"Death rates fall by 15 % after handheld devices replaced paper charts at hospitals in Coventry and Portsmouth, England."

Paper on Glass

THE MOMENT THE PENNY DROPPED

A news article recently caught my eye: *iPods save 750 lives during hospital trials.* **It detailed a recent study focusing on two hospitals in the UK collectively testing the use of Apple iPod Touch devices on the wards to record each patient's vital statistics. Very positive results were recorded: in one year 750 fewer patients died following the introduction of the new system.**

MOST OF US, at one time or another, have had the unfortunate experience of being in the hospital – either as a patient or visiting. Do you remember the chart hanging on the end of the bed? It's the chart that we all look at, feigning some latent medical knowledge and, for the most part, understanding nothing.

Well, it appears we were not alone in finding it difficult to interpret the chart. One nurse reports that "The old paper charts were very, very difficult to decipher. The crosses and arrows were written on the chart by the previous nurse and you couldn't distinguish where the cross was."

"With the new iPod system everything is color-coded, in more detail and accurate which means you can read it and you are more obviously able to see whether your patient is the same, better, or worse."

The nurses' procedure on the ward round is to ask the patient certain questions, measure certain clinical values and record the data on an iPod Touch device The vitals of each patient such as blood pressure, heart rate, oxygen levels, temperature, general well-being, and pain levels, are available live, with a history of readings displayed over time.

If we view the whole process in terms of the patient experience, very little has changed. The paper records of regular patient checks have been replaced by electronic records on tablets. The rules and procedures a nurse or

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doctor follows are exactly the same: patients have the same operations, with the same aftercare. The only change to the nurse is a small mobile device in place of a paper chart. Yet more useful and accurate data is gathered through the use of appropriate software, recording is never missed and care can now be targeted on those who need it and at the right time. It is fast, convenient and easy to use.

The bottom line is that 750 fewer people died in one year. The study was small, covering only two hospitals in a small corner of England. However, using exactly the same medical procedures and very little investment they have gained major benefits (especially if you are one of the 750!). If replacing hospital paper charts with medical software on mobile devices can achieve so much and change the lives of so many, where else can one replace paper charts with electronic records to such a positive effect? Take a look at the similarities we find using zenon in paper-based pharmaceutical batch production.

Process industries, particularly regulated life sciences, talk a lot about CQAs (Critical Quality Attributes). CQAs are process variables that enable us to monitor crucial stages of manufacturing. CQAs have strict control limits since any violation directly impacts product quality, possibly rendering it toxic and hazardous to a patient's health. In normal practice, a CQA has several warning stages indicating when the process is pushing the limits of acceptable performance, leading eventually to violation levels stating that an "out of tolerance" has occurred.

CQAs can be any measurable value in the process, for example temperature, pH or O2 levels, blending time, or tablet press speed. It is clear that a wide variation in any of these values would produce a product which is out of tolerance for a variety of reasons e.g. drug strength or potency, tablet coating imperfections or tablet hardness.

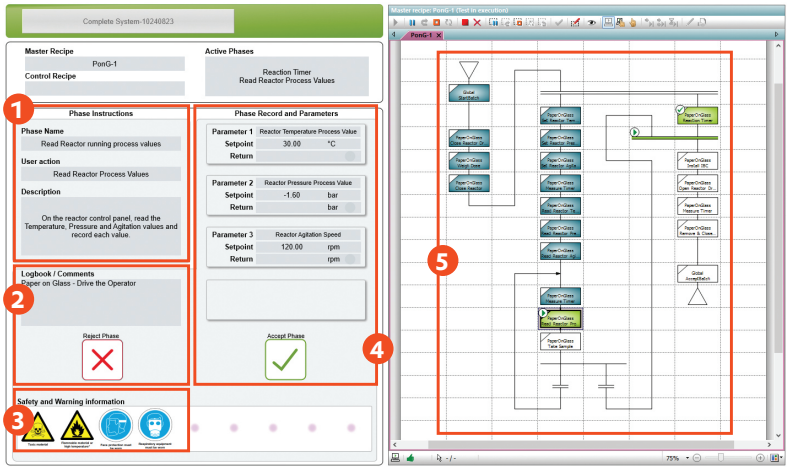
Swapping the paper-based operator instructions and paper-based batch records for a zenon-powered mobile tablet enables operators to record vital CQAs directly into a safe electronic system, then lets zenon's functionality expose opportunities never granted to manual production before. This is 'Paper on Glass'.

