

INTRODUCING THE ALL NEW INNOVATIVE *ESTEEM HMI*

“HUMAN MACHINE INTERFACE”FEATURE TO OUR PRODUCTS.



INTRODUCTION

Esteem Industries INC is a specialized manufacturer and supplier of autoclaves with innovative system controllers with HMI. Autoclave system controller board processes the autoclave system, where the surgical equipments are sterilized under standard pressure and temperature - 121 C/1.2 kg and 134 C/2kg for the set time. The company manufactures and supplies excellent range of autoclaves with digital controller, which is developed by highly qualified engineers and professionals to meet exact industrial needs. These are available in a variety of advanced features to cater to varied applications. The autoclave control systems designed and developed by us are extensively demanded amongst users because of their best quality and sensible price. All the items in this products range are delivered within the stipulated time frame to save clients' valued time.

FEATURES

- Temperatures select 121° C and 134° C.
- Temperature display.
- Timing display for sterilization processes and drying processes
- Water level detection and detection of distilled and non-distilled water.
- Error indications for temperature sensor failure, pressure switch failure, non-distilled water, less water level or no water.
- Displays the number of cycles used by a user.

APPLICATIONS

- The equipment is used for total sterilization in dental ophthalmic and E.N.T clinic.

TECHNICAL SPECIFICATIONS

- Input AC230V
- Output dry coil 1.5KW 230V
- Output wet coil 1.5KW 230V
- Output solenoids 230V

HMI BENEFIT:

We are pleased to introduce our reward winning innovative technology that combines the benefit of HMI (HUMAN MACHINE INTERFACE) and of Esteem Quality products. Now with the judicious blend of quality and technology, Esteem Industries Inc has reached the milestone that our competitors have been craving for. Just imagine a world where you would be able to digitally control your machine with just a click of your cell phone or should we say snap of your fingers. Never before was controlling your machine as easy and convenient as we have made it now.

So let's understand how does the Esteem HMI digital controller system works. The Esteem HMI's are available in a wide range of screen sizes and colours. Starting with a very economically priced 3.8" blue screen, the range includes 5.7" grey and 256 color screens, 8" and 10" 65K colour screen. Normally we provide 2 COM ports with Esteem series 1 (1 x RS-232 and 1 x RS-485) to allow the user to communicate with two different controllers simultaneously. The Esteem series 2 provides 3 COM ports (1 x EST-232, 1 x EST-485 and 1 x EST-232/RS-422/RS-485) and a USB for fast upload or downloading of programmes and/or connection to printers or external storage devices. The software editor-screen editor provides screen editing and program self debugging capability. A built in objects library is included and a build your own pictures library along with a multi-function objects library and text and graphics editing tools. The Esteem HMI's compliment the Esteem automation range of variable speed drives, PLC's servo systems and temperature controllers.

FEATURES OF ESTEEM HMI



Human Machine Interface



Features of HMI

Extension Module

Offer various kinds of optional extension modules to extend the HMI functionality.

Extension Printer Module:
Used to connect to printer.

Extension DIO Module:
Match the need for display, control and operation all-in-one application.

Extension Ethernet Module:
Peripheral equipment can be connected by Ethernet Module. The ability to long-distance data transmission enables fast and effective monitoring and controlling.

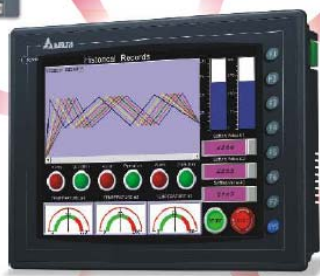
Display

Full-color Display:
Offer many different displays for the users to produce colorful, bright and high-resolution images. Max. 65536 colors TFT LCD display is provided. Clear and realistic images and graphs can be easily created.

Transferring Data

Rapid USB Download:
Efficiently reduce download time by using USB high-speed transmission interface.

USB Flash Drive for Copying Screen Data:
USB flash drive is used to copy the HMI screen data. It also provides password protection and can limit the frequency of copying the screen data. Using USB flash drive can protect screen data effectively and achieve easier maintenance of remote equipment.



