherm as the market leader in many demanding sectors.

High accuracy input measurement has always been a hallmark of Eurotherm products. The new range of equipment is designed to acquire process data and then to display, transfer and manage that data using secure yet flexible means to meet varying user needs.



RISC  
Internet  
Intranet FTP

The Series 5000 uses the very latest in RISC processor technology to give a powerful platform now and for the future. Communication via Ethernet makes it an industry standard networking tool – process data has never been so easily available while still maintaining integrity and security. This along with sophisticated graphics and archiving capability maintain Eurotherm products in the forefront of the recording industry.

The sophistication of Eurotherm products continues to grow. New features are constantly being added in response to customer needs. Our superb Research and Development team is continuously striving to improve and extend our range.

**Q** What benefits will Ethernet connection give me?

**a** *The Ethernet connection on all the 5000 series gives fast, simple and secure data acquisition – you no longer have to leave your desk to obtain live or historical data from your process. Using either your local network, Internet or dial-up connection, Bridge 5000 software allows you to view the instrument display remotely. Review software enables you to view and analyse historical data obtained via the FTP (File Transfer Protocol) feature.*

**Q** Traditional recording equipment would not work well with my batch process environment. How will the 5000 Series be better?

**a** *The 5000 Series 'V' range has the option to process data using Batch 5000 functionality. Batch 5000 is designed to help meet the requirements of FDA Title 21 CFR Part 11. Full batch information including: Operator details; Start/stop time and date, and Operator entered batch data can be viewed and reviewed on a batch by batch basis.*

**Q** Can I view data in a way that best shows my process?

**a** *The 5000 Series 'V' range has the option of Screen Builder software. Using existing components of Bargraphs, Trends and Numerics, the user can customise the screen layout. Any number of these components can be added to the 5000 display in a layout that best suits the user and the process.*

**Q** How can I be sure that my process data is stored without loss or tampering?

**a** *The 5000 Series has various archiving possibilities all of which use a proprietary tamper-proof data format. 5000 units have an internal Flash memory that will store historical data. This data can be extracted via either a PCCard, floppy disk or network to maintain your required long term records.*

File Transfer Protocol	Screen Builder	Bridge 5000 Compatible	Batch 5000
Standard	Available	Yes	Available
Standard	Available	Yes	Available
Standard	Not available	Yes	Not available

# Bridge 5000

A seamless interface from the plant floor to your PC



The 5000 Series instruments have an excellent capability to be fully integrated into a network environment. Eurotherm have harnessed today's technologies to provide viewing of live data from any distance using the Bridge 5000 software. Together with the ability to remotely acquire historical data for analysis utilising FTP, the 5000 Series gives you access to all data from any PC anywhere in the world. Your data security is

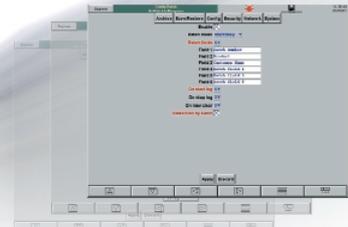
maintained with the use of specific User Names and Passwords for all types of remote access. Bridge 5000, FTP and Review software can all access a networked 5000 instrument over a local network, dial-up connection or via the Internet – never has it been so easy to view and archive your process data.

# Batch 5000

- Designed to enable your process to conform to FDA Title 21 CFR Part 11
- Batch specific logging of data
- Batch archive – search for a specific batch in Review software
- Operator details, time and date - logged at start and stop of a batch.
- Easy to configure to meet process specific needs

## Continuous or Individual Batch

### PROCESS



The 5000 Series 'V' range support the Batch 5000 option. This software enables you to enter information specific to a batch and record this with other process data. The Batch option can be configured for up to six operator entry fields. These free format fields may include data such as Batch Number, Job number, Charge number, Customer name, Product type and Order number. Batch 5000

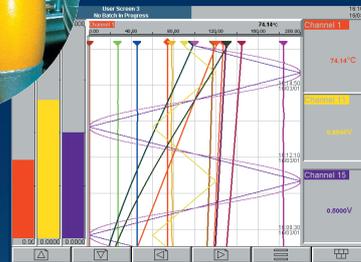
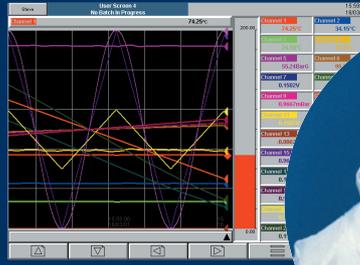
can be used in either a continuous or start/stop mode. Named user accounts can be created with individual passwords and access privileges. The operator details will be logged with the rest of the batch data on start and/or stop of batch providing traceability of operations. User accounts can also be disabled or deleted as required to maintain total security.

# Screen Builder

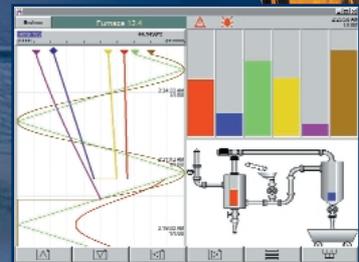
*Custom graphic screens tailored to your application needs*

The 5000 Series have colour, touchscreen displays designed for ease of use and simple configuration.

We understand the need for data to be represented in the most interpretable format for the operator. The 5000 series have vertical trend, horizontal trend, vertical bar graph, horizontal bar graph and numeric standard displays. In addition, the 'V' range is available with the Screen Builder feature. Screen Builder allows you to customise up to four additional displays to best reflect the given process. Any of the standard display formats can be placed anywhere on the screen. Pictures may also be loaded into a 5000V instrument for use as a background image. This truly makes a standard product into a process specific special!



Seamless  
User defined interfacing  
graphic displays



Channel 12	0.9941 v
Channel 13	6.3861 °C
Channel 14	0.9510
Channel 15	0
Channel 16	0.0000 V

# 5000 Series - Data Acquisition, Display and Data Management

The 5000 Series all offer unrivalled input accuracy with a 125ms total sample rate for up to 36 input channels. All input channels are freely configurable to suit your process requirements. Each instrument has an intuitive, touchscreen display to enable operators to clearly view process data in varying formats. All have onboard Flash data storage capability, Ethernet communication and either a PCCard reader or Floppy Disk. All data is stored in a tamper-proof binary format that can be used for secure, long-term records of your process. The 5000 Series is truly designed for today's network world and can be accessed via a Local Area Network, dial-up connection, Intranet or Internet.

## Seamless communications

Data Acquisition.

# 5180v

Display.

Management.

