



Pharmaceutical Metal Detection Systems



Specifications

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THS/PH21 series Specifications

Feature Highlights



- Superior and Consistent Detection
- Enhanced Product Throughput Rate
- Preventive Maintenance Not Required
- Maximum Configurability / Integration
- FDA 21 CFR Part 11 Compliant
 - Data Security
 - Data Integrity
 - Data Traceability
- Design and Construction Compliant with FDA Title 21 CFR Parts 210 and 211



Control Panel side

Feature Highlights



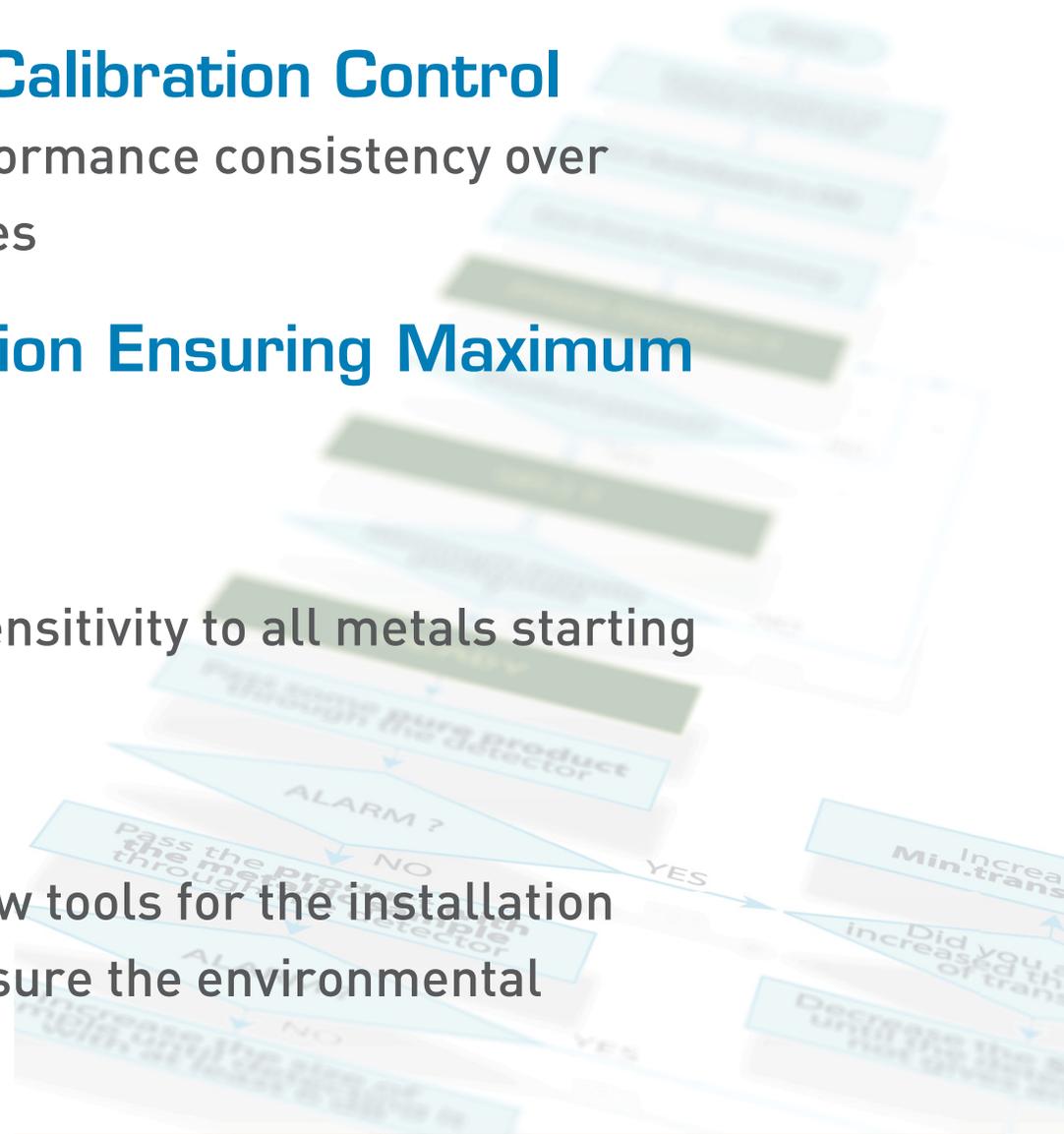
- AISI 316L stainless steel construction
- Control Power Box available according to UL 508A and CSA-C22.2 No. 14-05
- 500 product profiles, selectable by local programming or network software
- 10.000 storable events
- High-contrast graphic display
- Local programming: 16 stainless steel keys, 3 with double function
- Quick Access key for fast programming of user parameters



Ejection System side

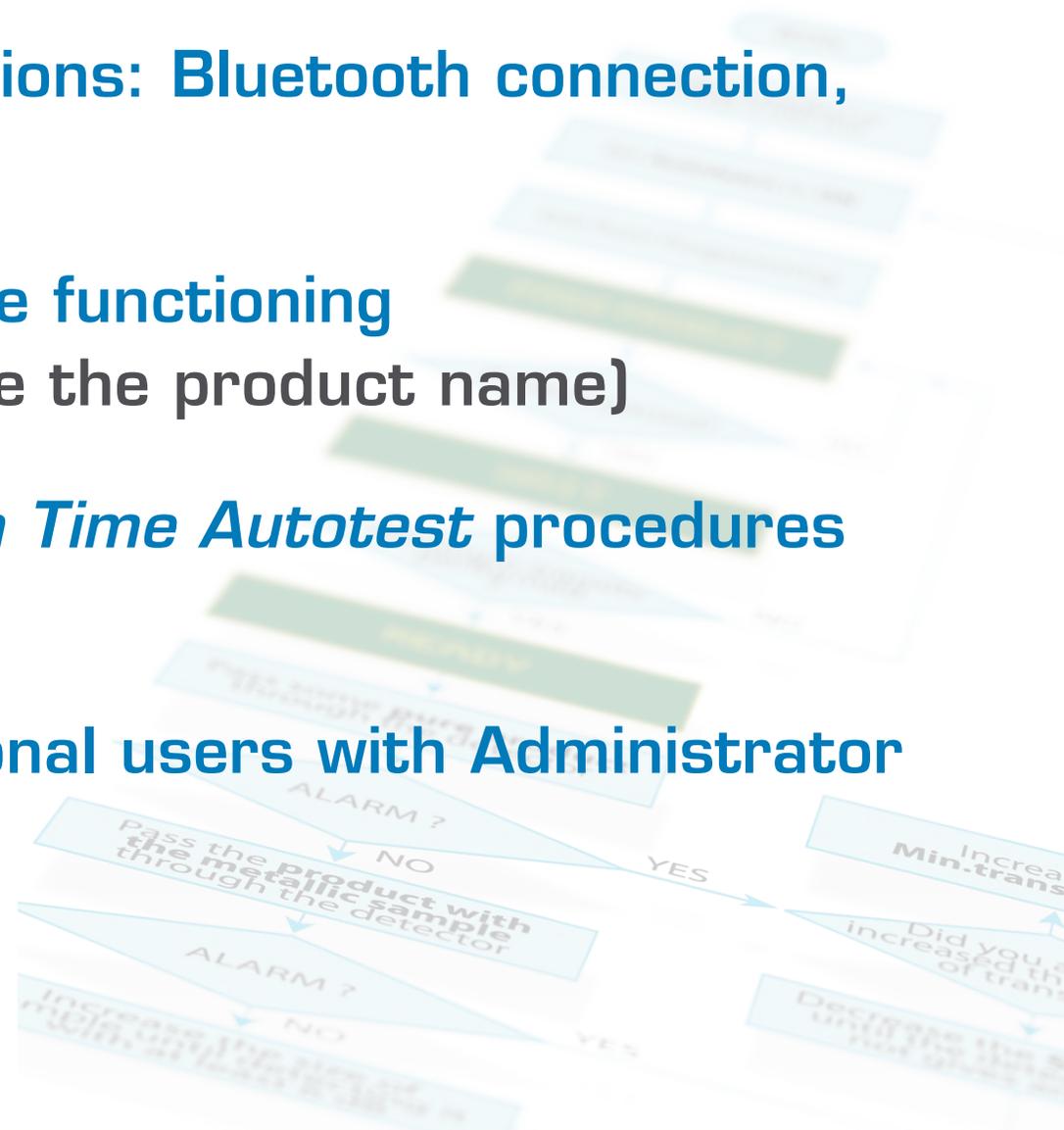
Feature Highlights

- ➔ **Continuous Embedded Self-Calibration Control**
for maximum repeatability and performance consistency over time and with environmental changes
- ➔ **Continuous Auto-Test Function Ensuring Maximum Production Safety**
- ➔ **New Auto-Learn System**
provides simultaneous maximum sensitivity to all metals starting from a single learning transit
- ➔ **New Diagnostic Tools**
The THS/PH21 Series introduces new tools for the installation and maintenance technician to measure the environmental compatibility of the metal detector



Feature Highlights

- ➔ Added some display indications: Bluetooth connection, Product Batch information
- ➔ Added indication of machine functioning (: character blinking before the product name)
- ➔ *Safe Test* and *Confirmation Time Autotest* procedures implemented
- ➔ Possibility to create additional users with Administrator rights



Feature Highlights

- ➔ **Alarm too big threshold parameter added (ATBT – Diagnosis Management menu)**
Used for triggering a fault in case the alarm generated by a metal mass is bigger than a predefined value (dB)
- ➔ **Lift flap product switch activation by connector J16 pin 14-15 from tablet press, capsule filler and other equipment before the THS/PH21 Metal Detector system**
- ➔ **Possibility, for the operators, to change the password**
- ➔ **Introduced the *Batch* information for each product (Parameter “*Batch*” BAT – *Products menu*)**

Feature Highlights

➔ Autotest log period parameter added (ATLP – Q-C Setup)

[046]	10/01/14 - 14:45:47 From:10/01/14 14:35:47 -003102-	Continuous autotest OK to:10/01/14 14:45:47	
[046]	10/01/14 - 14:55:47 From:10/01/14 14:45:47 -006107-	Continuous autotest OK to:10/01/14 14:55:47	
[046]	10/01/14 - 15:05:47 From:10/01/14 14:55:47 -130045-	Continuous autotest OK to:10/01/14 15:05:47	
[046]	10/01/14 - 15:14:37 From:10/01/14 15:05:47 -034208-	Continuous autotest OK to:10/01/14 15:14:39	
[134]	10/01/14 - 15:14:39 -222209-	Fault:	PROBE FAULT(5)
[109]	10/01/14 - 15:14:39 -153242-	Fault:	PROBE FAULT(1)
[234]	10/01/14 - 15:14:52 -244118-	Fault recovered:	PROBE FAULT(5)
[209]	10/01/14 - 15:14:56 -068213-	Fault recovered:	PROBE FAULT(1)
[046]	10/01/14 - 15:24:56 From:10/01/14 15:14:56 -156097-	Continuous autotest OK to:10/01/14 15:24:56	
[046]	10/01/14 - 15:34:56 From:10/01/14 15:24:56 -055245-	Continuous autotest OK to:10/01/14 15:34:56	
[046]	10/01/14 - 15:44:46 From:10/01/14 15:34:56 -024049-	Continuous autotest OK to:10/01/14 15:44:56	

