ATS Inspect
Medical Device Industry
Paperless Quality Control with ATS Inspect

Quality control is of paramount importance to manufacturers of medical devices and so it’s important to have in place the right, affordable solution. Read on to see how ATS Inspect can raise your standards while lowering your costs.

Capturing Quality Data

ATS Inspect makes light work of the quality control required by your manufacturing processes. The suite of applications provides a number of different approaches to assessing quality:

- Collects and analyzes attribute data where defect information is critical to the production of quality parts.
- Collects and analyzes variable data such as weight, length and pressure to ensure they stay within specified limits.
- Utilizes electronic checklists to vastly reduce human error and increase quality control efficiency.

Fast Installation and Setup

For both attribute and variable data collection the entire setup, from installation through to the first use on the production line, couldn’t be simpler. Out of the box ATS Inspect has everything you need to be up and running with the minimum of hassle.

Paperless Manufacturing

The use of paper to record defects, values and details during the manufacturing process has many flaws. These flaws can be eliminated using the electronic system offered by ATS Inspect.

Human error is reduced to a minimum by removing the requirement of re-entering information from a paper record into the database. With ATS Inspect information is entered directly into the system.

Time and money are saved by avoiding duplicate data input. The production of checklists is also simplified as questions and answers can be updated in real-time rather than having to re-write and re-print each checklist.

3D Inspection

Defects can be placed directly onto 3D CAD models. All major CAD formats are supported allowing you to import your existing models. The name and ID of every component within the model can also be imported into the database which will greatly reduce your setup time.

When you need to add a defect you can smoothly rotate the model, using a mouse or touch-screen, zoom in to the required area and assign the defect.
By bookmarking key positions the operator can jump to preset perspectives with cut-throughs and with components removed so that they can place defects inside the product without the need for multiple views and photos to be taken.

**Layered Inspection**

The operator can also place defects on multi-layer 2D views. This allows them to strip away information to see *inside* the object being inspected.

This layered approach mimics real-world inspections and speeds up data collection which reduces costs and means no defect can remain hidden for long.

**Built-in Audit Trail**

Having the complete quality control system in one place means that the audit trail for each item is automatically generated as it passes through the production process.

The item being manufactured is registered at each step of production and any associated defects, repairs and checklist answers can be reviewed and analyzed at anytime from anywhere in the world, but more on that later.

**Integrated Electronic Signatures**

ATS Inspect has built-in functionality allowing all actions to be carried out with the use of electronic signatures. This saves time and money by allowing actions to be carried out without the need for printing and excessive review and external verification.

All use of ATS Inspect is carried out after an authenticated login. Each user has pre-determined selection of functionality that they can and cannot use. This selection can be modified at any time by an administrator.

**Raising “Right First Time”**

Spotting individual issues during the manufacturing process is easy enough but identifying trends is a lot harder. ATS Inspect has several methods to help you identify and rectify trends and problem areas.

The results of In Process Verification are instantly collated and with the aid of real-time ATS Inspect reports you can resolve quality issues as soon as they arise.

ATS Inspect also has the ability to manage campaigns that will add an extra layer of quality control to ring-fence and monitor new processes or areas of interest within the manufacturing process.

**Effortless Data Entry**

An easy-to-use operator interface is one of ATS Inspect's principal strengths. ATS Inspect is always designed with the end-user in mind making configuration and use quick and simple.

When recording defect data ATS Inspect displays digital images of the part or assembly to be inspected and uses simple touch screen tools to identify and evaluate defects. Defects can be found, flagged and automatically routed to rework in a few seconds.
Recording variable data is just as simple. For each measurement the user can simply type in the value or automatically import it from an electronic device. Images can be included to show the user exactly which variable needs to be measured.

A typical Variable Data Collect screen

Real-time data collection drives the ATS Inspect system. Fast, flexible and reliable input, using keyboard, mouse or touch screen, makes operators and inspectors productive and open to using the system.