The 5180V is the largest of the 5000 Series, offering up to 36 input channels and 24 relay outputs. A 12.1 inch, colour, SVGA TFT touchscreen display gives unsurpassed visibility for the operator. It has either a PCCard reader or floppy disk drive as standard offering up to 260 Mbytes of data storage along with 18 Mbytes of Flash memory for data storage on board – making a powerful data storage unit.



# 5100v

## High visibility

Current and historic data sets

The 5100V offers up to 12 input channels and 12 relay outputs. It has a 5.5 inch, colour, – VGA TFT touchscreen display. It is also supplied with either a PCCard reader or floppy disk drive as standard and has 3 Mbytes of Flash memory for data storage onboard.



# 5100e

## Universal inputs

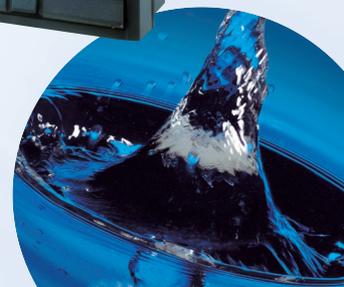
Unmatched Accuracy

The 5100e offers the software and input excellence of the 5000V products in a low cost, entry level instrument. It has 6 freely configurable input channels and a single relay output. The operator interface is via a 5 inch, colour, – VGA STN touchscreen display and is supplied with a floppy disk drive and 3 Mbytes Flash data storage on board.



# 125ms sample rate

Cost effective solution



# 5000 Series features

<b>Display</b>	Colour touchscreen
<b>Environmental Protection</b>	Bezel and display: IP65
<b>Sample Rate</b>	125ms parallel sampling
<b>Inputs</b>	dc V, dc mV, dc mA (with shunt), TCs, RTD, Contact closure

## Data Archiving

The 5000 Series is designed to store and protect your process data. Initially historical data is stored in the internal, non-volatile Flash memory. This data may then be archived to the removable PCCard or Floppy Disk – these media will store data for a length of time dependant upon card size, data log rate and number of channels. Storage capacity need no longer be a concern, however, as data may be also be automatically archived to a remote server utilising the Ethernet connection.

## 5180V/5100V/5100e Standard Software

### Review – Included with every 5000 Series

Review software is included free of charge with every 5000 Series data acquisition unit. This PC application acts as an efficient and secure library for data from which charts can be reviewed, printed and exported to other PC packages if required. Archive files from a 5000 instrument are stored in a tamper-proof binary format and Review uses this format to enable chart view on a PC – ensuring integrity of both historical and new data.

- Chart print capability
- Time compression – expand or compress longer time periods or to focus in on specific detail
- 125ms resolution
- Text messages displayed
- Data can be obtained via a network, including the Internet, or using the removable storage media from a 5000 instrument.

### Configuration Editor – Included with every 5000 Series

An offline configuration editor package is included free of charge with every 5000 Series. Configurations can be created and stored on a PC and easily loaded onto a 5000 Series instrument as required.

### FTP (File Transfer Protocol) – Standard on every 5000 Series

The 5000 Series instruments have FTP client and server as a standard communication protocol. FTP can be used to transfer files into Review software or as a means of obtaining any file from a 5000 instrument over a network – using either a specific FTP package or Internet Explorer.

## 5000 Software Options

### Batch 5000 for the V Series

Log specific batch data in the 5000 Series for view and review.

### Screen Builder for the V Series

Create User Screens to make a standard 5000 Series display specific to your process needs.

### Bridge 5000 for the V and e Series

For use on your PC – View live process data from any PC anywhere.

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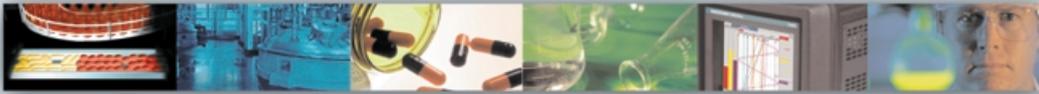
HA027125 Issue 3



**EUROTHERM**

CONTROLS  
PROCESS AUTOMATION  
RECORDERS

# 5000 Series with Auditor Features



## Data Management with 21 CFR Part 11 in Mind

Auditor features on the 5000 recorders have been specifically designed to meet the requirements of the FDA 21 CFR Part 11 document for Electronic Records and Electronic Signatures. Data is held in Human Readable and Electronic Record. Electronic data can be viewed, analysed and printed off-line using the secure Review package

Data security is paramount for FDA approved processes - 5000 products ensure that data is not lost or tampered with. Their Auditor Software features provide comprehensive security and traceability

Secure Audit Trails  
Password Aging  
Recorded Logins  
Electronic Signing  
Timed Logout  
Password Retries



### Secure Audit Trails

A secure, product-generated, time-stamped audit trail to record the date and time, operator details and actions taken on the recorder. The Audit Trail is kept with the electronic process data, records all actions and cannot be separated from the process data, removed or modified.



### Electronic Signing

Auditor features allow for signing of all actions - operator will need to re-enter user name and password before action is complete. Recorder can also be made to request authorisation - a second signature - before the action is completed.



### Signed Operator Comments

An authorised operator is able to add comments to the data record by entering their correct user name and password followed by the required text. The full comment complete with the operator name, date and time is recorded in the data file to become an integral part of the data record.



### Signature Element Controls

Passwords will automatically expire unless renewed within a set time. All standard user logins can be disabled and their associated passwords removed to prevent any unauthorised access.

User accounts are disabled after a selectable number of failed attempts to log in.

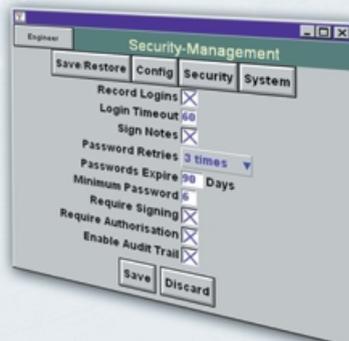
Passwords can be forced to be a minimum length.

Operators will be automatically logged out after a pre-defined period of inactivity



### Recorded Logins

Every time an operator logs in user name, date and time are recorded into the Audit Trail.



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DATA MANAGEMENT  
PROCESS AUTOMATION

# 5000 Series with Auditor Features



## Data Management with 21 CFR Part 11 in Mind

### Additional Security Features

- **Enforced Unique Signatures**  
Each user can have a unique set of access permissions to customise what they can do on the product. Each user name is unique and passwords are individual and cannot be view on the product. User ID cannot be duplicated and each user name must be unique within the product.
- **Protection of Records – Secure, Reliable, Accurate Records**  
Data is stored in a binary, compressed and checksum format proprietary to Eurotherm Ltd to protect from tampering with records.
- **Device Checks for Validity of Inputs**  
5000 logs system errors and input channel status. Remote operator access can be enabled or disabled on an individual user basis.