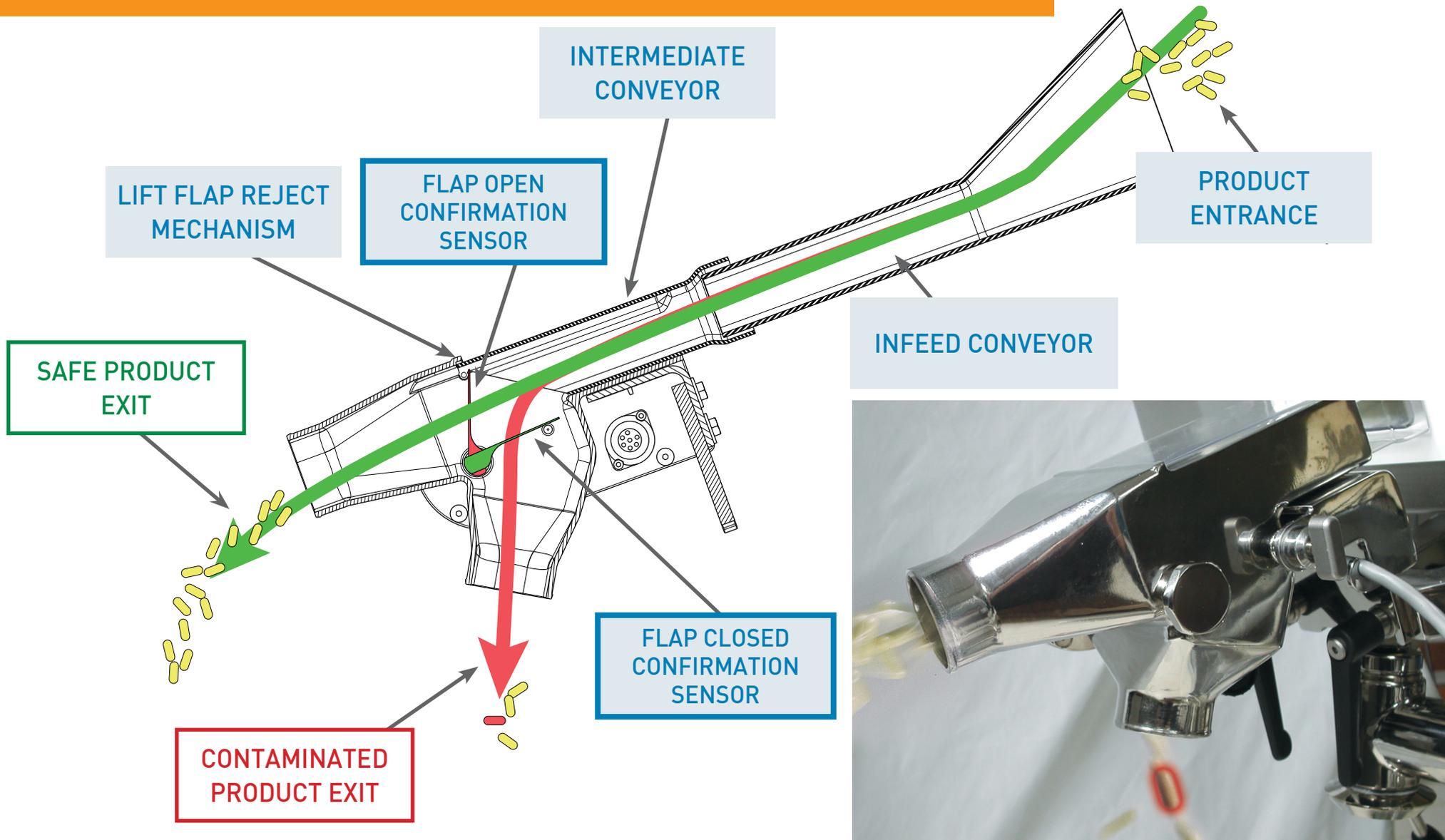
Ejection System



- Monolithic AISI 316L Stainless Steel Body
- Extremely quick response time provides full safety in the ejection of contaminated product
- Advanced mechanical and electronic solutions guarantee the integrity of the inspected product
- Double confirmation system carefully monitors and controls the complete opening and closing of the ejection flap
- Easy assembly and disassembly of the parts in contact with the product: no tools required



Product Path View



THS/PH21 series Specifications

Tri-Clamp® Ejection



- ➔ Conforming to ISO DN50 available as an option



Fail-Safe mode



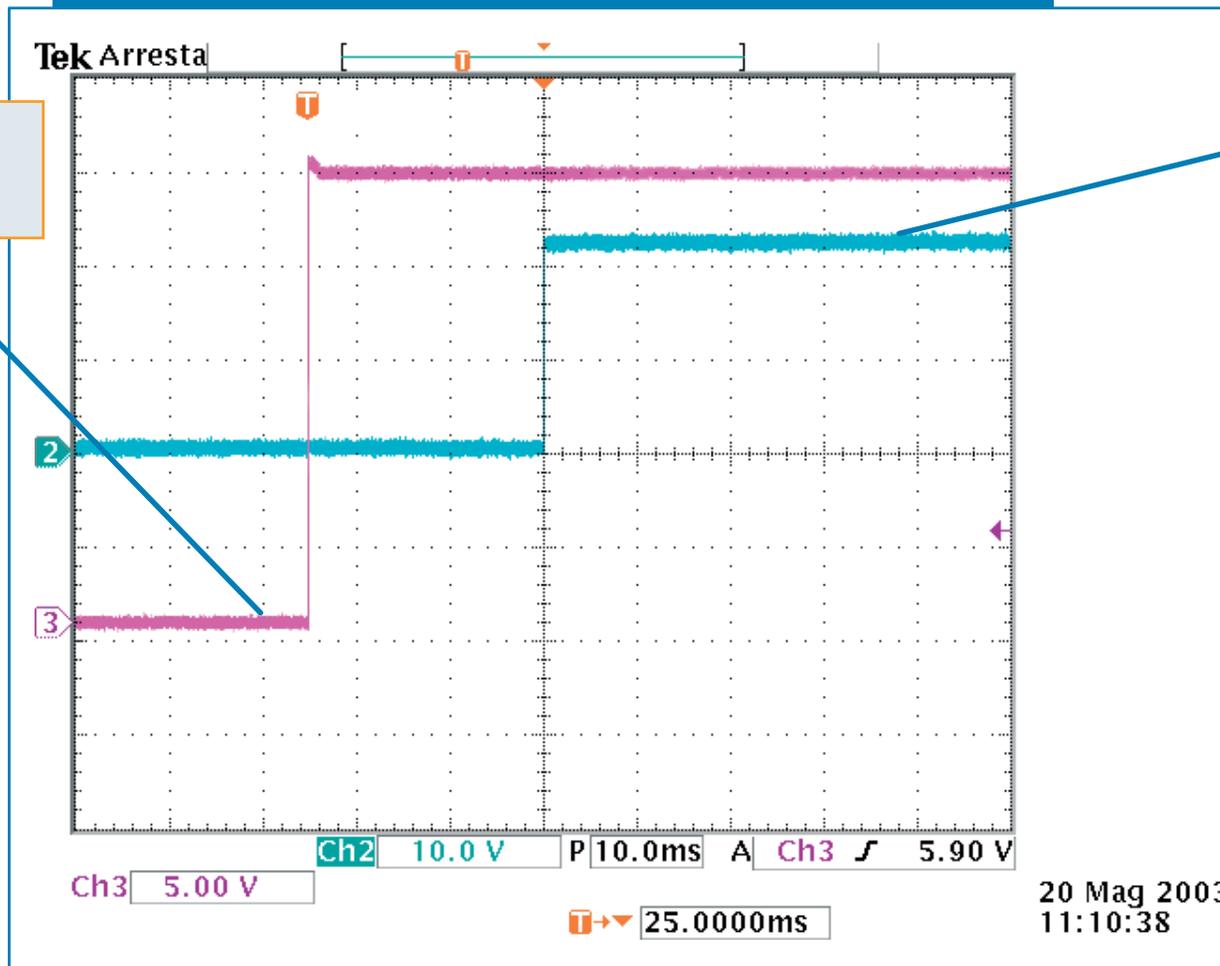
- The THS/PH21 Series operates in Fail-Safe mode, thus avoiding the risk of contaminants passing through even when the system is deactivated or when the electrical power supply is interrupted



Lift Flap Product Switch

Switch Reaction Time: 25 ms.