Printer

HMI can be connected to different kinds of inkjet printers and dot matrix printers by using USB Host or Extension Printer Module.

Connectable Printers:
 EPSON Stylus C45
 EPSON Stylus C65
 EPSON Stylus C67
 EPSON Stylus Photo
 HP LASERJET 1022N
 HP DESKJET 400
 MP_A16
 MF_A45
 EPSON LX-300+
 Panasonic KX-IP1150
 ZEBRA TL-P2844

Communication

Serial Communication Interface:
Support up to three COM ports for serial communication. It can connect to multiple controllers in serial simultaneously. Besides Delta Industrial automation products, Delta HMI product can also support more than twenty well-known brands of controllers and continue to increase.

Fast Operation

PLC program can be upgraded and maintained via HMI. It provides fast operation with less wiring and less connectors.

Saving Data

Screen data, history records and recipes can be easily saved through SM card or USB flash drive.

3
4

1. ESTEEM HMI EXTENTION MODULE:

Esteem HMI, offers various kinds of optional extensions modules to extend the HMI functionality.

Extension Printer module: This is used to connect to the printer.

Extension EIO Module: This matches the need for display, control and operations all in one application. **Extension Ethernet Module:** Peripherals equipment can be connected by Ethernet Module. The ability to long distance data transmission enables fast and effective monitoring and controlling.

2. ESTEEM HMI DISPLAY:

Full Color Display: Offer many different displays for the users to produces colorful, bright and high- resolution images. Max 65536 colors TFT LCD display is provided. Clear and realistic images and graphs can be easily created.

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MP_A16

MP_A40

EPSON LX-300+

Panasonic KX-P1150

ZEBRA TLP2844

4. COMMUNICATION

SERIAL COMMUNICATIONS INTERFACE:

Support upto three COM ports for serial communication. It can connect to multiple controllers in serial simultaneously besides Delta industrial automation products. Esteem HMI products can also support more then twenty well known brands of controllers and continue to increase.

5. TRANSFERRING DATA

This is one of the most important features of Esteem HMI. Now we have rapid USB download. It efficiently reduces download time by using USB high-speed transmission interface.

USB FLASH DRIVE FOR COPYING SCREEN DATA:

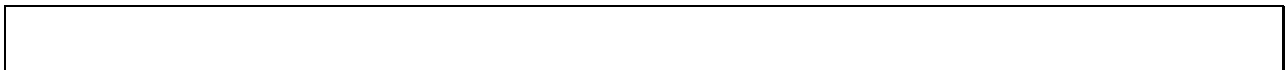
USB Flash drive is used to copy the HMI screen data. It also provides the password protection and can limit the frequency of copying the screen data effectively and achieve easier maintenance of remote equipment.

FAST OPERATIONS:

PLC programs can be upgraded and maintained via HML it provides fast operation with less wiring and less connections.

SAVING DATA:

Screen Data, history records and recipes can be easily saved through SM card or USB flash drive. Now it would also be worth noticing that how does The Esteem's controller provides the ultimate integrated solutions for Process and Automation Control.



ESTEEM CONTROLLER PROVIDES THE ULTIMATE INTEGRATED SOLUTIONS
FOR PROCESS AND AUTOMATION CONTROL

Anybody who has been involved in the process of steam sterilisation will appreciate that although the principles are simple, the mechanisms and processes applied to achieving these simple principles are both complex and subtle. To achieve sterilization, we at Esteem replaces all of the air in contact with the load to be sterilised with steam of the right quality and of the right temperature and pressure for the correct length of time. Our research and development team and scientists have focused on how such a process can be properly instrumented and controlled, examining the unique considerations for autoclaves.