### Additional Features

- **6 to 48 universal inputs**
- **Up to 27 changeover relay outputs**
- **Multi-batch recording**
- **Barcode Reader serial input**
- **Standard Networking via Ethernet**
- **FTP Client & Server**
- **Modbus TCP**
- **Time Synchronisation via Ethernet (SNTP) or digital input**
- **Maths functions, Totalisers, Timers and Counters**
- **Message Log and Alarm Summary Page**
- **Screen Builder software - user defined screen views**
- **Bridge Software – Remote viewing, configuring and operating software – via LAN, intranet or Internet**
- **Batch – Up to 6 user-defined batch fields to enter batch specific information on start and/or end of batch**
- **Adaptive Recording – record maximum and minimum values between recording intervals**

**Sales and support in over 30 countries worldwide**

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# 5000 SERIES



## 5100V/5180V Recorders and 21 CFR Part 11 (dated 8/11/01, applies to version 1.7)



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CONTROLS  
DATA MANAGEMENT  
PROCESS AUTOMATION

### SUB PART B – ELECTRONIC RECORDS

11.10 Controls for closed systems	
(a) Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records	<ul style="list-style-type: none"> <li>- Eurotherm offer assistance in validating products to GAMP guidelines.</li> <li>- Recorded files are in binary, compressed and checksummed format proprietary to Eurotherm. Details are not published.</li> </ul>
(b) The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying by the agency. Persons should contact the agency if there are any questions regarding the ability of the agency to perform such review and copying of the electronic records.	<ul style="list-style-type: none"> <li>- Complete and accurate copies on screen or printed out are available through the use of the Review package</li> <li>- Complete and accurate electronic copies are available by copying the raw data files or by setting up a 'pdf printer' (requires adobe acrobat or similar) in order to export graphs in pdf format.</li> </ul>
(c) Protection of records to enable their accurate and ready retrieval throughout the records retention period.	<ul style="list-style-type: none"> <li>- On the recorder files are held internally in Flash then archived to Removable media and/or via a network to an FTP server. Data can also be periodically pulled from the product using Review. Once data has left the recorder the media it is stored on and backup strategy is the responsibility of the user</li> </ul>
(d) Limiting system access to authorized individuals.	<ul style="list-style-type: none"> <li>- Individual password protected user accounts.</li> </ul>
(e) Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained for a period at least as long as that required for the subject electronic records and shall be available for agency review and copying.	<ul style="list-style-type: none"> <li>- Secure (embedded in the binary history file), computer generated, timestamped runtime audit trail of batch stop/start, alarm acknowledgments, logins, signature details, configuration changes</li> <li>- Record changes do not obscure previous data</li> <li>- Audit trail is embedded in the history file so guaranteeing retention alongside the records and availability for review / copying.</li> </ul>
(f) Use of operational system checks to enforce permitted sequencing of steps and events, as appropriate.	<ul style="list-style-type: none"> <li>- Interlocks can be achieved using the product configuration and relay outputs. The specifics are down to configuration.</li> </ul>

**SUB PART B – ELECTRONIC RECORDS (continued)**

<b>11.10 Controls for closed systems (continued)</b>	
(g) Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand.	<ul style="list-style-type: none"> <li>- Individual password protected user accounts. Each user can have a unique set of Access permissions or privileges to customize what they can do to the product.</li> </ul>
(h) Use of device (e.g., terminal) checks to determine, as appropriate, the validity of the source of data input or operational instruction.	<ul style="list-style-type: none"> <li>- System errors and input channel status are logged</li> <li>- Individual accounts can have remote access disabled in order to force changes to be made at the recorder:</li> </ul>
(i) Determination that persons who develop, maintain, or use electronic record/ electronic signature systems have the education, training, and experience to perform their assigned tasks.	Procedural
(j) The establishment of, and adherence to, written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures, in order to deter record and signature falsification.	Procedural
<p>(k) Use of appropriate controls over systems documentation including:</p> <ul style="list-style-type: none"> <li>(1) Adequate controls over the distribution of, access to, and use of documentation for system operation and maintenance.</li> <li>(2) Revision and change control procedures to maintain an audit trail that documents time-sequenced development and modification of systems documentation.</li> </ul>	Procedural

<b>11.30 Controls for open systems</b>	
Persons who use open systems to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity, and, as appropriate, the confidentiality of electronic records from the point of their creation to the point of their receipt. Such procedures and controls shall include those identified in Sec. 11.10, as appropriate, and additional measures such as document encryption and use of appropriate digital signature standards to ensure, as necessary under the circumstances, record authenticity, integrity, and confidentiality	The product is targeted at use in closed systems. However, data stored is encrypted and passwords can be configured for use on all remote access. With appropriate external systems/ procedures the product may be used in an open system.

<b>11.50 Signature Manifestations</b>	
<p>(a) Signed electronic records shall contain information associated with the signing that clearly indicates all of the following:</p> <ul style="list-style-type: none"> <li>(1) The printed name of the signer;</li> <li>(2) The date and time when the signature was executed; and</li> <li>(3) The meaning (such as review, approval, responsibility, or authorship) associated with the signature.</li> </ul>	Signed records contain printed name (ID), date and time, meaning. Meaning includes signed / authorised plus an automatically generated type (eg 'config' for a configuration change) plus an operator entered note.
(b) The items identified in paragraphs (a)(1), (a)(2), and (a)(3) of this section shall be subject to the same controls as for electronic records and shall be included as part of any human readable form of the electronic record (such as electronic display or printout).	Name (ID), timestamp and meaning are all embedded in the binary format history file.

<b>11.70 Signature/Record Linking</b>	
Electronic signatures and handwritten signatures executed to electronic records shall be linked to their respective electronic records to ensure that the signatures cannot be excised, copied, or otherwise transferred to falsify an electronic record by ordinary means.	Signature manifestation is embedded in the binary format history file. For hybrid systems, prints created via review for handwritten signature will always contain timestamp details which permit re-creation from the original data.

