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DARTRONICS, INC.
PACKAGING AUTOMATION SPECIALISTS

Tablex-PRO
Pharma GF-PRO

Maximum Detection Performance

Increased Productivity

Reduced Costs

Improved Competitiveness

Regulatory Compliance



Detecting Metal Contamination

Meeting Pharmaceutical Compliance Needs

METTLER TOLEDO

Maximising Product Quality

Meeting Compliance Requirements

In the fast moving pharmaceutical industry, you need to maximise product quality, protect the welfare of your customers and meet regulatory demands. When it comes to selecting a metal detection solution for the inspection of tablets and capsules, there can be only one choice – A METTLER TOLEDO Safeline Tablex-PRO detector.

Advanced Metal Detection Technology at Your Fingertips

Tablex-PRO metal detectors utilise sophisticated software technology to provide the most advanced metal detection systems for the pharmaceutical industry. A large, full colour touch screen interface with a Windows® style, icon driven menu provides easy, intuitive operator access. The interface simplifies procedures and places valuable process information at the fingertips of your whole manufacturing team.

Major Benefits for Your Business

Tablex-PRO metal detection systems utilise Safeline's advanced Profile software technology providing the means to deliver significant benefits for your business. Maximising product quality, enhancing manufacturing efficiency and delivering the ultimate level of protection for your customers is just the beginning.

Supporting Your Compliance Needs

Tablex-PRO metal detectors can be installed after tablet presses, dedusters and other pharmaceutical process equipment enabling your business to comply with the needs of both internal standards and external regulatory requirements.

All Tablex-PRO detectors support compliance with pharmaceutical regulatory standards and external codes of practice including:

- 21 CFR Part 210
 - GMP Predicate Rule
- 21 CFR Part 211
 - GMP Predicate Rule
- 21 CFR Part 11
 - Electronic Records & Signatures
- Good Automated Manufacturing Practice (GAMP)



Harnessing Quality and Compliance to Benefit Your business

Tablex-PRO metal detection systems harness key quality and compliance benefits to build a ring of protection around your business enabling you to increase productivity, reduce overall manufacturing costs and improve competitiveness for maximum profitability.

● Increased Productivity

Tablex-PRO metal detectors enable productivity to be optimised to ensure uptime is maximised and costly downtime is all but eliminated. This effectiveness is realised through:

- Simple set-up and operation
- Reliable, consistent performance
- Low maintenance requirements
- 'No-tool' system stripdown
- Easy clean system designs



● Reduced Manufacturing Costs

Tablex-PRO technology enables overall lifetime costs to be managed and kept to an absolute minimum through:

- Eliminating false rejects & product waste
- Reducing performance validation requirements and costs
- Utilising innovative, future-proof design

● Improved Competitiveness

The combination of increased productivity and reduced manufacturing costs enables your business to win more customers by providing:

- Compliance with regulatory and industry standards
- Improved hygiene standards
- Protection of your brand and your reputation
- Maximised product quality



Tablex-PRO shown with optional status beacon



Read more on Tablex-PRO

www.mt.com/safeline-tablexpro

Detecting More Metal

For Complete Customer and Brand Protection

Tablex-PRO systems are designed to detect all possible metal contamination encountered in pharmaceutical manufacturing processes including ferrous, non-ferrous and even the most difficult to detect non-magnetic stainless steels (grade 316). Contaminants less than 0.3mm in diameter can be readily detected and rejected.

Tuned Ultra-High Frequency to Detect the Most Challenging and Irregular Shaped Contaminants

Tuned ultra-high frequency operation pioneered by Safeline greatly improves detection sensitivity, particularly in the case of non-ferrous and non-magnetic stainless steel contamination. This in turn delivers the added benefit of improvements in the detection of non-spherical and irregular shaped contamination such as metal slivers, sieve wire and swarf.



Advanced Technology to Further Boost Performance to Unprecedented Levels of Sensitivity

Tablex-PRO metal detection systems incorporate an enhanced detection algorithm to boost performance levels to previously unseen levels. The system provides a 'normal' operation mode plus two 'boost' modes to enable performance to be tailored to suit challenging working environments and detection requirements.