Esteem's new controller reduces equipment costs, and the time for integrating discrete PLC and HMI combinations, by the simple means of combining both functions, as well as open bus communications, all in a single, easy-to-mount unit. Available with a combination of Digital and Analogue, the controller is ideal for both process control and factory automation applications. This technology also packs in levels of functionality that makes the unit the most flexible and cost effective in its class. This high level of functionality removes any need to compromise in the three operational areas: display, control and communication, provided by the Esteem. The HMI capability integrates a 128 x 64 LCD display featuring programmable IP65 (NEMA4) function keys, or high contrast Touch Screen 160 x 128 LCD and 4 programmable function keys; both providing high level graphics and text capabilities. In addition, the control capabilities provided by the unit's standard Analogue (4 Inputs, 2 Outputs) and Digital (24 Inputs, 16 Outputs) I/O are expandable by interfacing to remote I/O modules.

AUTOCLAVE CONTROL SYSTEMS | CURRENT TRENDS, VALIDATION & ESTEEM

ADVANTAGE

Most of the autoclave control systems that are in operations today were developed and installed with little or no regard to good software development practices. (Ref: Thompson. M,/ Managing Director. Honeyman Group limited). These systems are generally unreliable, unvalidatable and quickly becoming unsupportable. Keeping all this in mind Esteem has reviewed where does our system falls and what other actions are needed to be taken.

WHAT WAS THE TREND BEFORE AND HOW HAS INNOVATIVE [ESTEEM DIGITAL CONTROLLER SYSTEM](#) HAS CHANGED THE TREND AND EMERGED AS LEADERS

There has been just a little change in the requirements for the control and instrumentation of an autoclave, however the manner in which these requirements are satisfied has changed significantly. This change has mirrored the rest of the pharmaceutical industry, and industry in general as the introduction of microprocessor based control has provided operational flexibility undreamed of previously. Whilst the change from electro-mechanical control to microprocessor based control systems is well documented and understood, the impact that this change has had and the way in which it has had to be managed varies according to the type of system. What needs to be considered for autoclaves is the difference between automated packages and automated production processes. Production processes are very application specific and the applications are often unique, therefore the engineering solution applied is unique. This is of course based upon tried and tested solutions and best practice, but no two installations are quite the same. Automated packages however such as autoclaves or freeze dryers are not as application specific, they are often procured as a stand alone package and other than the connection of services they have

no direct link to the process. There are many installations throughout the pharmaceutical industry that are very nearly identical. There is therefore no need to redesign the autoclave package for every installation; the user requirements are more often met by configuration of a standard package rather than a redesign. For this reason, these packages are slower to change and therefore generally lag behind developing standards such as GAMP¹. Whilst some autoclave suppliers embraced the emerging standards and worked hard to deliver software packages validated to current acceptable standards and practices, others continued to develop software control systems job by job. This would involve copying the software from the previous job and then modifying to suit the new job with little or no trace-ability.

Another influence on the development and supply of autoclaves was the heightened awareness during the 80's for the need to validate sterilisation processes. There were several serious incidents involving poor control of sterilisation processes, which resulted in an increased focus by both the industry and the regulatory bodies. This increased focus created a boom in the late 80's and early 90's of new autoclave sales to the pharmaceutical industry as companies reacted by reviewing internal systems and equipment. At the same time there was an increased focus on automated systems and computer systems validation, again as a reaction to some incidents in the 80's. This started a journey through the 90's of frustrated users and suppliers who due to the lack of any formal guidance on computer systems validation applied widely varying standards across processes and throughout the industry. Although a never ending journey it is now well under control largely due to the guidance provided by professional bodies such as the GAMP¹ Forum. It is important that this background is understood because this process has moulded the autoclave installations operating today.

CURRENT-SITUATION

The autoclaves currently in operation have instrumentation and control packages varying from relay controlled with simple Bourdon tube pressure and vacuum gauges and a chart recorder, to microprocessor controlled systems with full SCADA² functionality.