DIVERTER COIL DRIVING



FLAP ACTIVATED SIGNAL

Modern, rugged and user friendly interface



- Industrial rate design
- Rapid data entry with extended keyboard
- Easy to read, high-contrast graphic display
- Rugged, antivandalic stainless steel keyboard
- Protection degree:
 - Power Supply Box: IP65 (IEC60529)
 - Antenna & Ejection System: IP67



Modern, rugged and user friendly interface

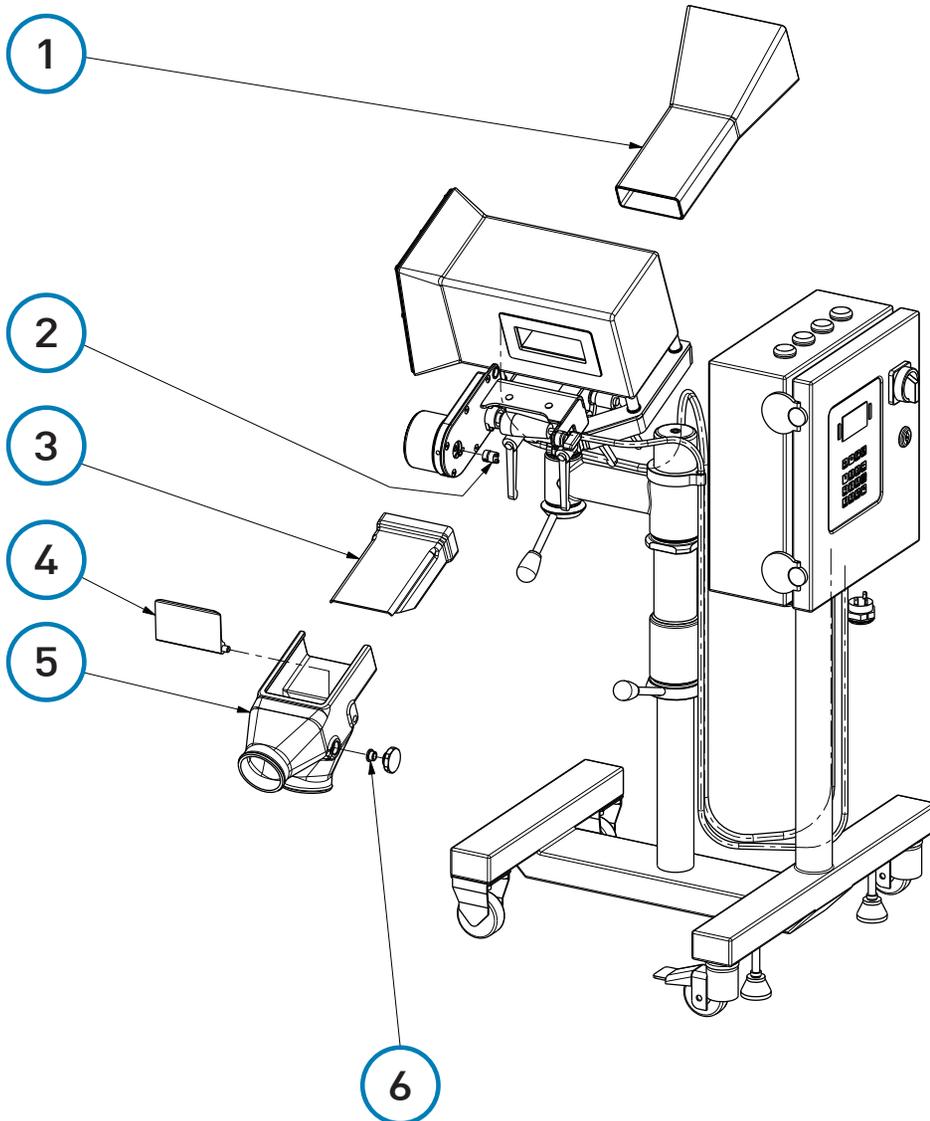


- Quick Access Function
- 40 Users available (including administrator)
- User friendly interface

```
===== QUICK ACCESS =====
0) Products
1) Autolearn
2) Sensitivity
3)
4) Reset
   # Scroll down
=====
```

```
===== STATUS =====
Sensitivity          280
FE perform.         0.15
NFE perform.        0.20
SS perform.         0.25
Prod alarms         100
Time                15:30
_____ # Scroll down _____
```

Parts in contact with the product



ITEM	NAME	DESCRIPTION
1	Infeed Conveyor	PETG - Smooth surface Manufacture: Moulded
2	Lift Flap Joint	Stainless Steel AISI316L Mirror finishing Manufacture: Injection Moulding
3	Intermediate Conveyor	PETG - Smooth surface Manufacture: Moulded
4	Lift Flap Product Switch	Stainless Steel AISI316L Mirror finishing Manufacture: Injection Moulding
5	Lift Flap Carter	Stainless Steel AISI316L Mirror finishing Manufacture: Injection Moulding
6	Flanged Bearing AFM-0812-08 IGUS	Plastic plane bearing Manufacture: Moulded

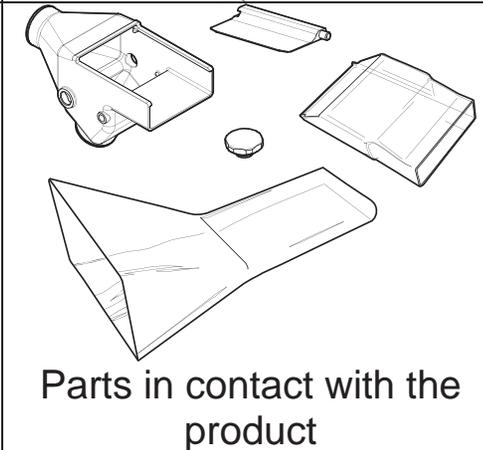
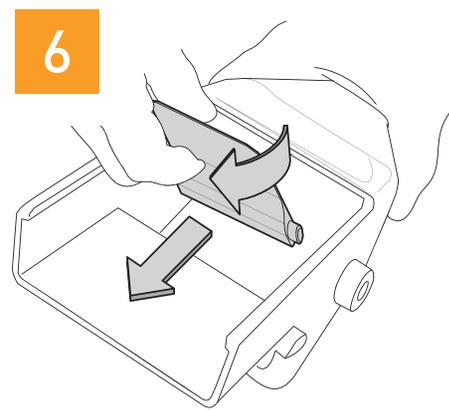
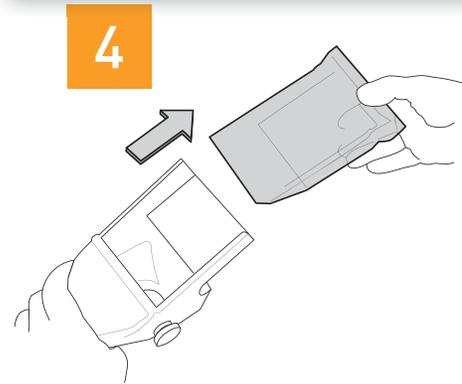
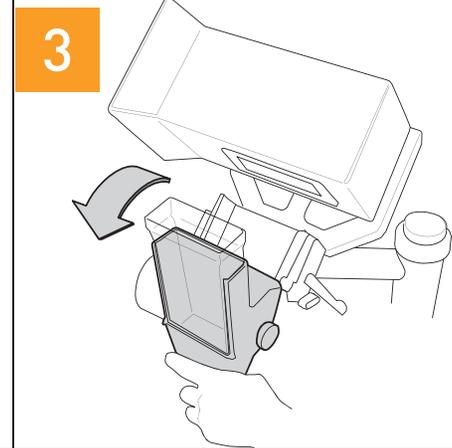
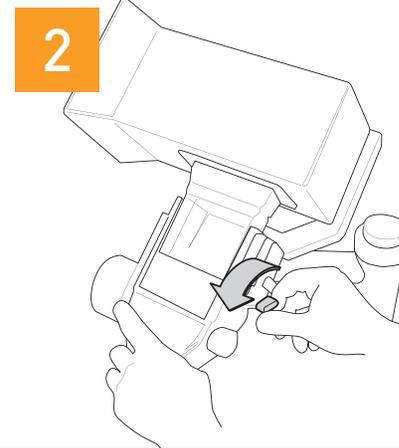
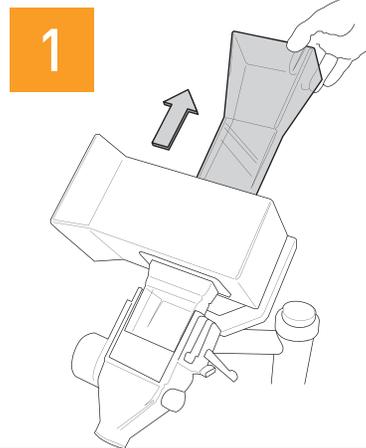
→ All parts compliant with FDA 21 CFR Parts 210 and 211

→ No lubricants or coolants required

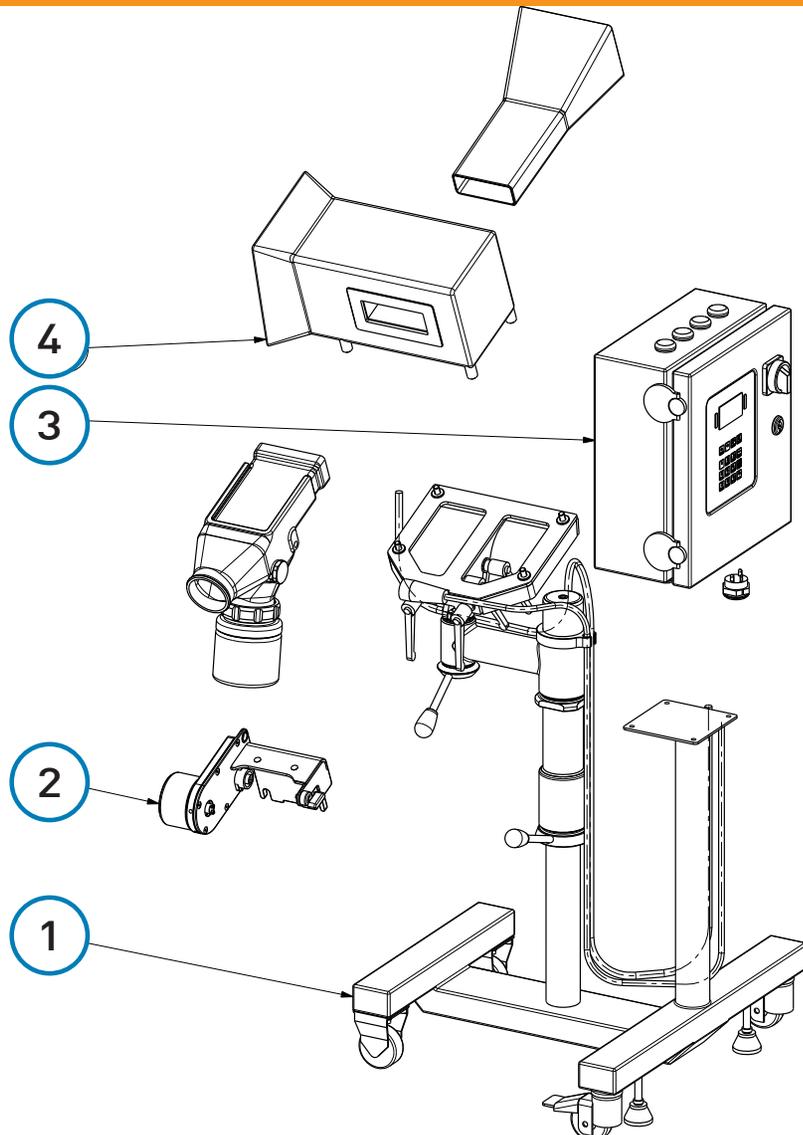
Cleaning of the Parts in contact with the Product



Assembly and Disassembly performed in **30 seconds only**
No tools required



Parts not in contact with the product



ITEM	NAME	DESCRIPTION
1	Adjustable Support	Stainless Steel AISI316L Mirror finishing
2	Lift Flap Driver	Stainless Steel AISI316L Mirror finishing
3	Power Box	Stainless Steel AISI316L Mirror finishing
4	Detection Head complete with lid and SCD card	Stainless Steel AISI316L Mirror finishing