**SUB PART C – ELECTRONIC SIGNATURES**

<b>11.100 General requirements</b>	
(a) Each electronic signature shall be unique to one individual and shall not be reused by, or reassigned to, anyone else.	The product ensures that no two user accounts have the same username. To ensure that a username is not reused it must NOT be deleted, just disabled, this will prevent the account being reused.
(b) Before an organization establishes, assigns, certifies, or otherwise sanctions an individual’s electronic signature, or any element of such electronic signature, the organization shall verify the identity of the individual.	Procedural
(c) Persons using electronic signatures shall, prior to or at the time of such use, certify to the agency that the electronic signatures in their system, used on or after August 20, 1997, are intended to be the legally binding equivalent of traditional handwritten signatures.  (1) The certification shall be submitted in paper form and signed with a traditional handwritten signature, to the Office of Regional Operations (HFC-100), 5600 Fishers Lane, Rockville, MD 20857.  (2) Persons using electronic signatures shall, upon agency request, provide additional certification or testimony that a specific electronic signature is the legally binding equivalent of the signer’s handwritten signature.	Procedural

<b>11.200 Electronic signature components and control</b>	
(a) Electronic signatures that are not based upon biometrics shall:	
(1) Employ at least two distinct identification components such as an identification code and password.  (i) When an individual executes a series of signings during a single, continuous period of controlled system access, the first signing shall be executed using all electronic signature components; subsequent signings shall be executed using at least one electronic signature component that is only executable by, and designed to be used only by, the individual.  (ii) When an individual executes one or more signings not performed during a single, continuous period of controlled system access, each signing shall be executed using all of the electronic signature components.	Requires re-entry of userID and password during a signing. Both components will be required for all signings
(2) Be used only by their genuine owners; and	Requires Users can change their own passwords and no read access to passwords is provided. It is also possible to have logins time out after a set period of inactivity; to limit the number of login retries before an account is disabled; to set a minimum length for passwords; and to force password expiry after a set number of days.
(3) Be administered and executed to ensure that attempted use of an individual’s electronic signature by anyone other than its genuine owner requires collaboration of two or more individuals.	Users can change their own passwords and no read access to passwords is provided. So, unless one user tells another their password, it is impossible to commit fraud without an audit trail of that fraud being left.
(b) Electronic signatures based upon biometrics shall be designed to ensure that they cannot be used by anyone other than their genuine owners	Not applicable.

**SUB PART C – ELECTRONIC SIGNATURES (continued)**

<b>11.100 Controls for identification codes/passwords</b>	
Persons who use electronic signatures based upon use of identification codes in combination with passwords shall employ controls to ensure their security and integrity. Such controls shall include:	
(a) Maintaining the uniqueness of each combined identification code and password, such that no two individuals have the same combination of identification code and password.	Providing user accounts are not deleted then all user names are forced to be unique.
(b) Ensuring that identification code and password issuances are periodically checked, recalled, or revised (e.g., to cover such events as password aging).	It is possible to force password expiry after a set number of days. If a user leaves, their account can be disabled.
(c) Following loss management procedures to electronically deauthorize lost, stolen, missing, or otherwise potentially compromised tokens, cards, and other devices that bear or generate identification code or password information, and to issue temporary or permanent replacements using suitable, rigorous controls.	Procedural - Compromised accounts can be disabled. On loss of password, the administrator may set a new password for an account which the account holder should then immediately replace by a password of their own.
(d) Use of transaction safeguards to prevent unauthorized use of passwords and/or identification codes, and to detect and report in an immediate and urgent manner any attempts at their unauthorized use to the system security unit, and, as appropriate, to organizational management.	It is possible to have logins time out after a set period of inactivity; to limit the number of login retries before an account is disabled; to set a minimum length for passwords; and to force password expiry after a set number of days.
(e) Initial and periodic testing of devices, such as tokens or cards, that bear or generate identification code or password information to ensure that they function properly and have not been altered in an unauthorized manner.	Procedural

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# Pharmaceutical/Biotechnology Validation of the 5000 Series Recorder

Applies to V1.3 of the 5000 series product software

## Introduction

Pharmaceutical and biotechnology manufacturing sites throughout the world are very concerned about quality, data traceability, instrument accuracy and stability. This is driven by ever increasing professionalism and the requirements of the US Food and Drugs Administration (FDA).

These sites manufacture drugs for human and animal use, pre-packed sterile equipment such as sutures, syringes etc. and primarily in the USA, food products. Product cannot be imported or sold into the USA market place unless it is produced in accordance with the FDA requirements.

The USA Food and Drugs Administration (FDA) validate a production process only. The equipment used on the validated process is not itself, validated. It is therefore not possible for an instrument manufacturer to claim that an instrument, to be used on a process, has been 'FDA approved'.

It is the responsibility of the company requesting FDA approval to satisfy themselves and the FDA inspectors that the manufacturing process is of satisfactory quality with full traceability.

## Summary

### Do the FDA accept Electronic Records?

Yes, see FDA document 21 CFR Part 11 at [http://www.fda.gov/ora/compliance\\_ref/part11/](http://www.fda.gov/ora/compliance_ref/part11/)

### What are the details of the Eurotherm ISO9000 Certificate?

The Eurotherm Limited ISO9001 certificate, including TickIT, is issued by Lloyd's Register Quality Assurance Limited, certificate number LRQ0871739. First issued April 1990 with TickIT added in 1994.

### International Company with manufacturing base back to 1966

Author: Neville Child

Approved: 

Ref: tibr03.doc

- Page 1 of 13 -

21/02/01

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Registered Office Carlisle Place London SW1P 1BX Registered in England No 853008

2100

2200

2400

2500

2600

2700

T2900

PC3000

iTools

5100

4100

4250

4181

ESUITE

T500

T600

T700

T800

T900

ALIN

This shows a history of high quality production and design.

### **Products and software designed and manufactured in an ISO9000/TickIT environment**

This shows that Eurotherm are currently working within respected design/manufacturing procedures that are referred directly to in the GAMP specifications.

### **Standard industrial, volume shipped, product with no special changes for FDA**

If the product has any design problems, other customers will have found them before the pharmaceutical companies!

### **Logged data is in binary format, encoded and checksummed to inhibit data tampering**

Stops accidental and malicious modification to the archived data.

### **Data can be archived to local disk and/or via comms. to secure optical WORM drive on PC running Review or third party software**

Once in the PC environment, the data can be stored and normal computer librarianship, security and backups can take place.

### **Company would welcome inspection from pharmaceutical inspectors**

Eurotherm will welcome any inspection of its manufacturing facilities and development site. Inspections have been successfully completed over many years, by several major pharmaceutical companies.

## **Company history**

Eurotherm was established in 1965, recognising the new opportunities that were emerging for transistor components and the emerging requirements for long-term data recording. Since then we have diversified, leading from the front with an unmatched vision in product design and application engineering. Now with three decades of experience in process measurement behind us, no one has a greater understanding of real-world problems and no one is placed better to provide creative practical solutions to the worlds most demanding application challenges.

## **Eurotherm Company Management systems**

To help the pharmaceutical and biotechnology manufacturing companies satisfy themselves that Eurotherm equipment is suitable for their process, all design of Eurotherm product and software is carried out in an ISO9001 environment incorporating TickIT software management systems.