From experience the systems which are often the most troublesome and the least well validated are some of the systems installed in the late 80's and early 90's where microprocessor based control systems were applied widely with little or no recognition of good control system software requirements. These systems not only failed to meet the validation requirements for control system software, which as mentioned previously were ill defined at that time, but many also failed to meet the good practice of the time. The worst examples have control system software which has no documented development, no configuration management, no version control, a large amount of dead code and were simply copied and modified job by job to achieve the autoclave functionality required. Some of these systems are still in operation and are generally unreliable, unvalidatable and quickly becoming unsupportable.

How do we at Esteem Industries INC, do auditing for autoclaves systems/ VALIDATION?

AUDITING THE EXISTING INSTALLATION.

If you do not know where your control system falls on the above scale of validated to unvalidatable, an audit of the installation is essential. A simple audit approach we follow at Esteem is described below. This is not meant to be a retrospective validation where you would commence with a URS³ and FDS⁴ then undertake a comprehensive assessment against this documentation. The audit is a more selective assessment to establish among other things whether or not retrospective validation is an option.

GATHERING THE DATA.

Before any system can be compared to the necessary standards you need to establish the current status. This data gathering exercise can be the most time consuming. It must include all 'as built' and 'as validated' documentation, maintenance history, validation history, change control and the current status. The current status must be established by monitoring operation of the autoclave and downloading as much of the software and configurable settings as possible.

SOFTWARE CATEGORISATION.

Categorisation of the control system software will assess the extent of any further validation work that may be required. This categorisation is explained in GAMP3¹, the categories are listed in *Table 1* together with examples for an autoclave installation. The examples are not exhaustive and are typical only, for each piece of equipment and software package there are good and bad examples which will consequently change the categorisation. Also there are different system configurations that will change the categorisation e.g. the autoclave control system could fall into either category 4 or 5 dependent upon whether it was based upon good configurable software or application specific.

Table 1

	Category	Example for Autoclave
1	Operating Systems	PC Operating Systems (e.g. Windows) PLC ⁵ Operating System
2	Standard Instruments, Micro Controllers, Smart Instrumentation	Chart Recorder Smart Instruments
3	Standard Software Packages	Microsoft Excel™ Used for Report Generation Multi-Point Data Loggers Used for the Routine Validation of the Autoclave
4	Configurable Software Packages	Autoclave Control Systems The SCADA ² Package
5	Custom Built or Bespoke Systems	Autoclave Control Systems

Many of the autoclave control systems that were sold as configurable software packages cannot be treated as such because the necessary control was not applied to their development. Therefore the control system would have to be treated as application specific. A fully instrumented and controlled modern autoclave installation could include Smart transmitters, PLC control and a SCADA package running on a PC. As **Table 1** shows this will include elements that fall into each category.

RISKASSESSMENT

Following the categorisation of the software a risk assessment should be undertaken to identify the impact that each software package and system component has on sterilisation effectiveness. A standard risk assessment approach can be taken here, assessing consequence and probability. **Table 2** illustrates one approach that can be taken listing all possible failures and then assessing each one.

Table 2

FAILURE RISK ASSESSMENT APPLIED TO ONE EXAMPLE OF A TYPICAL FAILURE

Failure Description	Simulator temperature fails, reading low
Will this failure adversely effect sterilisation?	No
Will this failure adversely effect safety?	Yes, doors could be opened before fluid temperatures have fallen below 80°C
Would this failure be identified in any other way?	Dependent upon control system. Control system should check that probe is reading high during sterilisation phase to ensure that it can rely on the reading at the end of the cycle. Does the control system do this?
What is the probability of the failure?	MTBF ⁸ for your temperature loop?

The risk assessment approach need not be prescriptive, it is better to use the system that is understood on the site and by the people undertaking the risk assessment. It is usual to assign a score to each of the above which will give a total score for the failure.

ACTIONPLAN

The Gap Analysis will clearly identify where action is required. This action will range from nothing other than documenting the audit findings to a complete replacement of an unvalidatable control system. A thoughtful approach here can actually prevent the knee jerk reaction of replacing the whole control system. Whatever your perception of the control system, the audit is a very worthwhile exercise as it may lead to a solution where some retrospective validation in the form of additional documentation or testing can be applied. This will not only save money but significantly reduce the level of operational disturbance and risk involved in control system replacement.