Paper on Glass uses zenon's Batch Control module to provide clear instructions for each task the operator needs to perform, e.g. a phase/step name, a user action, and a detailed description. Batch Control also prompts the operator to record information at certain times during specific points in the process, with an electronic logbook to add comments. The user interface enables inputs by the operator and the Historian archives the data. zenon pushes the final archived data to the Report Viewer or zenon Analyzer to provide batch reports, analysis data, material information, equipment information, a full audit trail and alarms. It can be operated stand-alone or as a client-server system.

When I recently introduced Paper on Glass to a veteran zenon user, I didn't expect the very passionate negative response:

"Not connecting zenon to the process? This is not useful. zenon's strength is about bringing automation and systems together."

Figure 1: zenon Paper on Glass application screen.



1. Name and description of the user action to execute
2. Comment must be entered before phase is rejected
3. Safety information and protection advice
4. User requested data must be complete before phase is accepted
5. Batch Control module commands production sequence

And then the penny dropped! Pharmaceuticals producers can't always make changes to equipment or, rather, certain quality and compliance obstacles are extremely difficult to overcome when making changes to validated equipment. COPA-DATA offers an additional solution, filling the gaps in current processes, and placing the latest technology on legacy systems.

This is the point when the veteran zenon user understood that the concept Paper on Glass is precisely about bringing processes together with automation: Keep the same processes, interface to the operator ergonomically, don't change the equipment, and don't change the procedures. Put the electronic recording into the operator's hands, secure the data and gain consistently accurate and detailed results.

The concept of Paper on Glass came from processes which are completely driven using paper Standard Operating Procedures (SOPs) and paper batch records. The operator is central to managing production execution and the recording of critical data. This user-centric environment holds a very important key to production success: how to deal with abnormality in a very complex critical process. The operator can react to any event, and avert events from critical failure. Loss of revenue in this costly production environment is mitigated with this user-centric approach.

Any zenon project can be expanded using the scalable modular functionality at zenon's core. Paper on Glass is no exception. Step by step the operator can link Paper on Glass to automated equipment and embrace the shades of gray between 'Manual' and 'Automated' environments, viewing both as one system, and integrate dated legacy processes with new technology. No gaps, no white spaces in the process, bridging quality across all production operations, controlling as one continuous process.

Having the tablet guide the operator through a production sequence, replacing paper instructions and the paper recording of critical data is only the start of this story. The benefits of zenon go further. It is reported that "Right First Time" when using paper in pharmaceutical production is less than 50% – with two thirds of rejects and reworks being caused by simple human errors such as missing the recording of a CQA, entering an incorrect value, or losing a paper record. We are talking about simple errors which, in the course of events, will happen time and time again.

Exactly as with the hospital study, by simply changing the mode of operator interface so many benefits are realized without changing the production process or the validation qualification state of these processes:

POINT OF ENTRY VERIFICATION

When a user writes a value on paper, it could be many weeks before the value is read again. Paper on Glass monitors the process in real-time and the value is checked against warnings and limits – instantly informing about any process violations. We can force the operator to acknowledge and verify the truth of this value, or we can force a different person (e.g. Quality Assurance) to verify the value. Automatically react to process exceptions and use Message Control to involve the right people at the right time before a critical event escalates.

