CATALOG

PINHOLE INSPECTOR

HIGH VOLTAGE LEAK DETECTION FOR PHARMACEUTICAL PACKAGING

NIKKA DENSOK LIMITED

HIGH VOLTAGE LEAK DETECTION

"THE ELECTRONIC EYES TO DETECT PINHOLES"

- inventor

Nikka Densok is a leading inspection machine manufacturer which ensures pharmaceutical container closure integrity. By leveraging more than 50 years of experience as the pioneer of high voltage leak detection technology, we continue to offer the best customized solutions and services to our valuable customers.

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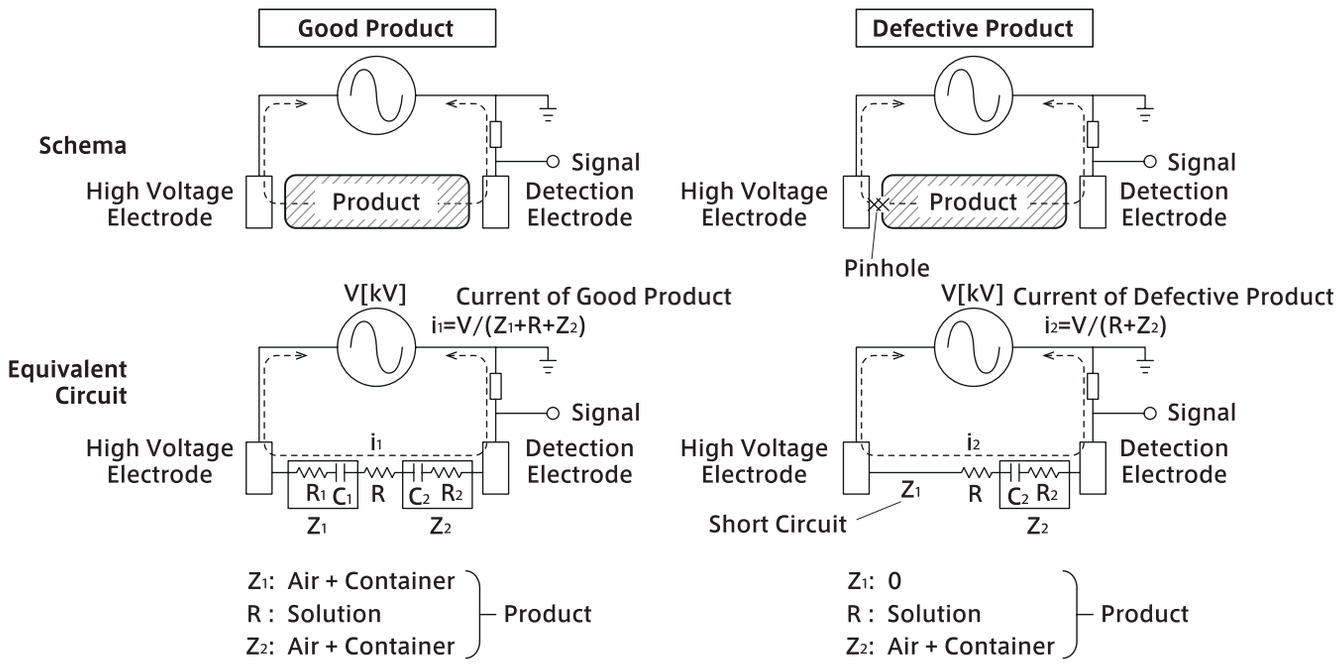
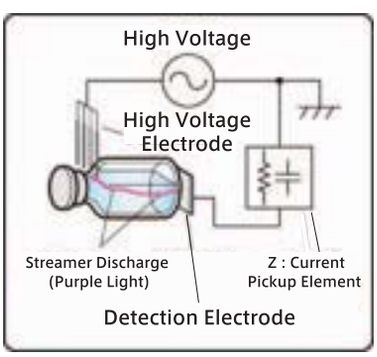
Lineup