CONTROL-SYSTEM/SOLUTIONS AVAILABLE

The autoclave suppliers bespoke control system packages are coming under increasing competition from the more conventional approach of utilising industry standard control and SCADA² systems. Indeed some of the autoclave suppliers are offering these packages. This has the great advantage of allowing the operating site to maintain their site standards for control systems hardware and software by specifying all of the control system components (PLC⁵, HMI⁶, SCADA², PC operating system etc). The software should be specified, written, tested and documented in full compliance to acceptable standards e.g. GAMP3¹ or to your internal standards. The software and all documentation should be fully traceable throughout the project with all documentation accurately reflecting the changes and developments made throughout the project lifecycle.

This is not advocating that autoclave control system software should be written from new for each application. A package such as an autoclave is ideally suited to having a library of software modules or objects that can be selected dependent upon the application and then configured by the user. However this can only be done when the quality, development and testing of the software modules is documented and verified. Particular attention should be given to code reviews where the software engineer will explain the functionality of the code linking this to the FDS⁴ and DDS⁷ and ensuring that any software descriptors are meaningful to others. From experience this is the single most valuable step in the software development lifecycle, ensuring that the software not only does what it should but that it is written and documented in a quality manner that can be understood by others. Another technique is to include control systems technicians in the code reviews. This can provide benefits by improving long term support in house as a thorough understanding of the code structure is obtained. This approach ensures a solution that meets any site standards, is validated to an industry recognised standard and can be supported through the lifetime of the

installation. This addresses the control system requirements for an autoclave installation. However a control system is only as good as the quality of data it receives. Therefore the audit and any subsequent upgrade should also cover the measurement systems connected to the control system. Certain specific issues could be discussed for autoclaves.

MEASUREMENT

The critical parameters for moist heat sterilisation are steam quality, temperature and time. The critical measurements for the sterilisation process are temperature, pressure and time.

TEMPERATURE

A typical multi-cycle (porous load and fluids) autoclave could have the following temperature probes:-

Jacket temperature

Chamber temperature

Drain temperature

Load Probe temperature

Air detector temperature

Air filter temperature

Simulator temperature

Typically these temperature elements will be Class A (EN 60751: 1996) Platinum resistance thermometers. The accuracy that Class A defines over the measuring range is as follows

0°C ± 0.15 °C

150 °C ± 0.45 °C

EN2859 and HTM201010 ask for a loop accuracy of ± 0.5°C . However as the accuracy of the element alone is ±0.45°C it is unlikely that a loop accuracy of ± 0.5°C will be achieved when we consider transmitter accuracy, recorder accuracy and ambient

temperature effects. This is not a robust loop design, the theoretical loop accuracy lies outside the $\pm 0.5^{\circ}\text{C}$ tolerance specified in the standards. Although the loop will be calibrated within this tolerance there is no real safety margin. Therefore be very careful when setting the recalibration frequency.

Because of the criticality of these temperature measurements, some installations choose to go further than this either by increasing loop accuracy or by providing other means of verification. One method of improving loop accuracy is to use Platinum resistance thermometers better than class A, these can be sourced from some suppliers (often referred to as 1/10th DIN). This increased element accuracy will provide a greater safety margin for the loop accuracy.

An independent means of verifying temperature during an autoclave cycle can be installed. This is actually a requirement of the standards but is infrequently applied. This independent means can be achieved by specifying an additional element within the temperature probe; therefore the duplex probes will become triplex. This additional probe is then wired to a socket on the side of the control panel. During an autoclave cycle a calibrated Pt100 transmitter can be plugged into this socket and a comparison made between this indication and the front of panel temperature indication. Whilst this is not a true loop calibration it is a very good check which can be carried out with no disturbance to the autoclave installation or operation and with the minimum of effort. Therefore this could very easily be carried out on a monthly basis to provide more confidence between true loop calibrations which are usually carried out on a 3 or 6 monthly basis dependent upon history.