- All parts compliant with FDA 21 CFR Parts 210 and 211
- No lubricants or coolants required

THS/PH21 series Specifications

Introducing the THS/PH21E



Features	THS/PH21E	THS/PH21N
Sensitivity	High	Ultra High
Product memories	250	500
Event storage	1000	10000
Display type	Alphanumeric OLED 4x20 characters	Graphic OLED 128x64 pixel
Local Programming	4 keys 3 with double function	16 keys 3 with double function
Alphanumeric data entry	No	Yes
Quick Access function	No	Yes



 THS/PH21E is the opportunity to enter the 21 Series Metal Detectors for price sensitive customers

Calibration Test Samples*



METAL CLASS	METAL TYPE	SPHERE DIAMETER (mm)				SAMPLE PICTURE
		(SE= 280)		(SE= 280)		
		THS/PH21E (90 x 25 mm)	THS/PH21N (90 x 25 mm)	THS/PH21E (100 x 40 mm)	THS/PH21N (100 x 40 mm)	
FERROUS	AISI E 52100	0.25 mm	0.22 mm	0.30 mm	0.25 mm	
NON FERROUS	70Cu 30Zn	0.30 mm	0.28 mm (93% Cu - 6,6% Sn - 0,03% P)	0.35 mm	0.30 mm	
STAINLESS STEEL	AISI 316	0.40 mm	0.37 mm	0.50 mm	0.40 mm	
BLANK	-	-	-	-	-	

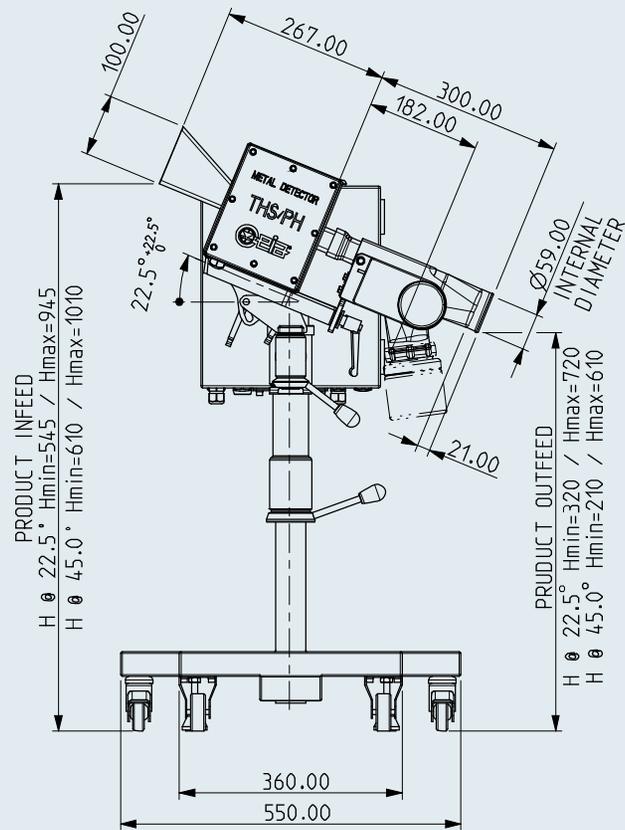
* **The Calibration Test Samples** are Standard References certified in composition and electromagnetic response. Maximum sensitivity exceeds the Calibration Test Samples

Examples of Throughput

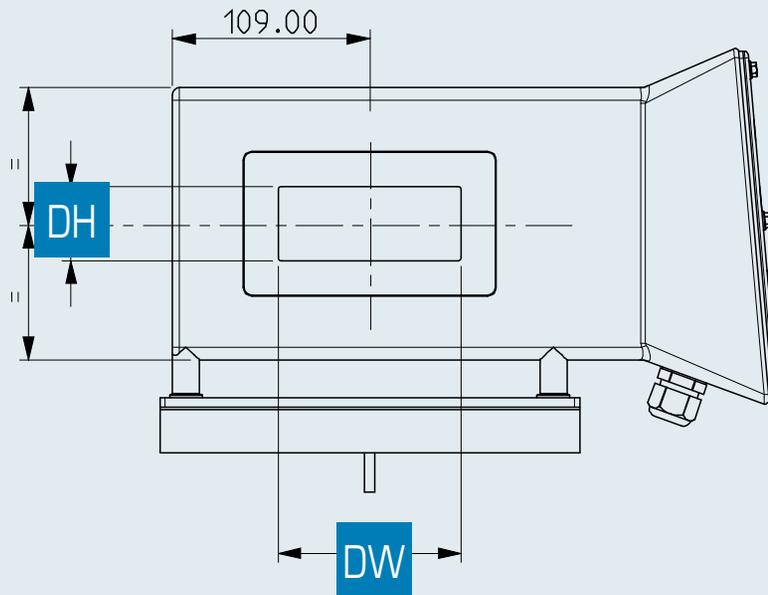
PRODUCT		VERIFIED THROUGHPUT (items / h)
		THS/PH21N - 100x40
	19 x 10.3 x 7.88 mm	1.400.000
	ø6.6 x 19 mm	2.100.000

- Tilt Angle: 35°
- Max Throughput Rates are related to the shape and to the size of the tablets

Mechanical Data



Dimensions (mm)



	Models		
	THS/PH21N THS/PH21E	THS/PH21N-DT THS/PH21E-DT	THS/PH21N-WIP THS/PH21E-WIP
Aperture size	90 x 25 mm	90 x 25 mm	90 x 25 mm
(DW x DH)	100 x 40 mm	100 x 40 mm	100 x 40 mm

THS/PH21N-D25



Specific inspection against tiny metal particle contamination

- ➔ Unsurpassed Detection
- ➔ Best Product Quality
- ➔ Round aperture
- ➔ Applications:
 - ✓ R&D analysis
 - ✓ Rework confirmation
 - ✓ Root cause analysis assistance
 - ✓ New product specification



METAL CLASS	METAL TYPE	SPHERE DIAMETER (mm)
FERROUS	AISI E52100	0.15 mm
NON FERROUS	70Cu 30Zn	0.20 mm
STAINLESS STEEL	AISI 316	0.25 mm

THS/PH21N-D25



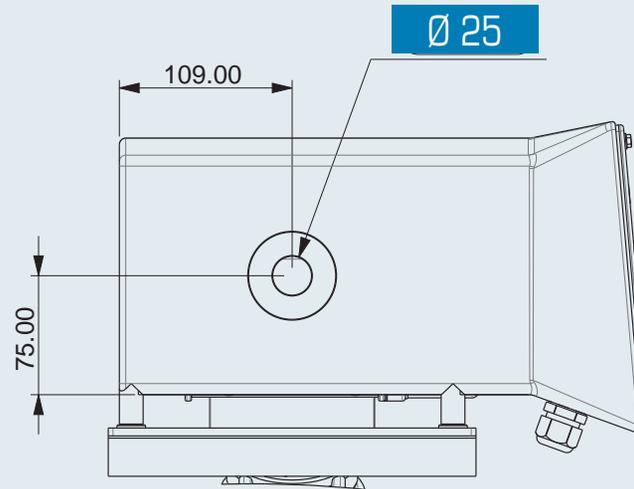
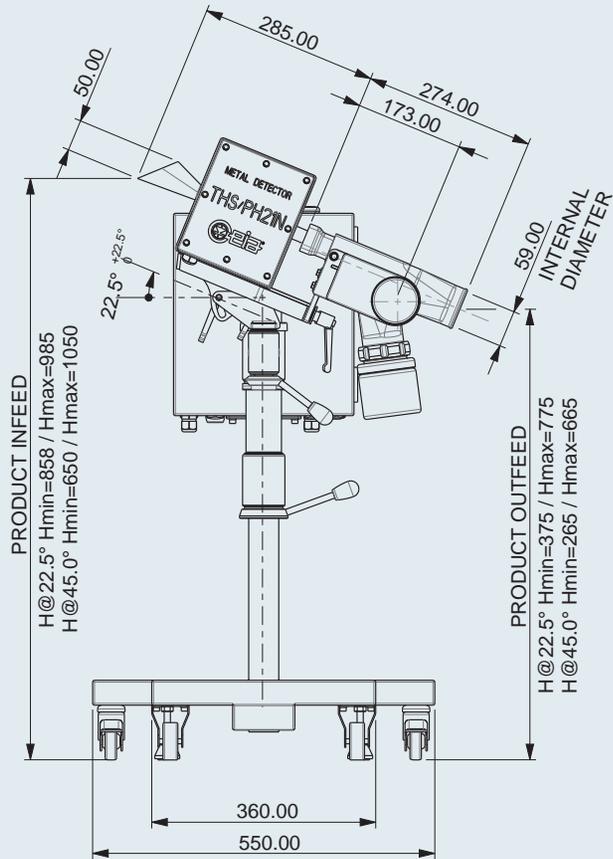
Examples of Throughput

PRODUCT		VERIFIED THROUGHPUT (items / h)
		THS/PH21N - D25
	Diameter: Ø 8,5 mm Thickness: 4,5 mm	30.000

- Tilt Angle: 35°
- Max Throughput Rates are related to the shape and to the size of the tablets

THS/PH21N-D25

Mechanical Data



Dimensions (mm)