*"This approach supports and interprets the ISO 9000-3 guidelines for software, and its associated 'TickIT' certification scheme, by providing suppliers with practical tools and methods to implement an appropriate quality management system within their organisation. In the future, it is anticipated that GAMP Forum will further develop its Guidelines for Suppliers to converge with the software industry's quality schemes – notably 'TickIT' – supported by an Industry-sector document as appropriate."* – GAMP Guide Validation of Automated Systems in Pharmaceutical Manufacture Version: V3.0, March 1998.

The TickIT scheme has been developed by a team of leading quality management specialists drawn from the British standards committee, BRD/3/1, the UK Software industry and interested European Organisations such as KEMA, Qualience, and SWEDAC.

Companies certificated to ISO9001 under TickIT are in over 40 different Countries world-wide, these include every country in the European Union, USA, Canada, Mexico, Brazil, Australia and many countries in Asia, including China, India, Japan, South Korea, and Taiwan.



## 5000 product features

### Overview

The 5000 Series acts as the interface between the process plant and operators. It acquires and displays process data from sensors on the process using input boards fitted internally, this data is then stored in a binary file format within the products internal flash memory (non-volatile). This data is not accessible and therefore cannot be tampered with or deleted, these data files are then copied automatically to archive media or over Ethernet to a file server. Once the internal instrument memory is full it is overwritten on a first in, first out basis.

### **Inputs**

The inputs to the instrument are all non-multiplexed, solid state circuits updating the PV (and alarms) of the instrument 8 times per second. Each input signal has its own circuit, isolated from every other input signal and ground to 250Vac. Each input can be individually configured for all common process signals such as thermocouple, RTD, V, Mv, mA, resistance and contact input.

### **Data Archiving**

Process values are initially logged, at the configured time interval, with full time/date information to data files within the 5000 Series products non-volatile flash memory. The values logged are a single snapshot of the PV at the time of the log, these data files are unique within the instrument, are stored in a packed binary format, each time-stamped record having a checksum to ensure integrity, whilst within the instrument there is no write access to this data from external sources. To help ensure that the minimum of data is lost in the very unusual case where flash memory may fail no data file greater than 400kbyte is generated.

### **Display**

Data is viewed on a 12.1 inch SVGA TFT LCD screen 800\*600 resolution (5180V) or a 5.5 inch ¼ VGA TFT LCD 320\*240 resolution (5100V). The display assembly has a toughened touch panel with a polyester coating that is impervious to virtually any chemical attack. Process data can be displayed in a variety of standard display types or the optional Screen Builder can be used to generate displays types as specified by the user.

### **21 CFR Part 11 - Electronic Records & Electronic Signatures**

Security is a very important consideration in data acquisition projects and is a standard feature on all 5000 Series recorders.

**The final ruling 21 CFR Part11 (20 March 1997) defines the 5000 Series recorder as a 'closed system' in being..."(4) Closed system means an environment in which system access is controlled by persons who are responsible for the content of electronic records that are on the system." ... (21 CFR Part11, Subpart A section 11.3 (4)). The 5000 Series features aid production process validation in the following ways:**

*21 CFR Part11, Subpart B Section 11.10 Controls for closed systems.*

*21 CFR Part11, Subpart B section 11.10 (a) Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.*

The configuration of the recorder can be carried out either online- or off-line, where a password MUST first be entered to gain access. Once configured, the binary and checksummed, instrument configuration file can be held securely for any validation and back-up requirements. Process data is stored automatically within the parameters laid out in the configuration, these data files are in a binary format with a checksums to confirm against any attempted modification. This file format detail is NOT published by Eurotherm Limited.

*21 CFR Part11, Subpart B section 11.10 (b) The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying by the agency. Persons should contact the agency if there are any questions regarding the ability of the agency to perform such review and copying of the electronic records.* The raw process data files from the recorder can be copied to the local archive media (floppy disk or PC card) or using the FTP option directly to a server on a local area network, using the integral 10BaseT Ethernet connection over TCP/IP. The raw data files are designed to be imported into Eurotherm Review software to enable post analysis of the data and generation of paper records if required.

*21 CFR Part11, Subpart B section 11.10 (c) Protection of records to enable their accurate and ready retrieval throughout the records retention period.* Data should either be printed onto paper records for storage or should be reliably and securely copied before existing file storage technology becomes obsolete and difficult to support. This is a procedural process and outside the scope of Eurotherm Limited.

*21 CFR Part11, Subpart B section 11.10 (d) Limiting system access to authorised individuals.* Access can be easily limited to authorised individuals using the standard user name/password feature within the Series 5000 recorder. This gives specific access permissions to specific individuals with their own user name/password.

*21 CFR Part11, Subpart B section 11.10 (e) Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained for a period at least as long as that required for the subject electronic records and shall be available for agency review and copying.* When using the optional batch functionality of the 5000 Series recorder, any operation to start/stop the process is recorded within the binary data file generated at the time, this information includes date/time and the user name of the operator that has performed the operation.

*21 CFR Part11, Subpart B section 11.10 (f) Use of operational system checks to enforce permitted sequencing of steps and events, as appropriate.* The configuration parameters of the 5000 Series can force particular operational interlocks with the use of relay contacts and the associated overall process design. The use of these interlocks need to be as part of the overall design of the process and can not be limited only to the 5000 instrument.

*21 CFR Part11, Subpart B section 11.10 (g) Use of authority checks to ensure that only authorised individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand.* When used with the optional batch functionality, the 5000 Series recorder will log the user name of any operator that starts or stops a process batch along with other batch parameters. The authority checks and password delinquency are outside the scope of Eurotherm Limited.

*21 CFR Part11, Subpart B section 11.10 (h) Use of device (e.g., terminal) checks to determine, as appropriate, the validity of the source of data input or operational instruction.* This is outside the scope of Eurotherm Ltd. and procedural where checks are periodically carried out to ensure that the instrument configuration is identical to that archived at system acceptance. Regular calibration checks should also be included to ensure that full system data can be relied upon.

*21 CFR Part11, Subpart B section 11.10 (i) Determination that persons who develop, maintain, or use electronic record/electronic signature systems have the education, training, and experience to perform their assigned tasks.*

This is generally outside the scope of Eurotherm Limited. Training should be carried out as part of system acceptance and the use of a fully documented operations manual is important. The 5000 Series recorder ensures that only those personnel who have appropriate access levels are able to perform certain tasks. It is important that personnel access levels and training are kept up to date and passwords changed regularly to maintain security. Product training can be organised by your local Eurotherm representative at any time.