PRESSURE

A typical autoclave installation will have chamber and jacket pressure measurement. The critical measurement here is the chamber pressure since sterilisation temperature is achieved by controlling steam pressure in the chamber not by controlling on temperature. For porous load autoclaves the pressure loop must have a range of 0 to 3.5Bar absolute [Bar(a)] and have a loop accuracy of between $\pm 0.5\%$ to $\pm 1.6\%$ at the sterilisation pressure, depending upon which standard you choose to work to. **(See Table 3).**

Table 3

BS EN285	$\pm 1.6\%$ at the sterilisation pressure
BS 3970	$\pm 1.0\%$ at the sterilisation pressure
HTM 2010	$\pm 0.5\%$ at the sterilisation hold pressure

Accuracy throughout the rest of the autoclave cycle is less important than repeatability. Repeatability is important as it is necessary to ensure for example that the negative pulse is as it was during validation, the fact that the negative pulse is 150mBar(a) absolute rather than 130mBar(a) is less important provided it is consistent. The pressure transducer has an arduous duty due to the internal temperature fluctuations throughout the cycle (ambient to 136°C) and due to the external influences

of the autoclave plant room, which can also have temperature fluctuations and high humidity. These are the factors to consider when selecting the transducer, good temperature compensation within the transducer and a robust compact design.

CALIBRATION

The critical calibrations are temperature, pressure and time.

TEMPERATURE

As discussed above there are ways of providing a quick check facility on the temperature loops by wiring temperature elements to sockets, this is not however a true calibration. Consideration needs to be given as to how the temperature probes can be calibrated when the autoclave is designed and installed. From experience many installations require the dismantling of parts of the autoclave and unclipping a lot of cable before a temperature probe can be removed for calibration, this not only lengthens the time needed for calibration but also disturbs the 'as validated' status of the. When the loop is being calibrated consideration should be given to calibration at the actual sterilising temperature rather than just dividing the 0 to 150°C range into four.

PRESSURE

As with temperature there are ways of providing a quick check facility for pressure loops by simply installing a boss adjacent to the pressure transducer. In addition to the quick check this boss can actually be used for the pressure loop calibration. By installing a pressure transmitter (with calibration traceability to a national standard) into the boss adjacent to the transmitter to be calibrated, the readings can be compared throughout a porous load cycle, which should cover the full operating range of the transducer both rising and falling. This is generally an acceptable and very representative calibration since it is carried out in the actual operating environment and with the minimum of disturbance.

(This approach cannot be taken for the temperature quick check comparison since you are using an uncalibrated temperature element for performing the quick check)

TIME

A very often forgotten calibration is important for two reasons. Firstly, it is essential that the sterilisation hold time is accurate, therefore a calibration of this using a certified stopwatch is essential. Secondly, computer clocks are not accurate; how far has the time drifted since it was set? Since this forms the basis of batch documentation some check on the accuracy of the computer time is required. This could be as simple as a quarterly check against the speaking clock.

FUTURE-TRENDS

STANDARD CONTROL SYSTEM.

The use of industry standard control equipment and solutions will continue, so treating the autoclave like any other piece of process equipment. There will of course be standard software modules that can be picked for particular applications.

APPLICATION SPECIFIC SOLUTIONS.

For simple autoclave applications where there are only one or two production cycles, or applications where changes to production cycles are very unlikely, or applications where a very high integrity approach is required by the user then a truly application specific solution could be adopted where there is no user configuration whatsoever.

CHART-RECORDER

Why have a separate chart recorder? The reference in the standards to the use of a separate chart recorder is probably a legacy from the time when control systems were unvalidated and a secondary means of checking timebase, temperature and pressure were-essential.

Most modern autoclave installations incorporate a SCADA package that can log and printout cycle parameters as required. Therefore the current situation is that there will be two cycle printouts that will not always be the same. The correct approach should be to have a properly validated and maintained control and instrumentation package. Efforts should be applied to ensuring and maintaining this. There should then be the confidence to eliminate secondary checking packages such as chart recorders. A quality assurance rather than a quality control approach.

