

THS/PH21-FFV

PHARMACEUTICAL METAL DETECTION SYSTEM
FOR GRANULAR AND POWDER PRODUCTS



*Design and Construction **Compliant with 21 CFR
Parts 210 and 211***

*Electronic Records and Signatures Management
Compliant with 21 CFR Part 11*

Validation Solutions Available:

- Calibration Standards
- Validation Manuals
- Compliance Tools
- Comprehensive Service & Support

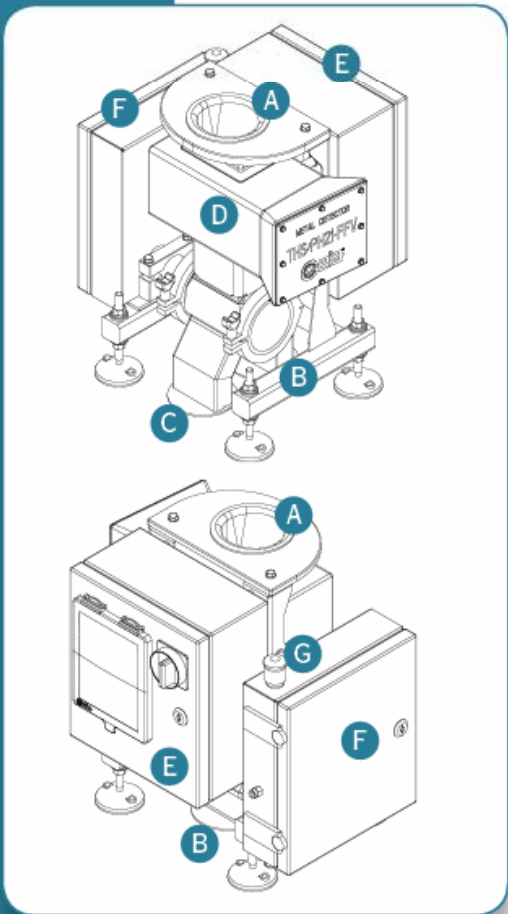
THS/PH21-FFV STATE-OF-THE-ART PERFORMANCE

CEIA is a Market Leader that has been designing and manufacturing Metal Detectors for industrial applications for over 35 years. The line of Quality Control detectors includes the THS/PH21-FFV Pharmaceutical Metal Detection Systems, featuring **state-of-the-art performance and full compliance with pharmaceutical sector regulations.**