*21 CFR Part 11, Subpart B section 11.10 (j) The establishment of, and adherence to, written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures, in order to deter record and signature falsification.*

This is outside the scope of Eurotherm Limited. The 5000 Series recorder aids this by identifying in the batch record, the operator responsible for starting/stopping any batch.

*21 CFR Part 11, Subpart B section 11.10(k) Use of appropriate controls over systems documentation including:*

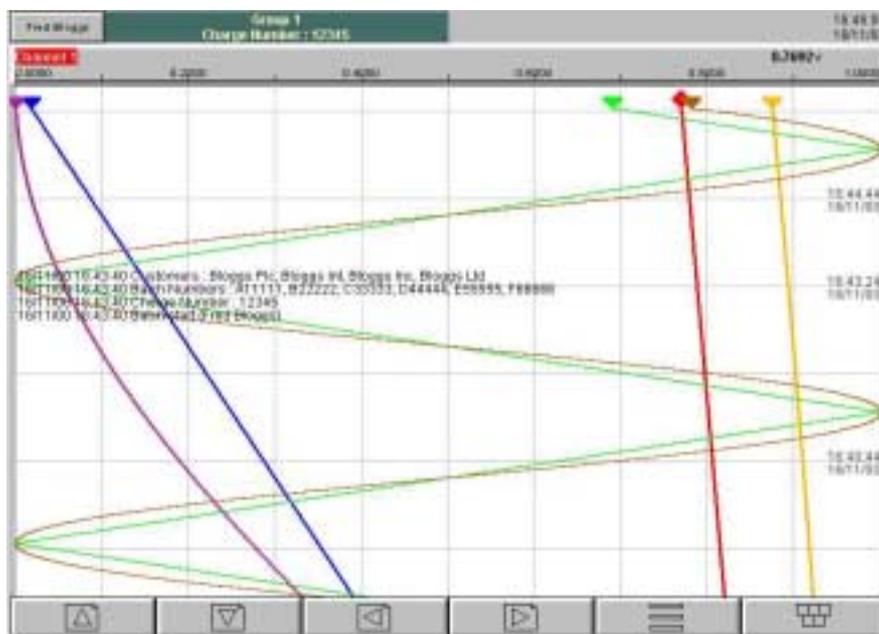
*(1) Adequate controls over the distribution of, access to, and use of documentation for system operation and maintenance.*

*(2) Revision and change control procedures to maintain an audit trail that documents time-sequenced development and modification of systems documentation.*

This is the responsibility of the process management in association with organisations employed to carry out any required works and is outside the scope of Eurotherm Limited.

### **Batch**

The 5000 Series batch recorder offers unparalleled features in logging process data for batch type applications. Up to six configurable fields can be enabled to hold information such as 'batch number', 'charge number', 'supervisor name', 'product code' etc. The batch record is unable to start until the process operator has logged in, using his unique login and password and completed ALL required data fields. Once started, the operator's user name is logged with the batch and process data. At the end of a batch, the operator has to again login and full details are again recorded. If the process is a continuous one, the 5000 instrument may be configured to record data associated only with batch starts. This batch data can then be archived and reported upon on a batch by batch basis using Eurotherm Review software.



### Communications

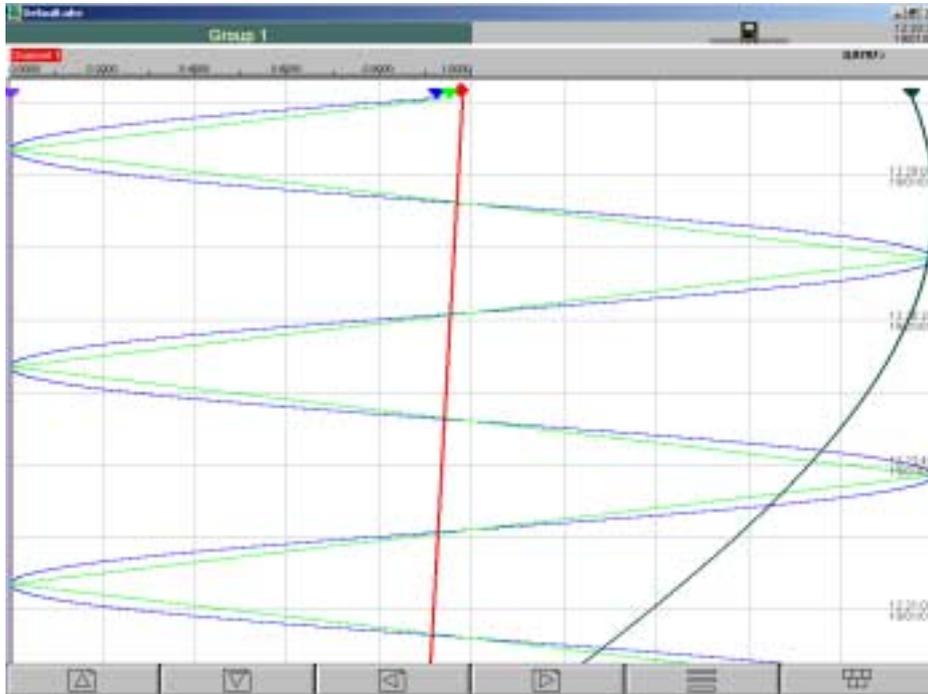
Communications facilities are becoming an increasingly important asset in modern production instrumentation and control. The 5000 Series comes as standard with an RJ45 10BaseT Ethernet connection. This connection can be securely accessed for the following functions as detailed below: FTP File transfer, Bridge 5000 remote viewer and connection to Review software. Future releases of software will support the Modbus TCP protocol over Ethernet.

### FTP

The 5000 Series recorder can be configured to act as an FTP Server and/or and FTP Client, this means that the instrument can automatically send data files to a server on the network or an application running on a PC can request data files from the instrument (or both!). All of this under individual username/password control.