Another consideration is that some companies internal standards and a requirement of the European standards is the installation of secondary elements in the temperature probes as discussed above in calibration. If this approach is taken and the auxiliary chart recorder is used it can mean the installation of a triplex RTD probe, one element for control, one for the chart recorder and one wired to the calibration check socket. This approach of having one control and indication loop backed up by two levels of checking is quite unique to autoclaves

It is possible to for-see that with the quality of control solutions available now, such that if they are properly implemented by people who understand sterilisation and control systems, it is logical to move away from the level of duplication currently insisted upon.

SMART-INSTRUMENTATION

The instrument considerations for the main measurements of temperature and pressure are quite specific to an autoclave as discussed above. Space is at a premium, cable runs are short and the duty is arduous. The duty is arduous for temperature measurement mainly in consideration of the load probe which even when protected by a flexible

stainless steel conduit is prone to get run over by the loading trolleys and damaged. In the case of pressure measurement, temperature linearity is a big consideration, the requirement for a transducer capable of measuring 0 to 3.5 Bar(a) is standard. The application where smart instrumentation could be applied is the chamber pressure transmitter. There are two key requirements for measuring chamber pressure, firstly for the control of the autoclave, pulsing, sterilising hold pressure and drying etc. where the measurement loop is expected to have an accuracy of $\pm 1\%$ at the sterilisation hold pressure.

The second requirement for measuring chamber pressure is for performing the leak rate test where an accuracy of $\pm 1\%$ over a range of 0 to 160mBar(a). Although the standards ask for a separate pressure transmitter for the leak rate test, some installations try to satisfy both measurement requirements with one transducer. From experience the required accuracy for leak rate testing is seldom achieved with the pressure measurement loop used for chamber pressure control. However because the calibration over the full range is satisfactory and the pressure readout is to two decimal places of mBar, the user thinks the leak rate test measurement is accurate. In practice the absolute accuracy is less important than the linearity and repeatability for this leak rate test. What is important is that the pressure has moved by less than 13mBar over the 10 minute period, whether or not this was from 40mBar to 53mBar or from 50mBar to 63mBar is not as important. Therefore when selecting pressure transducers for the autoclave installation it is important to check all constituents of the overall accuracy figure that will be quoted by the manufacturers. The temperature effect is very important due to the constant temperature cycling, and the linearity and repeatability is very important to ensure the leak rate figures are representative.

CONCLUSION

Before embarking on any upgrade, audit your current system, it may be redeemable. If it is likely to be at a fraction of the cost of an upgrade. If it is not, the audit will have

established clear project deliverables and business justification for the upgrade. The benefit of the latest control upgrade solutions are considerable. However, do not assume that the new solution will be fully compliant with GAMP3¹ or similar recognised standards. Many of the problems with some existing systems discussed above still can apply. Installations are still occurring where software is copied from job to job with little or no control over software development and testing. An audit by a control system engineer on the proposed supplier is essential, GAMP3¹ gives guidance as to how this should be carried out. This audit must include a review of software history if modular configurable software is to be applied and must include discussions with the software engineer who will be working on your project. Clearly define your requirements and do not be swayed by what suppliers are willing to provide. There is no reason why the solution that meets your needs cannot be applied, provided this is defined and agreed up front

REFERENCES:

GAMP¹ GAMP 3 1998 (Good Automated Manufacturing Practice) For Validation of Automated Systems in Pharmaceutical Manufacture

SCADA² Supervisory Control And Data Acquisition

URS³ User Requirements Specification

FDS⁴ Functional Design Specification

PLC⁵ Programmable Logic Controller

HMI⁶ Human Machine Interface

DDS⁷ Detailed Design Specification

MTBF⁸ Mean Time Between Failure

EN 285⁹ Sterilisation. Large Steam Sterilisers Requirements and Testing

HTM 2010¹⁰ Sterilisation of Medical Devices and Medicinal Products