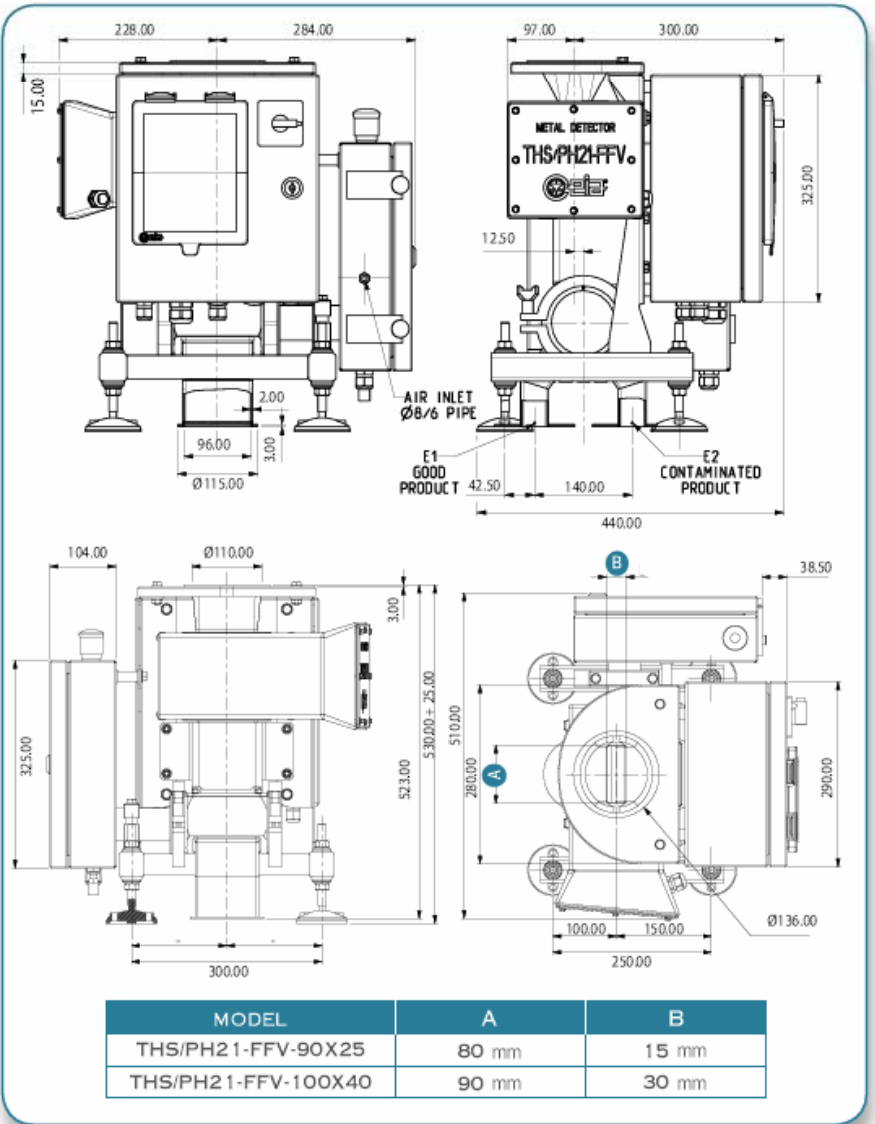
The design and construction of the THS/PH21-FFV Metal Detection Systems **comply with FDA requirements Part 210 – Current Good Manufacturing Practice in Manufacturing, Processing, Packing or Holding of Drugs; General – and Part 211 – Current Good Manufacturing Practice for finished Pharmaceuticals** – of Title 21 of the Code of Federal Regulations (CFR).

The carefully-selected materials used in construction do not interact with pharmaceutical products, and thus do not modify or alter their composition.

The mirror finish applied to the surfaces guarantees **quick, easy cleaning of the components that are in contact with the product.** The technological choices made by CEIA allow the parts in contact with the product to be disassembled and maintained in a short time and without the use of machine-specific tools.



- A) CHUTE SUPPORT PLATE
- B) EJECTION VALVE - CONTAMINATED PRODUCT
- C) EJECTION VALVE - GOOD PRODUCT
- D) CEIA METAL DETECTOR
- E) CONVEYOR CONTROL SYSTEM
- F) ACTUATION SYSTEM ASSEMBLY
- G) EMERGENCY BUTTON



HIGH LEVEL OF ELECTRONIC AND MECHANICAL RELIABILITY








CEIA THS/PH21-FFV Metal Detection Systems feature **extremely high detection sensitivity** towards contaminating metals, whether ferrous, non-ferrous or stainless steel, even when these are present in tiny quantities. **The ejection system**, housed in a one-piece casing moulded in AISI 316L stainless steel, **is fitted with an innovative deflector that features quick response**, precise ejection of the contaminated tablets and high production flow rate.

The THS/PH21-FFV Metal Detection Systems operate in Fail-Safe Mode, thus avoiding the risk of contaminants passing through even when the system is deactivated or when the electrical power supply is interrupted.

CEIA THS/PH21-FFV systems can be linked to local computer networks via a **TCP/IP (Ethernet) interface or RS-485**. Whether in stand-alone operation or centralised via a computer network, the CEIA THS/PH21-FFV Metal Detection Systems **satisfy the standards of Security, Integrity and Traceability of production data** as required by Part 11 of Title 21 of the Code of Federal Regulations (CFR) – Electronic Records; Electronic Signatures (ER/ES).