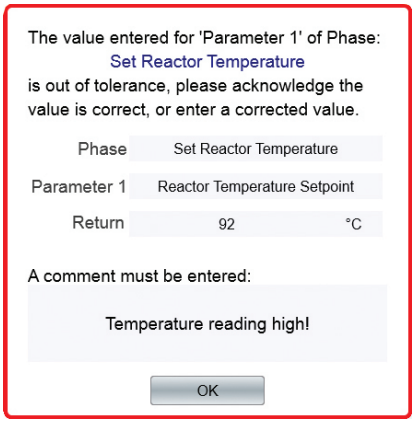


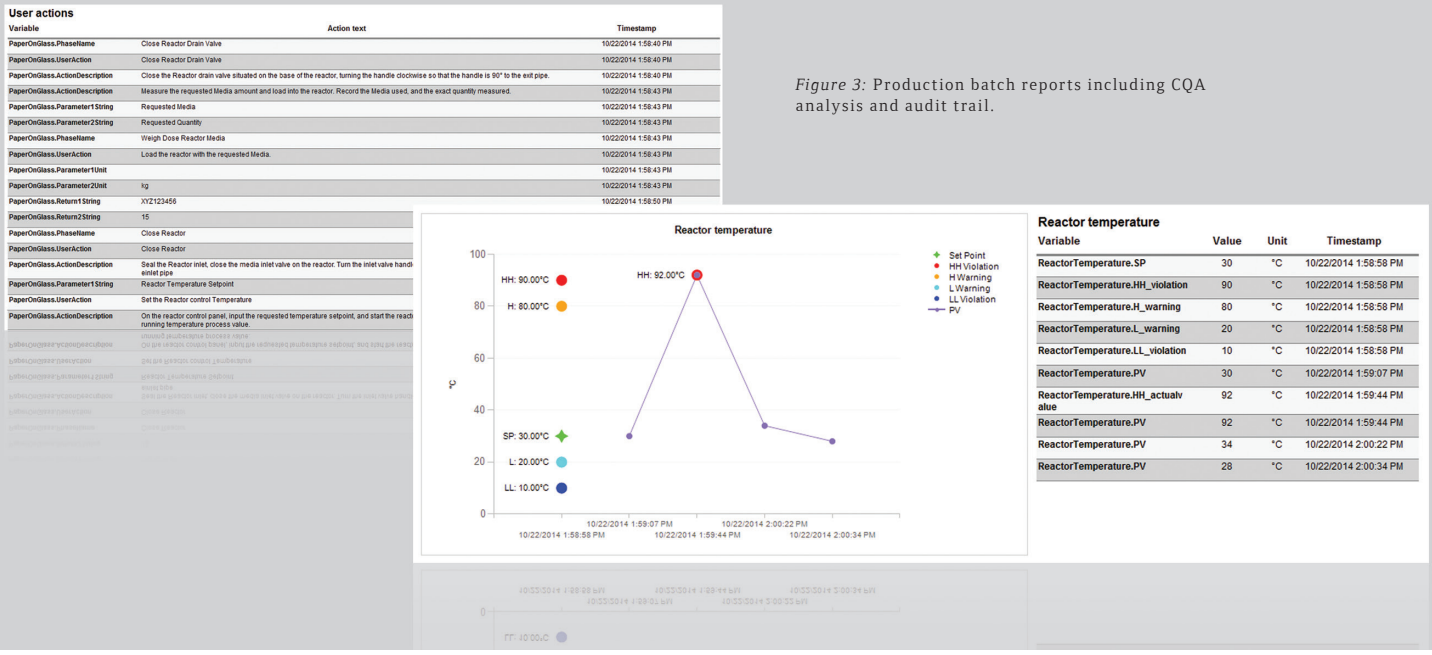
Figure 2:
Point of entry verification screen which pops-up when a warning or violation has been entered. The operator either has to acknowledge that the value is correct or enter a modified value. A comment must be given. Having the verified value and a comment reduces the number of investigations as complete data is recorded.

REDUCED OPERATOR TRAINING

Paper SOPs only give information regarding user actions, there is no description or physical sequence. Paper on Glass gives very clear instructions, detailed descriptions, and safety information at each stage of production. With less for the operator to remember, less can go wrong.

BATCH-TO-BATCH CONSISTENCY

The Batch Control module executes recipes in a strict automatic sequence. In this manner, no stage can be missed, diverted or delayed. Each stage has a time-stamped confirmation of its execution.