Reject tablet collection bottle

Designed and Built to Perform Reliably in Demanding Pharmaceutical Environments

Manufactured from mirror polished stainless steel, Tablex-PRO metal detection systems are designed and constructed to meet the everyday hygiene demands of pharmaceutical environments.

A Range of Aperture Sizes

Tablex-PRO detectors are available in a choice of 3 standard aperture sizes to accommodate a wide variety of tablet and capsule sizes and throughput rates.



Maximum Versatility and Mobility

Tablex-PRO systems are designed to offer maximum flexibility in process areas. A compact footprint enables systems to be inserted into areas where space is restricted throughout pharmaceutical plants. Robust, low profile, fully rotating castors provide ease of mobility enabling the system to be utilised in multiple locations. Flexibility is further enhanced through the ability of the detection head to be adjusted easily without the need for tools in all three axes to suit any configuration of process equipment.



Genuine Mechanical Failsafe and Reject Confirmation as Standard

All Tablex-PRO reject devices are mechanically failsafe automatically moving to the reject position on loss of power for maximum safety and peace of mind. The activation and operation of the reject device is monitored by a built-in reject confirmation system. Failure of the device to operate correctly results in the automatic shut-down of the system.

Easy Clean Hygienic Design

Reject devices are designed to be easily dismantled and assembled quickly without the need for tools. Electrical components of the units are fully removable enabling all contact parts to be fully submerged during wash down for thorough cleaning.



Lift Flap Diverter (Tablex-PRO L)

- IP66 in-situ cleaning
- Short overall throughput length
- Straight-line product flow



Side Diverter (Tablex-PRO S)

- IP65 in-situ cleaning
- Shortest overall throughput length
- Suitable for use in vertically restricted height installations

Removing the Contaminant Every Time - A choice of reject devices to suit every application

A choice of two interchangeable reject devices are available to suit all product types, applications and configurations. All devices are designed and constructed to meet the demands of 21 CFR part 210 & 211. A construction materials declaration of compliance can be provided as part of our EQ Pac system qualification package.

Capturing Critical Access Data For Regulatory Compliance

Meeting the exacting requirements of FDA 21 CFR part 11 can be a challenge in some pharmaceutical processing environments. Tablex-PRO metal detectors support full compliance with the standard by providing dedicated software to capture electronic signatures and other critical process data. This means you remain in total control of processes and the necessary compliance data is always at hand.

Dual-Level High Security Password Access Ensures Settings are Protected

All detector settings are password protected to ensure unauthorised personnel do not inadvertently adjust important parameters.

Individual operators can be assigned personal login user names and password details with their own user profile which can display information in a choice of 18 languages. This feature can be used to restrict unauthorised access to the operating system.



Dedicated 21 CFR part 11 mode with dual-level user name and password access login



Tracking User Access Through the Metal Detector Access Log

Details of all metal detector access activities are automatically logged and can be reviewed to establish when access was made and by whom. This can help in the management of process cells and ensure compliance with FDA 21 CFR part 11.



Ensuring the Quality of Your Products Whilst Reducing Risks

Producing high quality products consistently is a pre-requisite for your business. Achieving this with minimised manufacturing costs contributes to the profitability of your organisation. Tablex-PRO detectors deliver the support your quality programme demands giving you the peace-of-mind that you are protecting the welfare of your customers and the integrity of your reputation. Tablex-PRO detectors include an on-screen batch and production code display to support process control and traceability.



Ensuring Scheduled Performance Verification Tests are Not Missed

Missed performance validation tests can compromise quality standards and lead to non-compliance issues. Tablex-PRO detectors advise when test routines need to be performed and when testing is overdue via highly visible screen messages. These messages can be distributed to key personnel within your business via a range of communication methods to ensure corrective action is taken.



