P·E·T Process Equipment Tracking®

EQUIPMENT IDENTIFICATION & LIFECYCLE ANALYSIS SYSTEM

Process Equipment Tracking, or PET, offers a new degree of safety and reduced risk for the pharmaceutical processing industry, as well as other high purity applications in the food and beverage, cosmetic, chemical, and biomedical sectors. Using RFID (radio frequency identification) technology, all process equipment involved with a particular batch of product is monitored from start to finish. Briefly stated, PET tracks who did what to each batch and when. It's a logical approach to tracking all critical process components.

IDENTIFICATION

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PET ADVANTAGES

- Identifies individual process equipment devices such as pumps, bio-bags, diaphragm valves, filters, UV lamps, and hoses using RFID tags
- Tracks key wear-related events such as cleaning cycles/dates and batches of material processed or other user-defined events
- Ensures timely maintenance and replacement before parts begin to fail, risk product integrity, and waste time and labor
- Provides an audit trail to assist in validation processes; helps accelerate data collection procedures and lower costs
- Reduces errors on the production floor
- Consolidates documents by electronically linking to notes, cleaning schedules, files, certifications, photos and illustrations, installation instructions, warning notices, and other protocols
- Safe for use with CIP, SIP, and autoclave processes
- Various tags address applications involving high temperatures, gamma irradiation, and mounting to metal
- **Gamma-radiation-resistant RFID tag** – GammaTag® – now available
- Different tag sizes and shapes available
- Field installation methods available to immediately start tracking existing equipment
- U.S. Patents 7,195,149; 7,259,675 and 8,519,846

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P·E·T Process Equipment Tracking®

Equipment Identification & Lifecycle Analysis System

Advantages

Minimizes Risk

- Tags are encoded with serial numbers and other information and are externally attached to each piece of process equipment – no contact with material flow
- An administrative level access, known as Kiosk mode, restricts usage to prevent changes to the system
- Identifies individual process equipment parts such as pumps, bio-bags, diaphragm valves, filters, UV lamps, and hoses using RFID tags
- A fast, efficient, and precise identification system for critical process equipment
- Eliminates dependence on manual log book record keeping, its inefficiencies and inaccuracies, and the books' contribution as a contamination source

Reduces Costs

- Accesses and records the current status of any tagged component on the spot
- Reduces errors on the production floor
- Limits failures and helps calculate equipment life expectancy using actual data
- Eliminates the inefficient calendar method of swapping out used parts – reduces wasted production life and underutilized equipment
- Field installation methods available to immediately start tracking existing process equipment
- Applicable to predictive maintenance systems (PdM)

Consolidates Documents

- Eliminates inefficient paper labels and hang tags
- Reduces dependency on paper records and their inherent problems, such as transposed numbers, incorrect dates, handwriting legibility, misread data, and misfiled documents
- Electronically links to notes, cleaning and maintenance schedules, files, certifications, photos and illustrations, installation instructions, warning notices, and other protocols
- Allows recording and storage of all critical information
- Links to a database that contains the complete biographical history of parts
- Allows information access from any networked computer running the PET program

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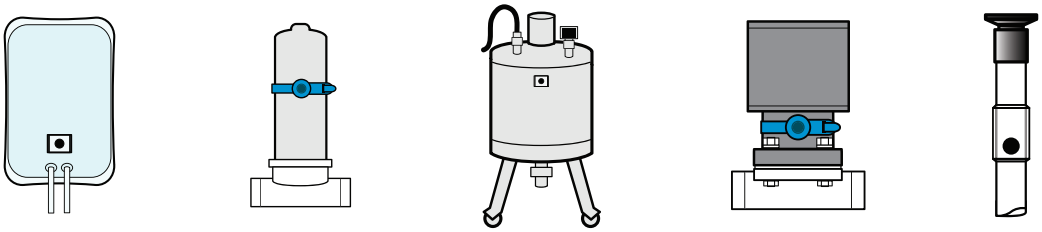
Provides an Audit Trail

- Speeds audits and lowers their costs by eliminating the time and labor of locating, retrieving, and gathering paper records and traditional log books
- Tracks key wear-related events such as cleaning cycles/dates, batches of material processed, calibration, and other user-defined events
- Provides a secure, tamper-proof record to track time, date, and operator data

Easy to Use

- Unlike bar code labels, tags do not require a clear sight line for reading/writing
- Safe for use with CIP, SIP, and autoclave processes
- Integrates with existing workflows
- Custom engineered to best meet individual needs
- Select the tag attachment method best suited for each particular item – choose from a molded pouch, lamination, watchband style encasement, silicone fusible tape, or any customized design



GammaTag®

GAMMA STERILIZABLE RFID TAGS

It's here: the first read/write RFID (radio frequency identification) tag that's safely sterilizable by gamma radiation up to 45 kGy – GammaTag.