Model

THS/PH21N-D25

Aperture size

Ø 25

THS/PH21N-FFV & THS/PH21E-FFV

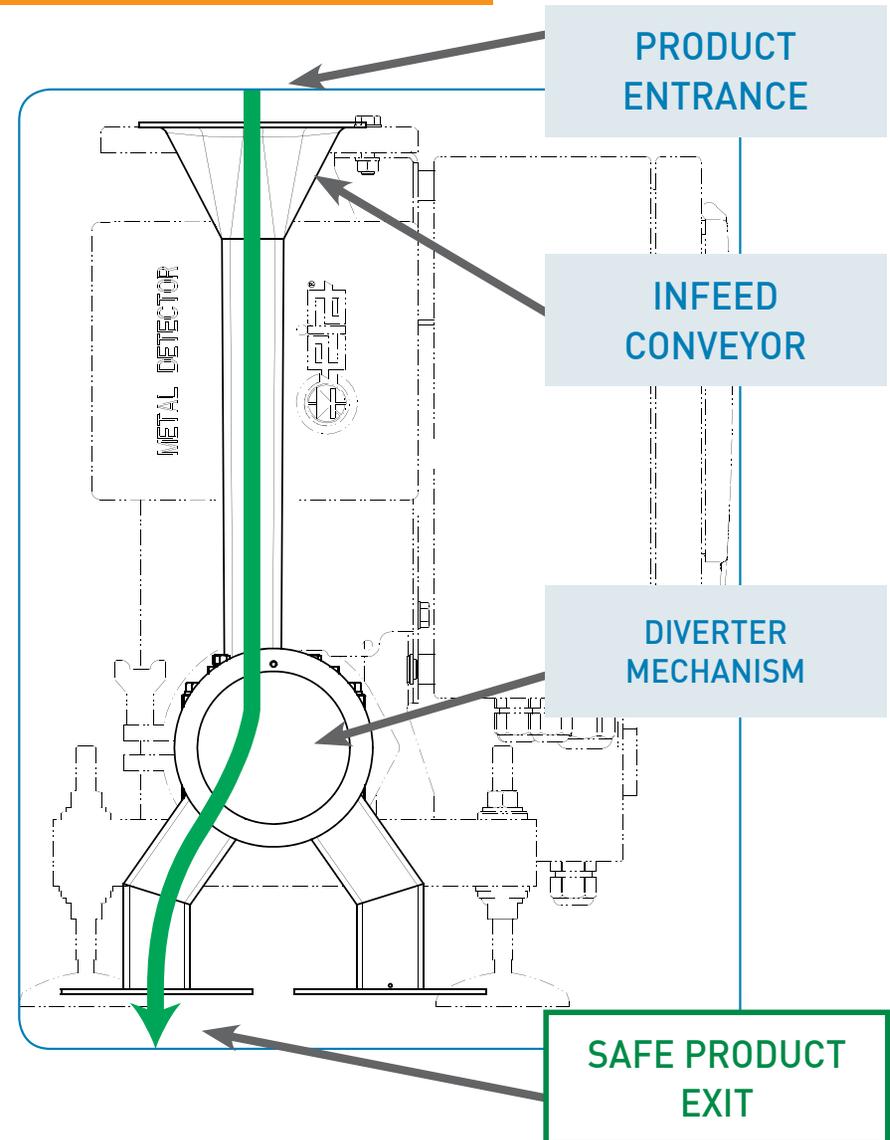
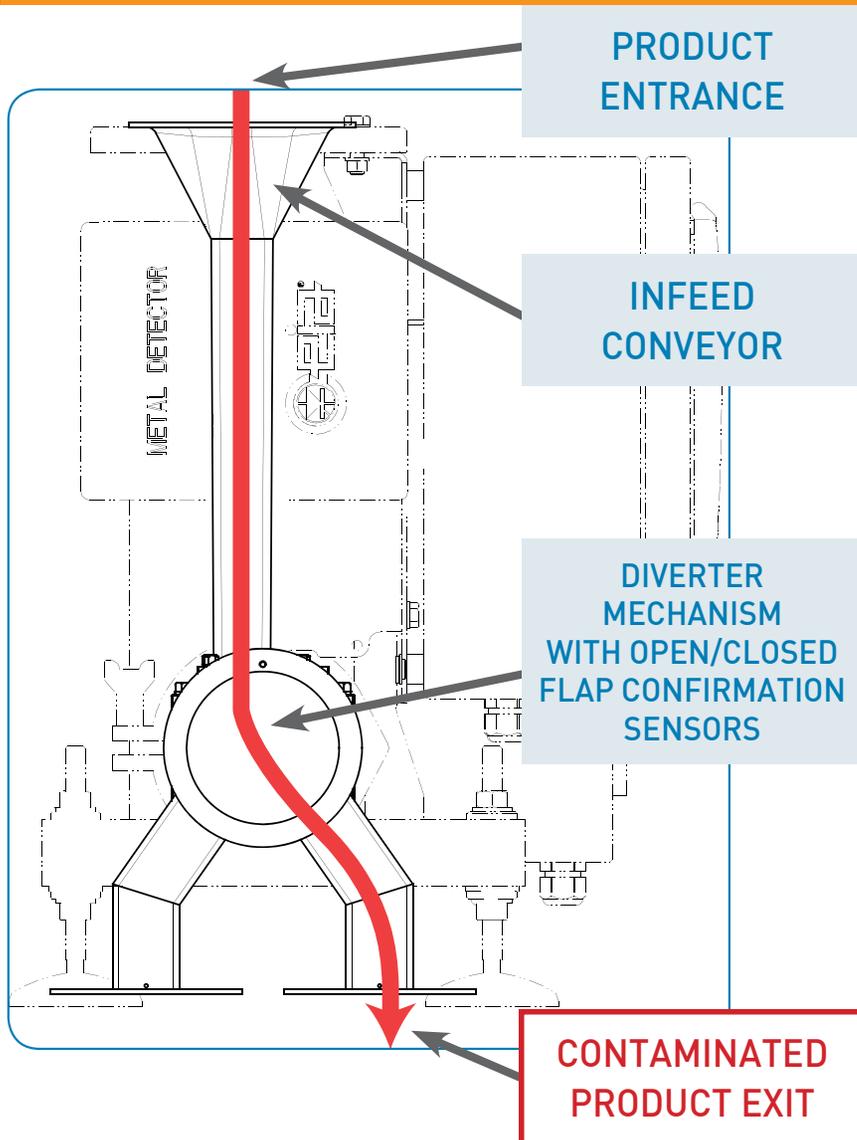


Integrated System for Granular and Powder Products

- ➔ Ultra High Sensitivity to all metals
- ➔ Very compact size
- ➔ AISI 316L stainless steel construction
- ➔ Control Power Box available according to UL 508A and CSA-C22.2 No. 14-05
- ➔ ATEX ZONE 21 version (available on demand)

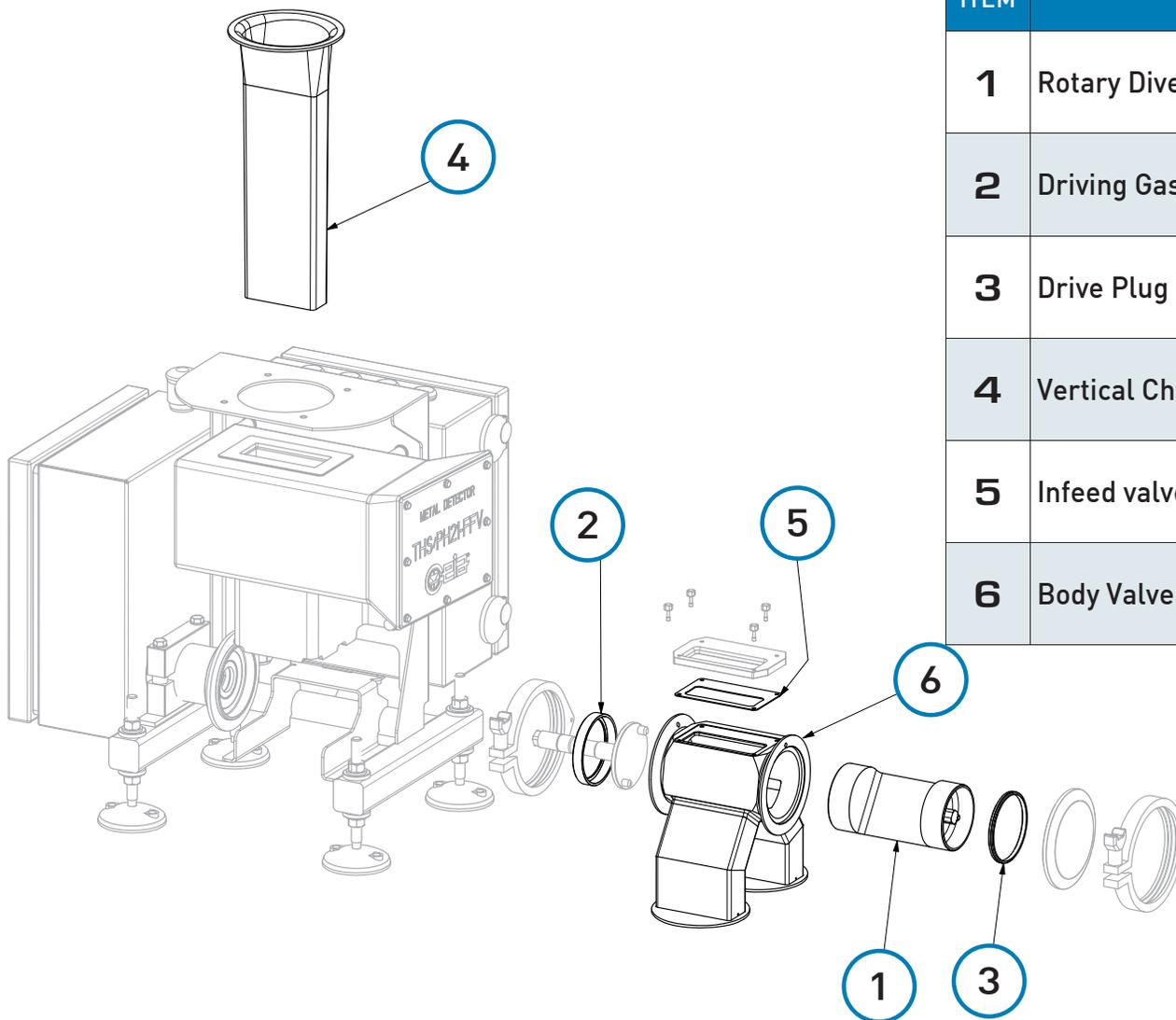


Product Path View



THS/PH21N-FFV & THS/PH21E-FFV

Parts in contact with the product



ITEM	NAME	DESCRIPTION
1	Rotary Diverter Cylinder	Stainless Steel AISI316L Mirror finishing
2	Driving Gasket	POMC - Smooth surface Manufacture: Machined
3	Drive Plug Bush	POMC - Smooth surface Manufacture: Machined
4	Vertical Chute	PETG - Smooth surface Manufacture: Moulded
5	Infeed valve gasket	Silicon Manufacture: Machined
6	Body Valve	Stainless Steel AISI316L Mirror finishing

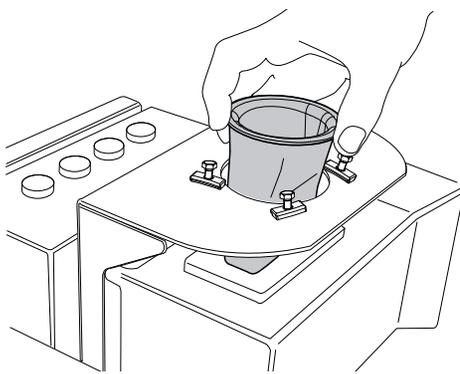
- All parts compliant with FDA 21 CFR Parts 210 and 211
- No lubricants or coolants required