Saving Time - Making Testing Easier

In-built pharmaceutical industry specific performance validation software (PPVR) provides intuitive, step-by-step guidance for quality assurance testing. Test routines can be configured to ensure that system performance is validated and results are captured in order to meet internal procedures and external industry standards or regulations.



Staying In Control - Collecting Historical Data

A "Discriminated Detection Event Logging" feature ensures all detection event data is captured and logged in an easy to interpret user screen. The data gathered including time and date stamp information is displayed in a colour coded format to clearly differentiate between scheduled performance validation (PPVR) tests and actual contamination events.



Maximising Efficiency, Minimising Downtime For Operational Excellence

Ensuring your manufacturing processes are robust, efficient and streamlined adds value to your business and enables you to develop the edge over your competition. Tablex-PRO metal detection systems provide a vital building block in helping to establish improved processes and manufacturing efficiency.



The Detector that Communicates Directly with You

Tablex-PRO metal detectors include the facility to communicate important messages to key business personnel using unique email and SMS text messaging facilities.

Quality teams can receive messages advising of overdue performance validation testing which could lead to compromised product quality and potential non-compliance with regulatory requirements. Meanwhile, maintenance teams can receive advanced early warning information from the Condition Monitoring function of the metal detector allowing preventative maintenance to be planned in advance. This supports improved efficiency by avoiding unnecessary downtime.

Addressing Issues Before They Occur

The costs associated with a line stoppage due to inspection system failure can have a serious impact on business performance. Being forewarned of potential line-stopping issues before they happen enables you to make contingency plans to avert costly unscheduled downtime.

Tablex-PRO metal detectors utilise advanced Condition Monitoring technology which constantly analyses the performance of major detector components. Adverse trends are identified and highlighted as an early warning of a potential problem in advance of actual failure.

Advanced warnings are communicated via on screen messages and via an optional high visibility status beacon. This enables production to continue uninterrupted until there is a convenient break in the manufacturing process when the issue can be addressed.



System Healthy



Early Warning



Fault Condition

Automated Data Collection

Solutions to Aid Record Keeping

Tablex-PRO detectors assist in gathering information by automatically collecting and storing ongoing production data and building an in-depth historical picture of critical process information over extended periods of time. This data is viewed in the form of full colour histograms on the operation screen. Unlike conventional detection systems, Tablex-PRO allows decisions to be made based on data gathered and stored over extended periods of time, making decisions made far more meaningful.

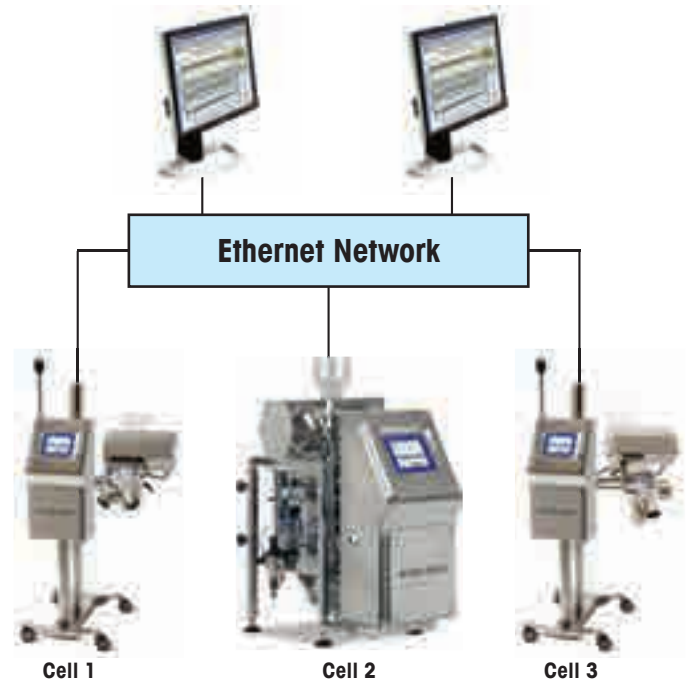
Improving Methods of Data Collection

Tablex-PRO detectors can be configured to incorporate a data access socket to enable external print devices to be plugged into the equipment and data tickets to be generated. These can be stored as hard copy records for future reference.