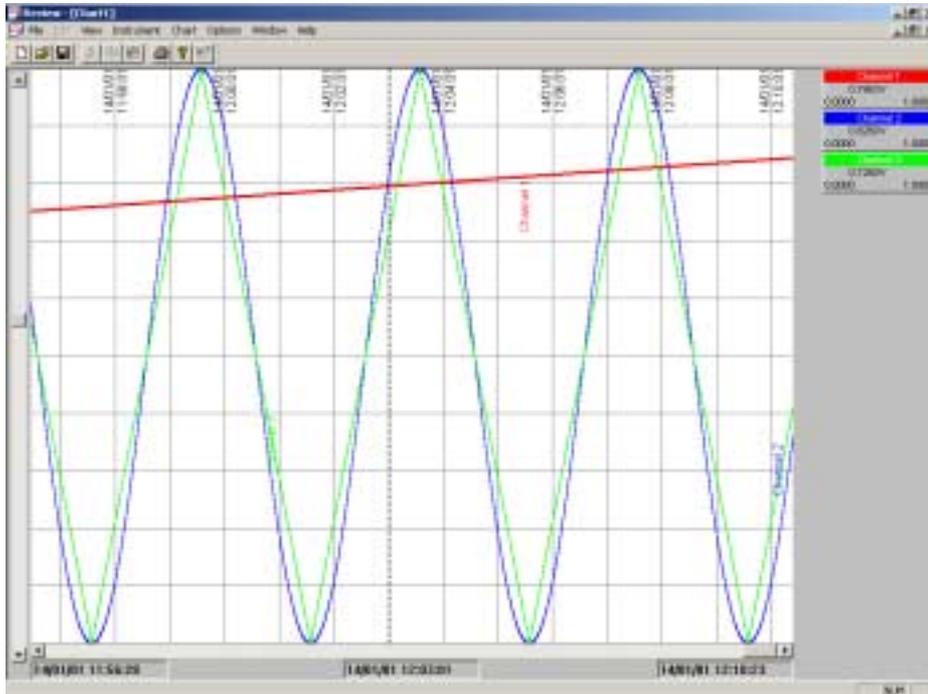
### Remote viewing (bridge 5000)

Bridge 5000 software enables the 5000 instrument to be viewed from any PC connected to the network that the instrument is on. This viewing is under username/password control. It does not interact in any way with the process running on the instrument, but merely views the process as if you were stood next to the instrument display. It is a convenient way for an on-call engineer to view a process from home before being called out or for a supervisor to check progress from their desk.



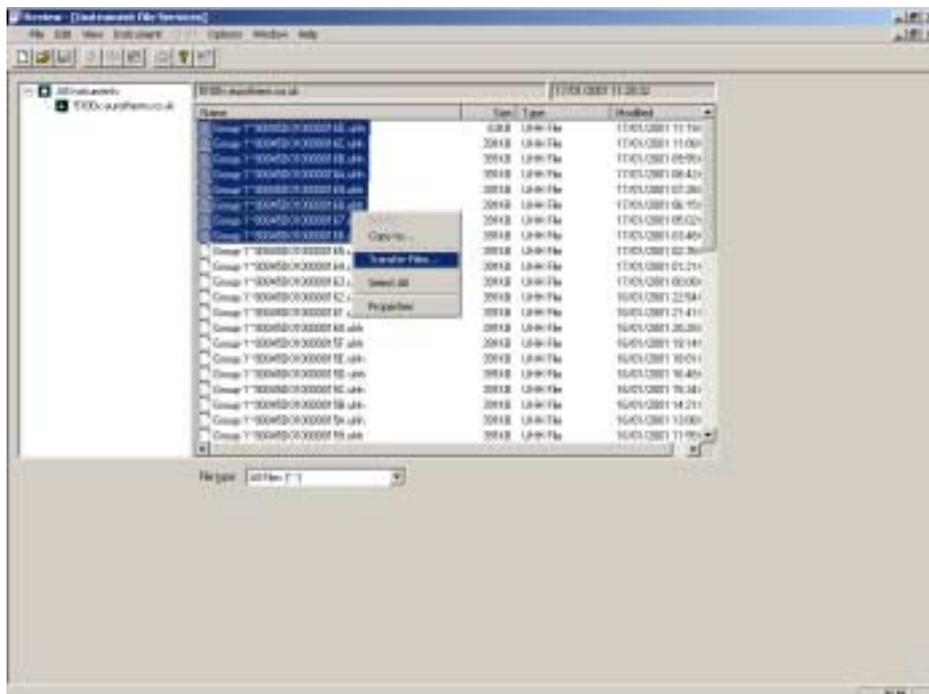
### Post process Data Analysis (review)

Eurotherm's Review software combines a database that takes a copy of process data from any of Eurotherm's recorder range to create a single database covering multiple instruments. This data can then be reported on in several formats to create displayed or printed charts of the original data. This can also be exported in ASCII format for further analysis as required.



### ***Transfer of Data***

Data is transferred from the raw data files in the instrument into the Review database in a 3 pass system, where the raw data file is first checked to ensure that there is no corruption, the data is then transferred across into the Review database (without affecting the raw data file which remains intact), then the data that has been added to the Review database is rechecked with the original raw data file to ensure that no corruption has taken place.



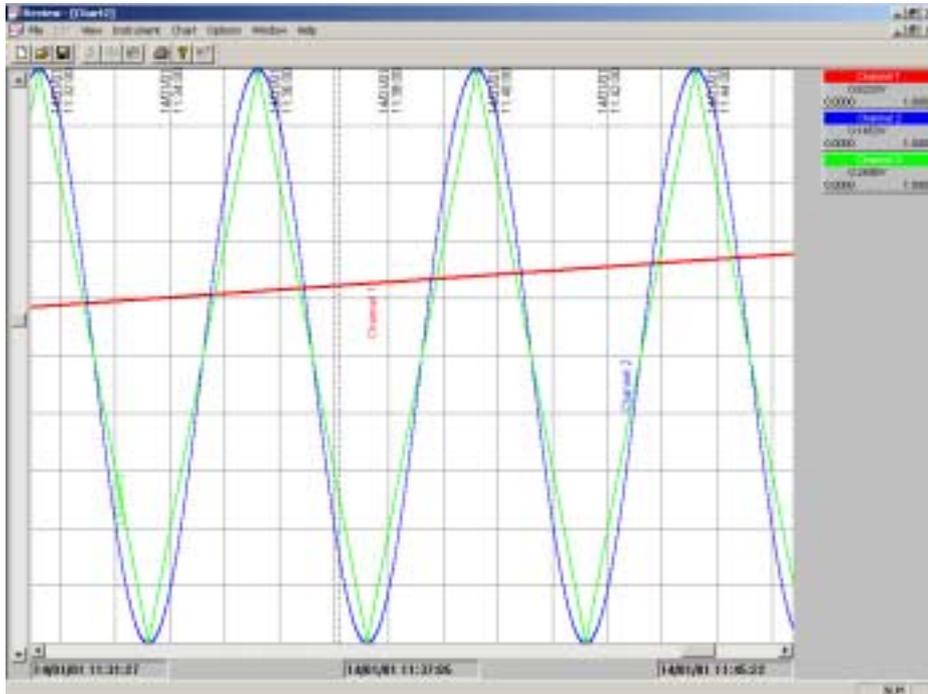
### Database structures

The Review database is held as a single packed binary file that has a full checksum to ensure that the data it contains is not corrupted in any way.