THS/PH21N-FFV & THS/PH21E-FFV

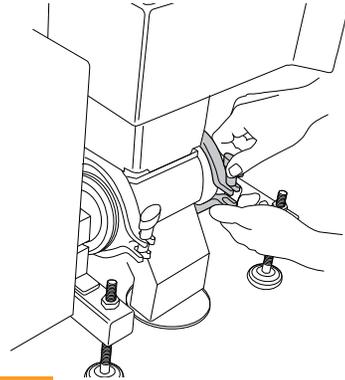
Cleaning of the Parts in contact with the Product



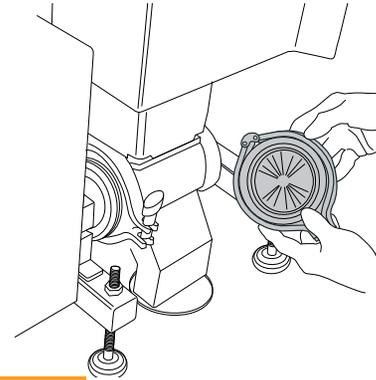
Assembly and Disassembly No tools required



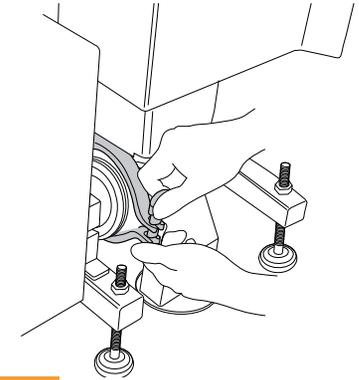
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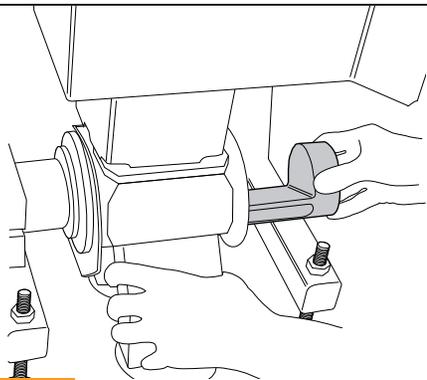
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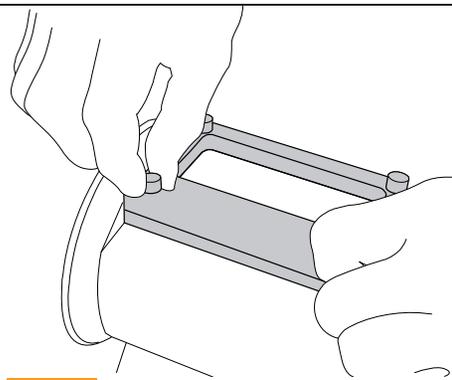
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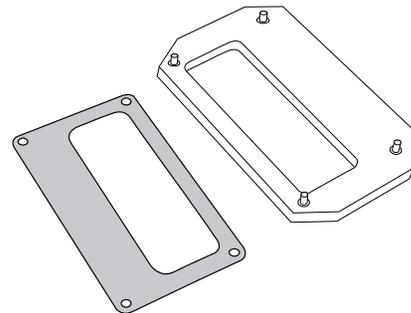
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5



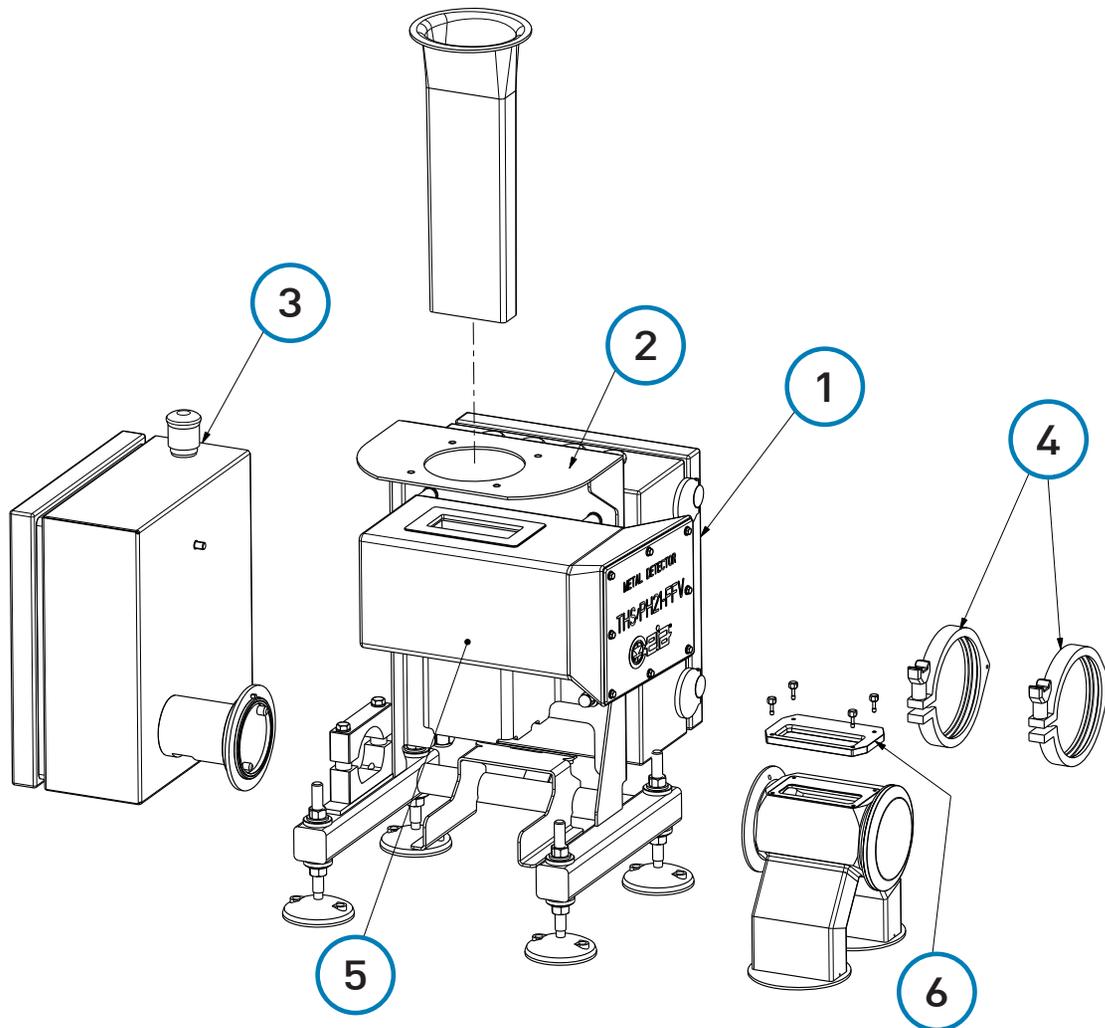
6



7

THS/PH21N-FFV & THS/PH21E-FFV

Parts not in contact with the product



ITEM	NAME	DESCRIPTION
1	Control Power Box	Stainless Steel AISI316L Mirror finishing
2	Welded frame	Stainless Steel AISI316L Mirror finishing
3	Actuation System Assembly	Stainless Steel AISI316L Mirror finishing
4	4" Clamp	Stainless Steel AISI316L Mirror finishing
5	Complete Detection Head	Stainless Steel AISI316L Mirror finishing
6	Infeed Valve Flange	Stainless Steel AISI316L Mirror finishing

→ All parts compliant with FDA 21 CFR Parts 210 and 211

→ No lubricants or coolants required

THS/PH21N-FFV & THS/PH21E-FFV

ATEX 21 version



CESI

CESI
Centro Elettrotecnico
Sperimenziale Italiano
Giacinto Motta S.p.A.
Via R. Rubattino 54
20134 Milano - Italia
Telefono +39 0221251
Fax +39 0221255440
www.cesi.it

Capitale sociale € 550.000 €
interamente versato
Codice fiscale e numero
iscrizione CCIAA 00793580150
Registro Imprese di Milano
Sezione Ordinaria
N. R.E.A. 452227
P.I. IT00793580150

CERTIFICATE

Ex

EC-TYPE EXAMINATION CERTIFICATE

Equipment or Protective System intended for use
in potentially explosive atmospheres
Directive 94/9/EC

[1] EC-Type Examination Certificate number:
CESI 09 ATEX 026 X

[4] Equipment:
**Industrial metal-detector
model THS/PH21N-FFV-ATEX**

[5] Manufacturer:
CEIA S.p.A.

[6] Address:
**Zona industriale Vicomaggio 54/G-56
52041 Vicomaggio - AR (ITALY)**

[7] This equipment or protective system and any acceptable variation thereto is specified in the schedule to this certificate and the documents therein referred to.

[8] CESI, notified body n. 0722 in accordance with Article 9 of the Council Directive 94/9/EC of 23 March 1994, certifies that this equipment or protective system has been found to comply with the Essential Health and Safety Requirements relating to the design and construction of equipment and protective systems intended for use in potentially explosive atmospheres given in Annex II to the Directive.

The examination and test results are recorded in confidential report n. EX- A9015892.

[9] Compliance with the Essential Health and Safety Requirements has been assured by
EN 61241-0: 2006 EN 61241-1: 2004 EN 13463-1: 2009 EN 13463-5: 2003

[10] If the sign "X" is placed after the certificate number, it indicates that the equipment or protective system is subject to special conditions for safe use specified in the schedule to this certificate.

[11] This EC-TYPE EXAMINATION CERTIFICATE relates only to the design, examination and tests of the specified equipment or protective system in accordance to the Directive 94/9/EC. Further requirements of the Directive apply to the manufacturing process and supply of this equipment or protective system. These are not covered by this certificate.