User actions

Variable	Action text	Timestamp
PaperOnGlass.PhaseName	Close Reactor Drain Valve	10/22/2014 1:58:40 PM
PaperOnGlass.UserAction	Close Reactor Drain Valve	10/22/2014 1:58:40 PM
PaperOnGlass.ActionDescription	Close the Reactor drain valve situated on the base of the reactor, turning the handle clockwise so that the handle is 90° to the exit pipe.	10/22/2014 1:58:40 PM
PaperOnGlass.ActionDescription	Measure the requested Media amount and load into the reactor. Record the Media used, and the exact quantity measured.	10/22/2014 1:58:43 PM
PaperOnGlass.Parameter1String	Requested Media	10/22/2014 1:58:43 PM
PaperOnGlass.Parameter2String	Requested Quantity	10/22/2014 1:58:43 PM
PaperOnGlass.PhaseName	Weigh Dose Reactor Media	10/22/2014 1:58:43 PM
PaperOnGlass.UserAction	Load the reactor with the requested Media.	10/22/2014 1:58:43 PM
PaperOnGlass.Parameter1Unit		10/22/2014 1:58:43 PM
PaperOnGlass.Parameter2Unit	kg	10/22/2014 1:58:43 PM
PaperOnGlass.Return1String	XYZ123456	10/22/2014 1:58:50 PM
PaperOnGlass.Return2String	15	
PaperOnGlass.PhaseName	Close Reactor	
PaperOnGlass.UserAction	Close Reactor	
PaperOnGlass.ActionDescription	Seal the Reactor inlet, close the media inlet valve on the reactor. Turn the inlet valve handl einlet pipe	
PaperOnGlass.Parameter1String	Reactor Temperature Setpoint	
PaperOnGlass.UserAction	Set the Reactor control Temperature	
PaperOnGlass.ActionDescription	On the reactor control panel, input the requested temperature setpoint, and start the reacti running temperature process value.	

Reactor temperature

Variable	Value	Unit	Timestamp
ReactorTemperature.SP	30	°C	10/22/2014 1:58:58 PM
ReactorTemperature.HH_violation	90	°C	10/22/2014 1:58:58 PM
ReactorTemperature.H_warning	80	°C	10/22/2014 1:58:58 PM
ReactorTemperature.L_warning	20	°C	10/22/2014 1:58:58 PM
ReactorTemperature.LL_violation	10	°C	10/22/2014 1:58:58 PM
ReactorTemperature.PV	30	°C	10/22/2014 1:59:07 PM
ReactorTemperature.HH_actualvalue	92	°C	10/22/2014 1:59:44 PM
ReactorTemperature.PV	92	°C	10/22/2014 1:59:44 PM
ReactorTemperature.PV	34	°C	10/22/2014 2:00:22 PM
ReactorTemperature.PV	28	°C	10/22/2014 2:00:34 PM

Figure 3: Production batch reports including CQA analysis and audit trail.

AUTOMATIC COLLATION OF DATA

Entered values go directly into the central zenon Historian. At no stage can requested information be overlooked, and so the company has complete, time-stamped and clear batch documentation. With central storage of process data, the tablet can be lost, dropped, smashed, or stolen, and the data is still safe. A batch has typically around one thousand manual entries. With paper activities, documentation needs to be manually collated and entered into electronic systems for analysis and reporting. Paper on Glass reduces post-batch tasks and the head count in this critical process.

POST-BATCH ANALYSIS: BATCH REPORTS ARE AVAILABLE INSTANTLY

The instant the batch finished, complete batch information is available and archives are accessed by the Report Viewer or zenon Analyzer to produce analysis and final compliance documentation. Reports give clear and precise information on CQAs, materials, equipment, operator actions and comments. Paper-based environments need an additional 10 - 30 days post-batch. Paper on Glass significantly reduces post-batch analysis time, and reduces the effort involved in producing compliance documentation.

COST AVOIDANCE

Paper is costly. It needs to be printed, tracked, and stored in environmentally secure areas over the long-term, with storage durations of eleven years being common. Paper on Glass requires no paper to drive production, thus no large scale storage of paper is needed. Given that the pharmaceutical branch uses a lot of paper, this is a huge cost advantage.

Paper on Glass offers the latest technology to complement manual processes, embracing legacy processes with new equipment. It is a simple and elegant cost-reducing solution that improves operational performance.

zenon's Paper on Glass is a complete batch solution in the palm of your hand.

ROBERT HARRISON,
INDUSTRY MANAGER PHARMACEUTICAL

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