### Electronic Checklists

ATS Inspect utilizes electronic checklists to record issues and to make sure all required visual checks and safety checks have been completed. This eliminates paper checklists and the difficulty of preserving, retrieving and using checklist data for later review and analysis.

Data can be entered using a PC, tablet or handheld device. Entering data directly into the system reduces the risk of human error.

The checklist functionality is particularly useful at the Point of Delivery before a device leaves the plant. Once the device number has been entered, a tailor-made checklist will be presented to the operator, allowing them to confirm that the correct product, packaging and quantities are being sent.

### Exceptional Reporting

The powerful reporting abilities of ATS Inspect give you easy access to data critical for quality audits as well as providing proof that traceability exists.

Collected data and checklist information can be viewed in real-time in a wide range of charts and tables. You can even export reports to spreadsheets and PDFs.

The web-based reports can be viewed anywhere in the world using a web browser on a secure connection. This allows management to review production even while on the road.

Reports can be generated for each product tracked in the system, and can be based on factors such as batch number, date, time, production area, historical quality data, operator, checklist category, control point, product status and current location.

### Display recorded data in charts and tables

On top of all this you will have the ability to create your own fully customized reports. Designing reports in-house means you can respond to the needs of your business as soon as they arise.

If required each user can create their own set of fully customized reports so that they're just presented with the information that's relevant to them.
Up-to-the-minute reports can be scheduled to be sent to the relevant people at regular intervals automatically. Do you need that report on your desk first thing Monday morning? It’ll be there.

### Quality Certification

ATS Inspect software enables electronic data capture and storage to be carried out in accordance with the latest standards such as GAMP and ISO 13485.

In addition it assists with the incorporation of Unique Device Identification (UDI) with is a growing requirement globally.

### Take a Picture

Digital photos and CAD drawings can be imported and included in inspection screens for defect location accuracy.

If you wish you can even take a photo of a quality concern and store it alongside the defect in the system. This gives you a true record of what’s happening on the production line.

### Instant Event Notification

Personnel can be instantly informed of quality issues throughout the production facility by utilizing ATS Inspect’s automated messaging service that conveys information via e-mail and static display devices overhead monitors. It can even be configured to send out information-based or exception-based messages.

Criteria for event messaging are user defined and may include:

- Quality thresholds
- Production thresholds
- Critical issues
- Quality statuses
- Production statuses

Send alerts to interested parties instantly

### Customize User Interfaces

ATS Inspect allows you to design custom screens that will be used by the operator collecting data. The designer is able to move, resize and remove different controls (such as buttons, images and labels) and define actions based on user interaction.

This flexibility also allows you to use different data collection platforms as need dictates in your facility. You can design a different set of screens for each device and assign them directly to each terminal.

Create easy-to-use screens in Form Composer

### See the Cost of Quality

You know that ATS Inspect delivers information on the quality of your products. But what about the cost of quality?
ATS Inspect allows you to see the cost of quality. You can calculate the repair cost of each product or how much labour and material cost is tied up on the plant floor at a given time.

Reference Documents

It’s often useful to have some extra information about how to carry out an inspection. This is where Reference Documents come in handy. Operator instructions, visual aids or whatever else you may need can be accessed by the operator when they need them most.

Data Management Tools

ATS Inspect lets users import product types, locations, concerns, details and other product data directly from an Excel spreadsheet into the ATS Inspect database. Data Importer eliminates the need for manual data entry of information already stored in other databases or files.

If you find your database is getting too large you can remove your historical data from the ATS Inspect database and store it on a separate file. This frees up online resources and increases the analytical speed of your production systems by reducing the amount of data in the system.

A Complete Solution

For attribute and variable data ATS Inspect has all bases covered, from checklists through to analysis and reporting. For further information please go to www.ats-inspect.com or give us a call.

ATS is an Independent Solution Provider, with over 30 years’ experience in the manufacturing systems arena and a wealth of experience undertaking Continuous Improvement initiatives and Manufacturing IT solution design, deployments and 24/7 support assignments.

www.ats-global.com