[12] The marking of the equipment or protective system shall include the following:
Ex II 1/2D Ex e I D A21 IP65 T85°C

This certificate may only be reproduced in its entirety and without any change, schedule included

Date 29th May 2009 - Translation issued on May 29th 2009

Prepared
Tiziano Cola

Verified
Mirko Balaz

Approved
Firenze Bregani

Page 1/3

CESI S.p.A.
Divisione Energia
"Area Tecnica Certificazione"
Il Responsabile

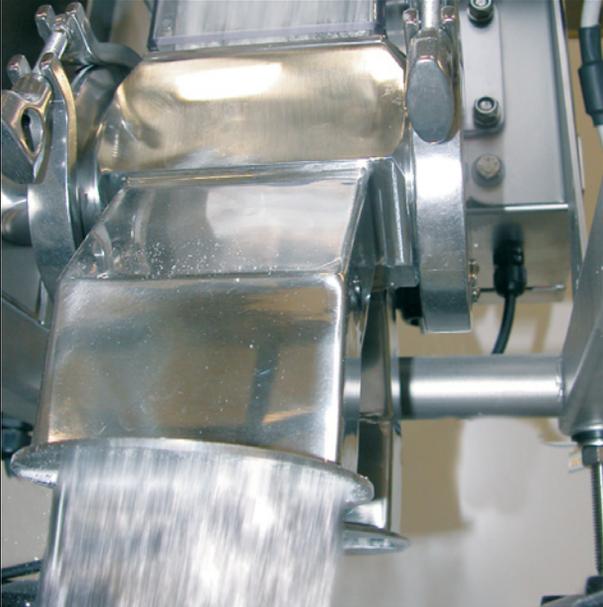
Schema di certificazione
CESI-ATEX

Il CESI è stato autorizzato dal governo italiano ad operare quale organismo di certificazione di apparecchi e sistemi destinati all'uso in atmosfera potenzialmente esplosiva con D.M. 12/1983 D.M. 19/5/1990, D.M. 20/7/1998 e D.M. 27/6/2000

THS/PH21N-FFV & THS/PH21E-FFV

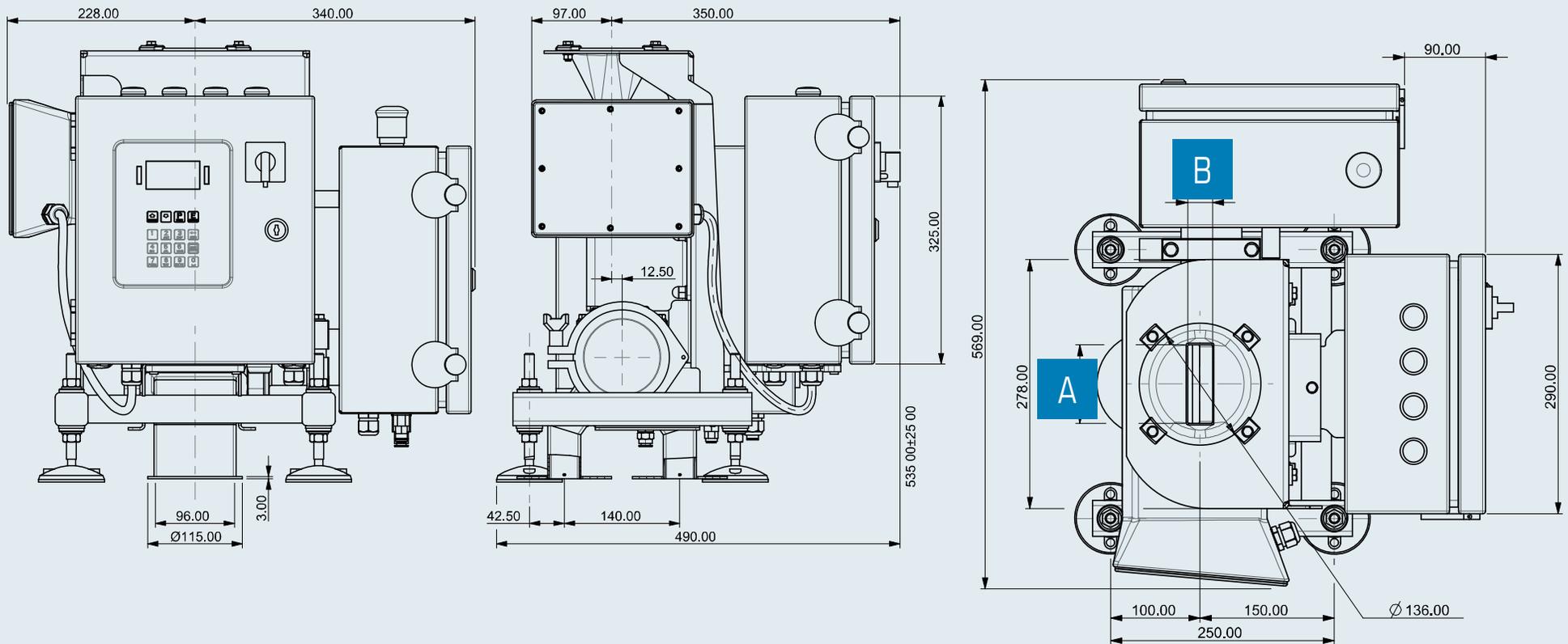
Examples of Throughput



PRODUCT	NOMINAL VERIFIED THROUGHPUT (kg / h)	
	THS/PH21N-FFV (90x25)	THS/PH21N-FFV (100x40)
 <p>POWDERS</p>	<p>1800</p> <p>(Ref. density: 0,8 kg/dm³)</p>	<p>3600</p> <p>(Ref. density: 0,8 kg/dm³)</p>

THS/PH21N-FFV & THS/PH21E-FFV

Mechanical Data



Models	Aperture size	A	B
THS/PH21N	100 x 40 mm	90	30
THS/PH21E	90 x 25 mm	78	13



Pharmaceutical Metal Detection Systems

Name	Serial Number	Online	Product Name	System Status	Actions	Today Tests
1. THS/PH21N-WP	21100208062	✓	P2	Working properly		0
3. THSMS21	21000224065	✓	DEFAULT	Working properly		0
4. THS/21E	21000238032	✓	Y	Working properly		0
5. THS/FFV21	21100213069	✓	A	Working properly		0
6. THS/PLVMS21	21000218048	✓	P1	Working properly		0
7. THS/PH21N-FFV	20900246015	✓	TABLET1	Working properly		0
8. T/PLMS21	21000205021	✓	P1	Working properly		0

Management Software

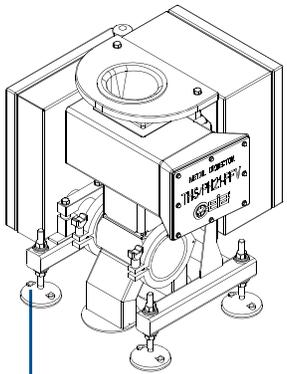
www.ceia.net

THS/PH21 series Management Software

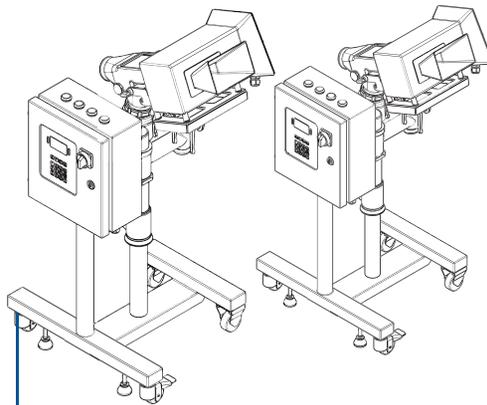
Sophisticated Network Communication Capabilities



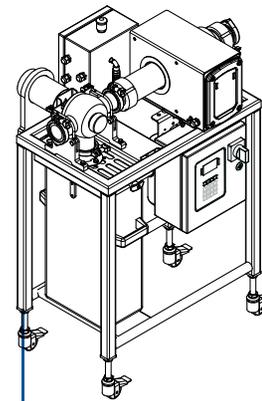
THS/PH21 Series offers a wide range of interface capabilities



PRODUCTION LINE #1



PRODUCTION LINE #2



PRODUCTION LINE #N

ETHERNET

THS PRODUCTION PLUS



Sophisticated Network Communication Capabilities



```

[000] 11/07/03 - 9:01:27 Metal Detector Off
-024027-
[A] [B] [C]
[001] 11/07/03 - 9:01:32 Metal Detector On
-185128-

[005] 11/07/03 - 9:02:01 LogIn (LOCAL)
Name: JOHN Surname: SMITH Descrip.: ADMINISTR
-150002- [D]
[009] 11/07/03 - 9:02:01 Product Modified: PROD01
Sensitivity 280 -> 278
Name: JOHN Surname: SMITH Descrip.: ADMINISTR
-185191- [E]
[006] 11/07/03 - 9:02:11 LogOut (LOCAL)
Name: JOHN Surname: SMITH Descrip.: ADMINISTR
-212118-

[005] 11/07/03 - 9:02:49 LogIn (LOCAL)
Name: ALAN Surname: BLACK Descrip.: SUPERVISR
-143028-

[012] 11/07/03 - 9:02:53 Alarm
Sensitivity: 278 Amplitude: 23.9 dB
-051038- [F]
[015] 11/07/03 - 9:02:59 Test Passed
Prod.: PROD01 Fe diameter: 1.00
Name: ALAN Surname: BLACK Descrip.: SUPERVISR
-177205- [G]
[013] 11/07/03 - 9:03:00 Ejection: PROD01
-076195-

[006] 11/07/03 - 9:03:02 LogOut (LOCAL)
Name: ALAN Surname: BLACK Descrip.: SUPERVISR
-096201-

+169130+

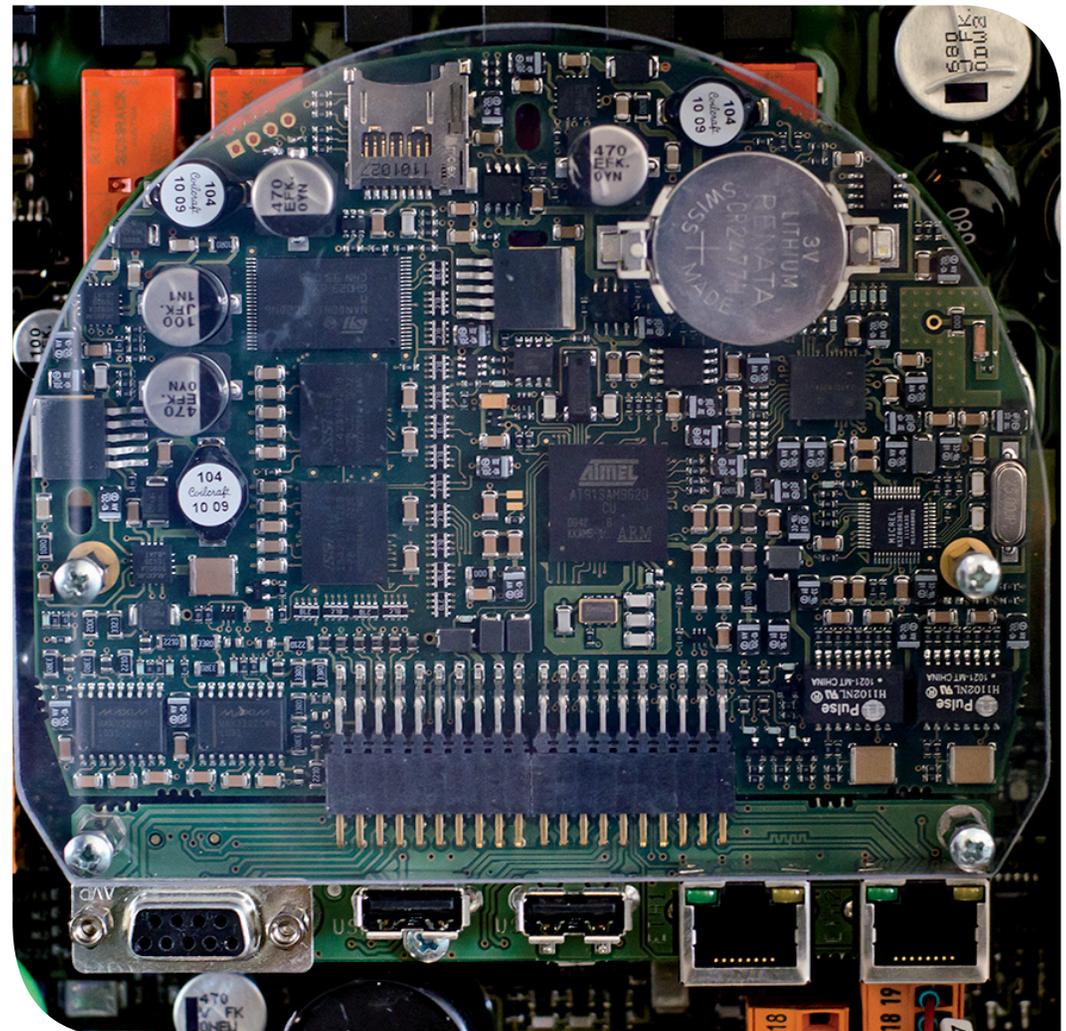
#
    
```