Unrivalled Communication Capabilities - Delivering Detailed Information to Your Desk Top

When more sophisticated data collection is required, Tablex-PRO metal detectors can incorporate advanced connectivity technology. This can be achieved by a simple 'one-to-one' serial connection or by utilising full Ethernet network connectivity which could include wireless functionality.



Factory Management System Integration

OPC DA is one of the world's fastest growing standards for the exchange of process control data. Tablex-PRO detectors are OPC compatible and can communicate with a host of SCADA based systems and factory management software solutions.

Traceability, performance validation and proof of regulatory compliance have become essential requirements for modern metal detection equipment. Tablex-PRO detectors are equipped with software routines that assist validation. More importantly, Tablex-PRO detectors can be equipped with advanced data collection facilities that record detector usage and provide information on product throughput. Cache storage, histogram displays and Ethernet communications allows the metal detector to be used as a useful data collection device.



Metal Detection Solutions For Fine Powders and Granules

The efficient inspection of powdered and granular pharmaceutical products is equally as important as inspecting tablets and capsules. The the full range of **Tablex-PRO** features and benefits are available in **Pharma GF-PRO** gravity fall inspection systems.

Compact Design and a Choice of Aperture Size for Maximum Flexibility

Pharma GF-PRO detectors are compact in size enabling installation to take place in highly restricted spaces. Apertures are available in a choice of 2 standard sizes to accommodate a wide variety of throughputs.



Fully Integrated Diverter to Ensure Contaminants are Removed

Pharma GF-PRO gravity fall detectors incorporate a fully integrated high-speed reject device to divert contaminated product flow. Reject devices can be rapidly dismantled and re-assembled without the need for tools for easy cleaning.



Equipment Qualification Assured Documentation for Compliance



At METTLER TOLEDO we appreciate the importance of regulatory compliance and the need for equipment qualification to comply with industry demands and legislation. Our comprehensive EQ Pac-PRO equipment qualification package ensures new machines are correctly installed and are performing to their full potential both now and into the future.

DQ Pac-PRO Design Qualification Support

Our experienced pharmaceutical engineers are able to provide guidance and design support to develop the right solution along with the necessary documentation to meet the necessary Design Qualification protocol (DQ) when required.

EQ Pac-PRO Satisfies IQ, OQ, PQ and MQ Requirements

Tablex-PRO and Pharma GF-PRO detectors are supplied with an EQ-Pac-PRO qualification documentation package as standard. The system binder contains full installation, operation, performance and maintenance protocols. A certified test kit to ensure ongoing compliance is included as part of the EQ Pac-PRO package.

The protocols can be executed by specialist METTLER TOLEDO engineers and can form part of your regulatory compliance documentation.

EQ Pac-PRO - See the Benefits

A fully executed EQ Pac-PRO qualification package from METTLER TOLEDO provides:

- Compliance with FDA, GMP and GAMP regulations
- Performance Verification Certification
- Optimised system performance from day one and throughout the life of the equipment
- Improved operator efficiency through effective familiarisation training
- Documentation for monitoring maintenance procedure and requirements



 **Read more on Safeline EQ-Pac**
www.mt.com/safeline-eqpac

Total Flexibility

Metal Detectors for All Pharmaceutical Applications

METTLER TOLEDO Safeline metal detectors provide the ultimate in flexibility and offer a high degree of customisation for easy integration into any pharmaceutical manufacturing process regardless of the application.

Pharmaceutical metal detection solutions available include:

Tablex-PRO



Available with side-divert or lift-flap rejection systems for the inspection of tablets & capsules.

Pharma GF-PRO



For the inspection of fine powders and granular products under gravity-fall conditions.

System Integration

All METTLER TOLEDO Safeline metal detectors can be fully integrated with leading tablet de-dusters and other production equipment to provide seamless pharmaceutical process lines.

For more information

www.dartronics.com/metal-detection-solutions/

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