### Analysis

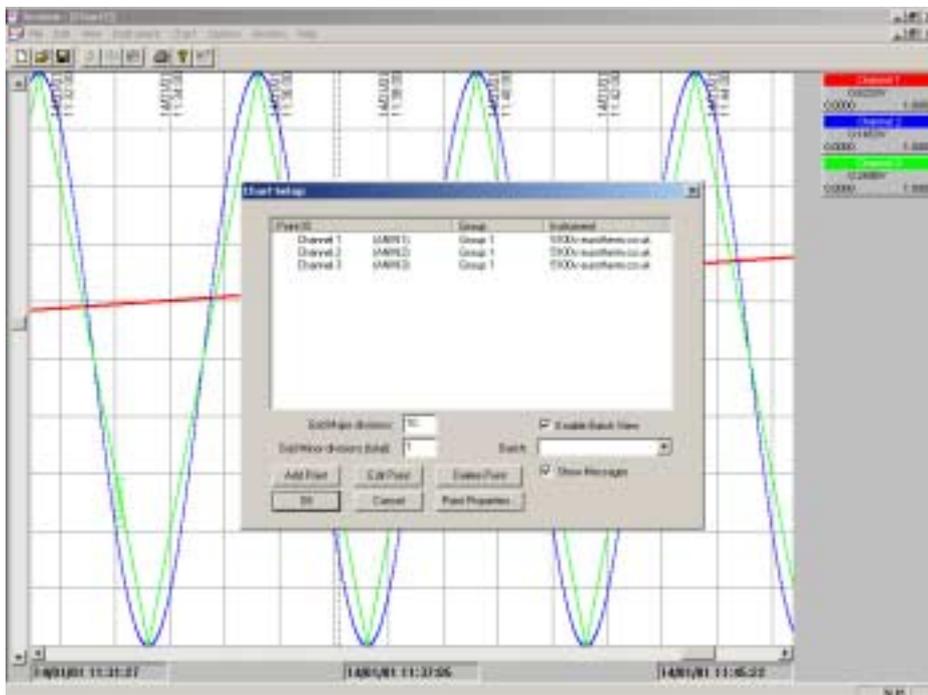
Data points from any instrument in the database can be displayed as a chart on the PC screen. This can then be exported as ASCII data for such analysis packages as Excel™, again the data in the Review database remains untouched. The chart display includes features such as:

- Review continuous or batch data
- Clear chart time base
- Time base compression to get more time on the screen
- Cursor bar with associated digital values for all channels at a particular time
- The same trace colours as on the instrument
- All traces annotated with channel tag



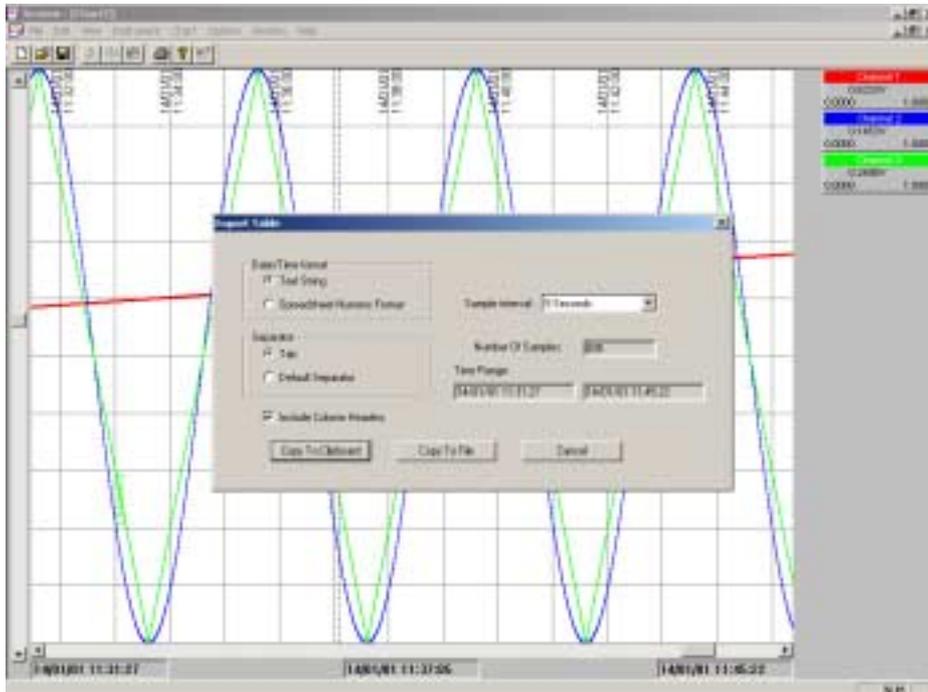
**Batch Analysis**

Data from a specific batch can be selected and displayed, printed or exported as an ASCII data file. Again the Review database is not written to in any of this process.



## Export of Data

Process data can be exported in an ASCII format for any data points defined and viewed in a chart on the PC screen. Once in the ASCII format however the data becomes unsecure, however it can be reproduced again from the more secure Review database.



## Further information

- <http://www.fda.gov> - FDA Home page
- <http://www.fda.gov/opacom/hpview.html> - The Food and Drug Administration: An Overview
- <http://www.ispe.org/gampinto.htm> - Where to order **Good Automated Manufacturing Practice**
- <http://www.fda.gov/cder/esig/index.htm> - Document that proves FDA acceptance of electronic data
- <http://www.21cfr11.com/> - Website concerned only with 21CFR part 11
- [http://www.fda.gov/ora/compliance\\_ref/part11/FRs/background/pt11finr.pdf](http://www.fda.gov/ora/compliance_ref/part11/FRs/background/pt11finr.pdf) - 21CFR11 Final rule

- The Good Laboratory Practice Regulations 1997 ISBN 0 11 064105 1
- Quality Systems for Sterile Medical Devices and Surgical Products 1990: Good Manufacturing Practice ISBN 0 11 321341 7
- Rules and Guidance for Pharmaceutical Manufacturers 1997: Incorporating - EC Guide to Good Manufacturing Practice [GMP] and Good Distribution Practice ISBN 0 11 321995 4
- Guidelines for Good Manufacturing Practice of Cosmetic Products (GMPC) ISBN 9 28 712849 9
- Good Manufacturing Practices for Pharmaceuticals ISBN 0 82 479770 1
- The Rules Governing Medicinal Products in the European Union Vol4: Pharmaceutical Legislation: Good Manufacturing Practices: Medicinal Products for Human and Veterinary Use 9 28 282029 7

Any reference to 21 CFR Part 11 refers to the Food and Drug Administration federal register document 21 CFR Part 11 Electronic Records; Electronic Signatures; Final Rule dated 20 March 1997 [Docket No. 92N-0251]

All references valid January 2001