A	Event code
B	Date and Time
C	Event description
D	User data
E	Parameter change
F	Alarm data
G	Test performed using a ferrous sample

IXC module



- Gateway to THS Production Net Management System
- Integrated Web-server
- Dual 100base-T Ethernet
- Dual Full Speed USB interface
- Wi-Fi 802.11b/g
- 100.000 events internal data logger



THS/PH21 series Management Software

Bluetooth® Connectivity



- ➔ The Bluetooth connection can be used for programming, monitoring of the signals via the CEIA MD-Scope program and the transfer of the data contained in the Metal Detector's events memory.



THS Production Plus



- Connects and Acquires Data from Multiple THS Detectors via Ethernet LAN
- Provides Connection to an External Database (OLE DB) and Definition of a Programmable Block of SQL Instructions for each Metal Detector Event
- Enables Data Base Management and Back-Up of Metal Detector events

THS Production +

THS Metal Detectors' Summary

	Name	Serial Number	Online	Product Name	System Status	Tests	Today Tests	Last Sy
	1. THS/PH21N-WIP	21100208062	✓	P2	Working properly		0	2/8/201
	3. THS/MS21	21000224065	✓	DEFAULT	Working properly		0	2/8/201
	4. THS/21E	21000238032	✓	Y	Working properly		0	2/8/201
	5. THS/FFV21	21100213069	✓	A	Working properly	0	0	2/8/201
	6. THS/PLVMS21	21000218048	✓	P1	Working properly	0	0	2/8/201
	7. THS/PH21N-FFV	20900246015	✓	TABLET1	Working properly	0	0	2/8/201
	8. T/PLMS21	21000205021	✓	P1	Working properly	0	0	2/8/201

Context Menu:

- Serial Number
- Online
- Product Name
- System Status
- Today Ejections
- Today Tests
- Last Synchronization
- Polling
- TCP/IP Settings
- Partition Name
- Next Report

Buttons: Add, Edit, Delete, Webservice, Total:

THS Production Plus



- Report Data Exportable in HTML and CSV format
- Provides User Authentication and Manages Electronic Signatures and Records
- Allows Data Integrity and Operator Auditing
- FDA Requirements Compliant, Title 21 of the Code of Federal Regulations (CFR)

Metal Detector Report

REPORT INFORMATION

Partition Name :	THS	
Serial Number - Metal Detector Name - Last Synchronization :	320037 MDI THSSL	20/01/2012 17.20.48
	442009 MDI THS	20/01/2012 17.26.41
Report Creation :	20/01/2012 17.30.00	
From :	-	
To :	-	

EVENTS LIST

Date & Time	EN	Event	Product Name	Parameter	Review	Value	Control / Result	Info	Prop. TC	Send	Operator
12/01/2012 8:02:33	442009	Injection	P1				Injection OK				
12/01/2012 8:02:33	442009	Injection	P1				Injection Fail				
12/01/2012 8:02:55	442009	Injection	P1				Injection OK				
12/01/2012 8:00:03	442000	Change parameter	P1								
12/01/2012 8:00:49	442009	Change parameter	P1	Analytic mode	6	0					SD10100000
12/01/2012 8:06:56	442009	Change parameter	P1	Sensitivity	270	299					SD10100000
12/01/2012 8:09:33	442009	Change parameter	P1	TXsystem	9	260					SD10100000
12/01/2012 8:09:43	442009	Change parameter	P1	Sensitivity	299	297					SD10100000
12/01/2012 8:09:51	442009	Change parameter	P1	Analytic mode	0	6					SD10100000
12/01/2012 7:59:21	442009	Change product	PP1	Sensitivity	297	280					SD10100000

SUMMARY STATISTICS

Ejections :	04
Quantity :	2018
Eject rate (PPM) :	11892,963330030
Tests Passed :	0
Tests Failed :	1
Param. Modified :	13
Product Change :	2
Faults :	0

PRODUCTS STATISTICS

Serial Number	Metal Detector Name	Ejections	Tests Passed	Tests Failed	Quantity
320037	MDI THSSL	3	0	1	1791
442009	DEMO NASTRO	21	0	0	227

QUANTITY / EJECTIONS GRAPH

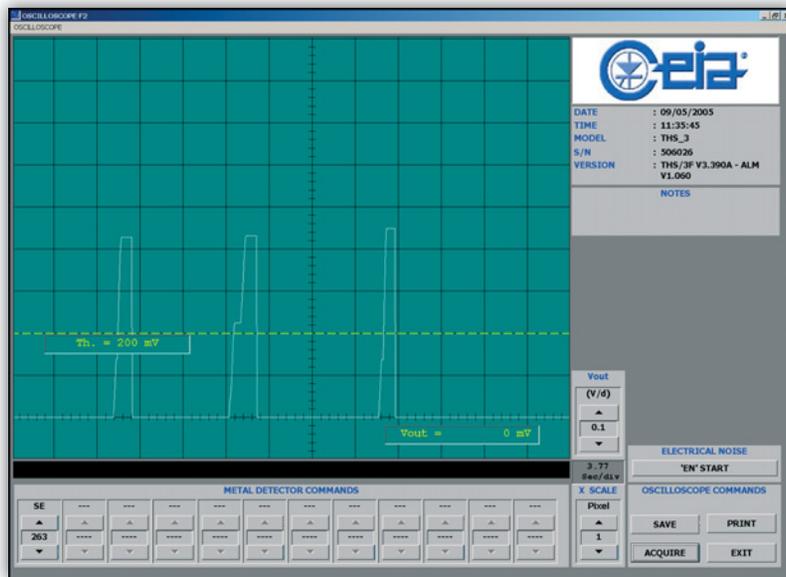
PARTITION - THS : Quantity and Ejections by product in this period (Completed) 17/01/2005 18.00.07

Product	Quantity	Ejections
DEFAULT	~50	0
P1	~10	0
PP1	~100	0
PP2	~20	0
PRODUCT1	~250	0
PRODUCT2	~600	0
PRODUCT3	~400	0
PRODUCT4	~450	0

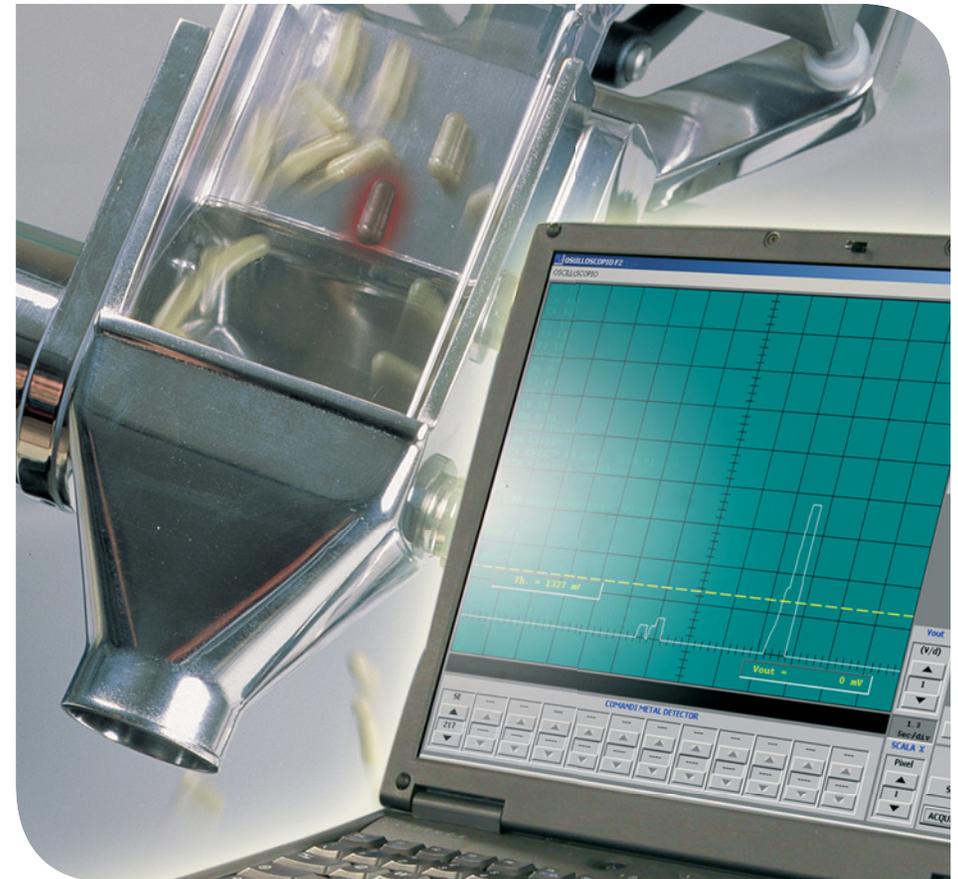
MD-SCOPE



Software for oscilloscope simulation and terminal operations on CEIA Metal Detectors



- The oscilloscope screen displays the signal amplitude and the alarm threshold level (yellow)



Thank you for your attention



Call or visit us today!

www.ceia.net

pharma@ceia-spa.com

Phone: +39 0575 4181