GammaTag provides reliable electronic data storage of single-use bioprocess components from inception to disposal.

GammaTag is available *exclusively* from Verigenics. Call Verigenics to find out more, or visit **www.gammatag.com**.

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Comparison

IDENTIFICATION

COMPARISON
of the pen-and-paper Log Book method vs. the PET system

Situation/Action	Log Book Method	PET Solution
Back up data	The log book can be copied and archived, although archiving requires adequate storage space. Loss of, or damage to, the book prior to copying means a permanent loss of data.	Information about the device and its most recent activity is on the RFID tag physically attached to the device.Total back-up of all data is on the user database. Further back up of data can be maintained on a company network.
Link device documentation	No system for linking documentation exists – log books are often scattered throughout the production area and associated locations.	A complete information system is linked to the device. All electronic files including certifications, Word files, PDF files, digital photographs, etc., are in chronological order.
System for an audit trail 	Audit trails must be constructed when needed. For example, creating an audit trail for a specific product could entail examining dozens of log books for various entries. Unless a master index has been kept, there is little way of knowing if all entries have been found.	A complete information system in chronological order is available at the touch of a finger for a documentation audit trail. The information is searchable and sortable.
Security of data being entered into records	A signature may be required, although dates/times can be omitted or changed leaving this type of system vulnerable.	A username and password are required to enter records. Files cannot be changed without leaving a trail.
System for operator training about the device	Operator training documentation is typically not found within log books.	Training files may be linked to the device in the user database in the form of Word documents, PDF files, or digital photos. A compete training protocol or SOP may be associated to the device.

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Situation/Action	Log Book Method	PET Solution
How does the device operator know what recent activities have taken place?	Operator goes to the log book – time consuming.	Operator goes to the device and uses the reader/writer to obtain the information immediately.
How does the device operator know when the useful life of the device is met?	Log books are typically not used to determine device life spans. Data is kept in chronological order but may be difficult to sort for comparison and analysis. If a calendar method of replacement is used, a device may be taken out of service sooner than necessary or used too long, leaving it at risk for failure.	All data about the device's history is in one file and may be sorted, compared, and analyzed in different ways to determine the useful life of the device. Information can be networked and shared among different departments and functions.
Notice of "Use only for . . . " must be on the device in order to avoid cross contamination.	Information can be written in the log book, and information can be put somewhere on the device using markers or hang tags.	Information about "Use only for . . . " is linked directly to device via the RFID tag, and the operator must acknowledge that the notice has been read.
Operator communicates to Supervisor observed "warning" problems about the device.	Information can be written into log book.	Operator can data enter "warning" directly into reader/writer. The information is transferred to the Supervisor's data base. The Supervisor can then put a warning onto the device which all operators will see.
Supervisor provides "warning" to all operators about the device.	Information can be written into the log book, or a "warning" hang tag may be attached to the device, however, these tags are not permanent and are subject to degradation.	Supervisor can data enter the "warning" information into the user database. That data is linked to the device the next time the reader/writer is synchronized.
Availability of data	Log books can only be accessed from a single location.	Database storage allows access from any networked computer.

COMPARISON
of Bar Code Identification vs. an RFID Tag

Situation/Action	Bar Code Method	RFID Tag Solution (13.56 MHz passive)
Line of sight	A bar code reader must be aligned with the bar code at the correct angle in order to read the code properly.	An RFID tag can be read at a distance of 2 to 3 inches and does not require reader/writer alignment. The reader/writer can operate through materials such as opaque plastic packaging.
Data storage	A 1D bar code is usually limited to a 15-20 character product number; a 2D style can hold more information.	An RFID tag can store up to 100 times more variable data – up to 2,000 characters – in addition to its Globally Unique Identifier (GUID).
Read/Write	Not possible – a bar code provides static information.	An RFID tag that takes advantage of read/write technology allows storage of 2k of reprogrammable data.
Size	The size of a bar code label varies and can be limiting. In some cases multiple labels must be used to provide sufficient data.	Tags are manufactured in a range of sizes for various purposes. An RFID tag can be small enough to fit on items that a bar code would be too large for, yet it holds more information than a bar code.