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ACCESSORIES AND OPTIONS

INFEED CONVEYOR		CODE 32590 (VERSIONE 100x40) CODE 33659 (VERSIONE 90x25)
TEST SAMPLES FE (AISI E 52100)		CODE 17051 CODE 29074
TEST SAMPLES NON-FE (70Cu30Zn)		CODE 30117 CODE 29843
TEST SAMPLES STAINLESS STEEL AISI316		CODE 29489 CODE 29073
TEST SAMPLES STAINLESS STEEL SUS440		CODE 31791 CODE 17052
TEST SAMPLE BLANK		CODE 16793
MD-SCOPE (SOFTWARE DIAGNOSTIC PACKAGE COMPLETE WITH CONNECTOR CABLE AND HARDWARE KEY)		CODE 26894
THS PRODUCTION (SOFTWARE)	CONNECTS AND ACQUIRES DATA FROM MULTIPLE THS/PH21-FFV THROUGH ETHERNET LAN	CODE 30463
THS QA REPORT (SOFTWARE)	CONNECTS TO THS/PH21-FFV PRODUCTION DATABASE THROUGH ETHERNET LAN FOR LOT PRODUCTION DATA RETRIEVAL	CODE 30464
PLUG-IN ETHERNET MODULE (OPTIONS)		CODE 29756
PLUG-IN RS 485 MODULE (OPTIONS)		CODE 17828



THE EJECTION SYSTEM IS FITTED WITH AN INNOVATIVE DEFLECTOR THAT FEATURES QUICK RESPONSE, PRECISE EJECTION OF THE CONTAMINATED TABLETS AND HIGH PRODUCTION

GENERAL FEATURES

- Construction Compliant with 21 CFR Parts 210 and 211
- Stainless Steel AISI 316L and FDA-approved plastic materials for all parts in contact with the product
- Mirror finish for metal parts
- Fast disassembly and cleaning; no tools required
- Fail-Safe operations
- Very High Tablets Throughput
- Precise ejection of the contaminated tablets

METAL DETECTION FEATURES

- Metal Detector apertures: 100x40 mm or 90x25 mm
- Very High Sensitivity to Ferrous, Non-Ferrous and Stainless Steel Metals
- Very High Immunity to external electrical and mechanical interferences
- Automatic Balancing
- Built-In Self Diagnosis System

DATA MANAGEMENT

- Electronic Records and Signatures Management compliant with 21 CFR Part 11:
 - Data Security
 - Data Integrity
 - Data Traceability

PRODUCTION DATA MANAGEMENT

- Management by Batch/Lot
- Complete Production Logging:
 - Ejections
 - Test Results
 - Programming Operations
 - Programming Accesses
 - Faults
- Network Interface: Ethernet or RS-485

SIGNALLING

- Acoustic through Internal Sounder
- Optical:
 - Mains Supply (Green lamp)
 - Metal Detector Alarm - Fault (Red lamp)

PROGRAMMING

- Local: Keyboard and 80 character LCD Display
- Remote: managed by Data management Software

I/O AND ENVIRONMENTAL DATA

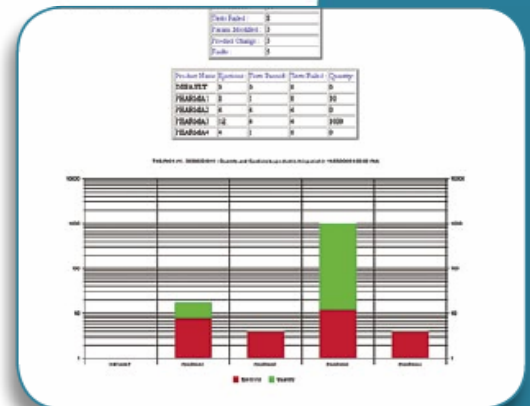
- Power Supply: 115/230 Vac -22%; +10 %, 48-62 Hz, 80 VA
- Operating Temperature: -10 +55 °C.
- Relative Humidity: 0-95% (without Condensation)
- Relay outputs
 - Metal Detector Alarm
 - Ejection
 - Test request
 - Fault
 - Ejector position
- Direct RS-232 connection to Printer or Personal Computer

CERTIFICATION AND CONFORMITY

- Conforms to current Regulations for Pharmaceutical Metal Detection Systems.
- Complies with EC Regulations and International Standards relating to Electrical Safety and Electromagnetic Compatibility.
- Construction Compliant with 21 CFR Parts 210 and 211



ACCESS SCREEN VIEW - THS QA REPORT SOFTWARE



ENVIRONMENT SCREEN VIEW - THS PRODUCTION SOFTWARE

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