20 characters:	***2,000 characters:***
`Bar codes limit data`	*Almost all the data on these two pages.*

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continued

Situation/Action	Bar Code Method	RFID Tag Solution (13.56 MHz passive)
Durability 	A bar code is fragile and subject to rough handling and harsh environments. When lines become damaged or obscured, the code may be unreadable.	A tag may be encapsulated in polymer materials for protection and a long life span. It can be autoclaved, steam sterilized, and/or gamma irradiated.
Cost	A bar code label costs pennies.	A tag can cost $1.50 to $6.00 depending on the type of tag, quantity purchased, and complexity of requirements.
Link documents to a label or tag	Not possible.	Easily achieved – any electronic document (PDF, Word, Excel, photograph) relating to the product may be linked to a tag.
Replication	Easily done by photocopying or scanning and printing.	Extremely difficult as tags are produced in secured semiconductor wafer manufacturing facilities and involve assigning an industry-controlled GUID to each tag.
Allow electronic stamping of events to assist with audit trails	Not possible.	Information written to the tag during the life of the product, such as cleaning dates, times, personnel involved, and other data, acts as a traveling history and provides an audit trail when used in conjunction with tracking software such as PET.

DATE	TIME	TECH	ACTION
2011-05-22	04:24:35	JAT	04 - installe
2011-05-10	11:07:09	DDR	03 - inspect
2011-04-06	19:43:40	DDR	01 - cleaned
2011-04-02	07:14:22	TIR	08 - remove
2011-02-28	21:19:02	DDR	04 - installe
2011-02-19	14:21:11	JAT	01 - cleaned
2011-02-05	10:58:41	TIR	02 - receive

P·E·T Process Equipment Tracking®

Equipment Identification & Lifecycle Analysis System

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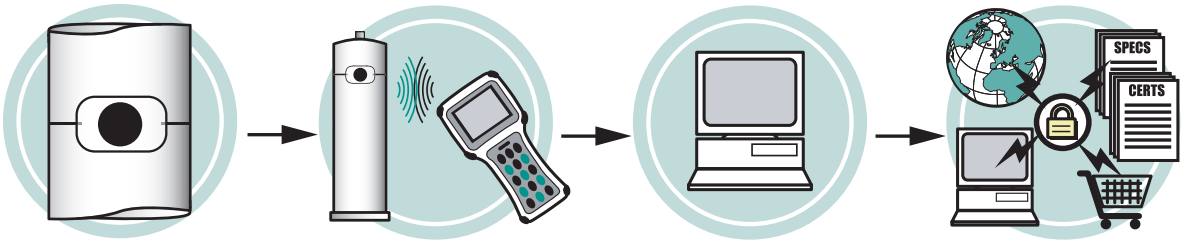

RF Identification Attachment Methods

The PET RFID tag is attached to each device and encoded with a unique serial number. Several attachment methods are available, and many allow tag attachment to process equipment currently installed in facilities. Tag encoding can be customized to meet specific needs. Other quick visual identification methods can be incorporated with the RFID tag.

Portable Handheld Reader/Writer

The handheld reader/writer identifies each device by its serial number for reference in a database. The reader/writer logs and tracks ongoing wear-related events such as the number of cleaning cycles and dates performed (CIP, SIP, autoclave), and the number of batches of material processed. Current data is linked to the RFID tag and may later be downloaded to a database for analysis.

Lifecycle Analysis Tool

Specific data is transferred to a local computer using the Lifecycle Analysis Tool (software) to catalog process equipment, maintain wear-related events, and store application data associated to a particular location. Personnel can perform lifecycle analysis for individual locations for an accurate, application-specific replacement schedule prior to excessive degradation or failure.

Secure Internet Ordering

In the case of tracking AdvantaPure high purity hose products, a secure web site allows access to hose origin information such as manufacture date, batch number, lot number, material specifications, material lot number, certificates of compliance, hose size and fitting specifications, and hose description. It also facilitates the ordering of replacement AdvantaPure hose assemblies.

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U.S. patents 7,195,149; 7,259,675 and 8,519,846. Other U.S. and foreign patents pending.

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Developed in partnership with ProcessHQ Pure and Simple℠

9/23/13