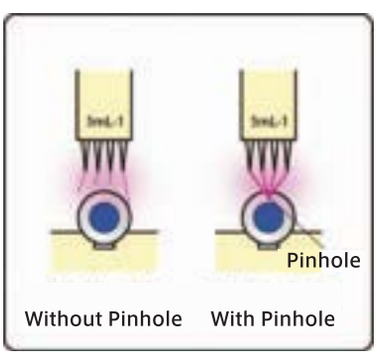
Inspection Principle

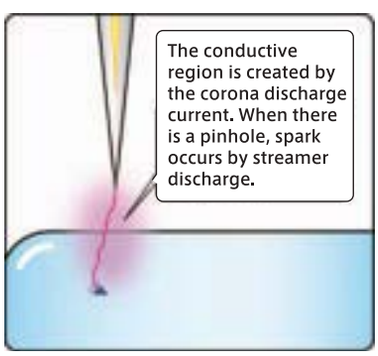
High voltage (V) is applied from inspection electrodes to a specific area of a sealed container made of non-conductive material. If the inspection area of the container is defective, current flows through pinhole, crack, or improperly sealed area in the solution (R) of the container. As a result of the loss of Z1 resistance in this figure, a change occurs in the amount of current.

Detecting this change in the amount of current makes it possible to recognize the presence of a defect. The current is converted to a readable VDC in the electronic circuit to be displayed on the operation panel.









Current Calculation by Equivalent Circuit

Comparison of Current

Circuit is : $V = i\,(Z_1 + R + Z_2)$

$Z_1 = R_1 + \frac{1}{j\omega C_1}$ $\quad Z_2 = R_2 + \frac{1}{j\omega C_2}$

C_1 or C_2 = Container capacitor $\quad R_1$ or R_2 = Air resistance

j = Imaginary unit $\quad \omega$ = Angular frequency

If good product : $i_1 = \frac{V}{Z_1+R+Z_2}$

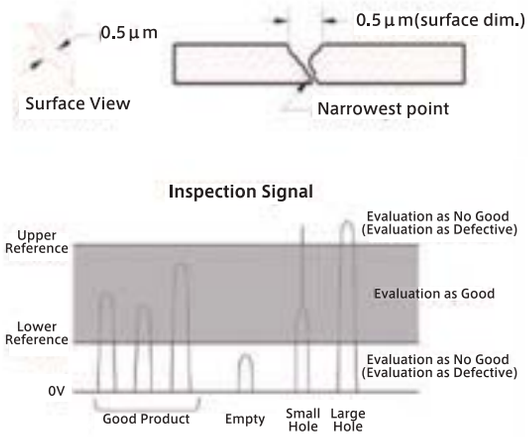
If defective product : $i_2 \fallingdotseq \frac{V}{R+Z_2}$ $\quad Z_1$: small

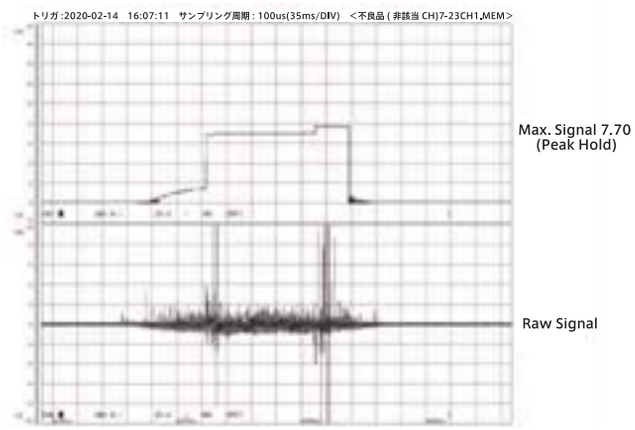
The result is : $i_2 > i_1$

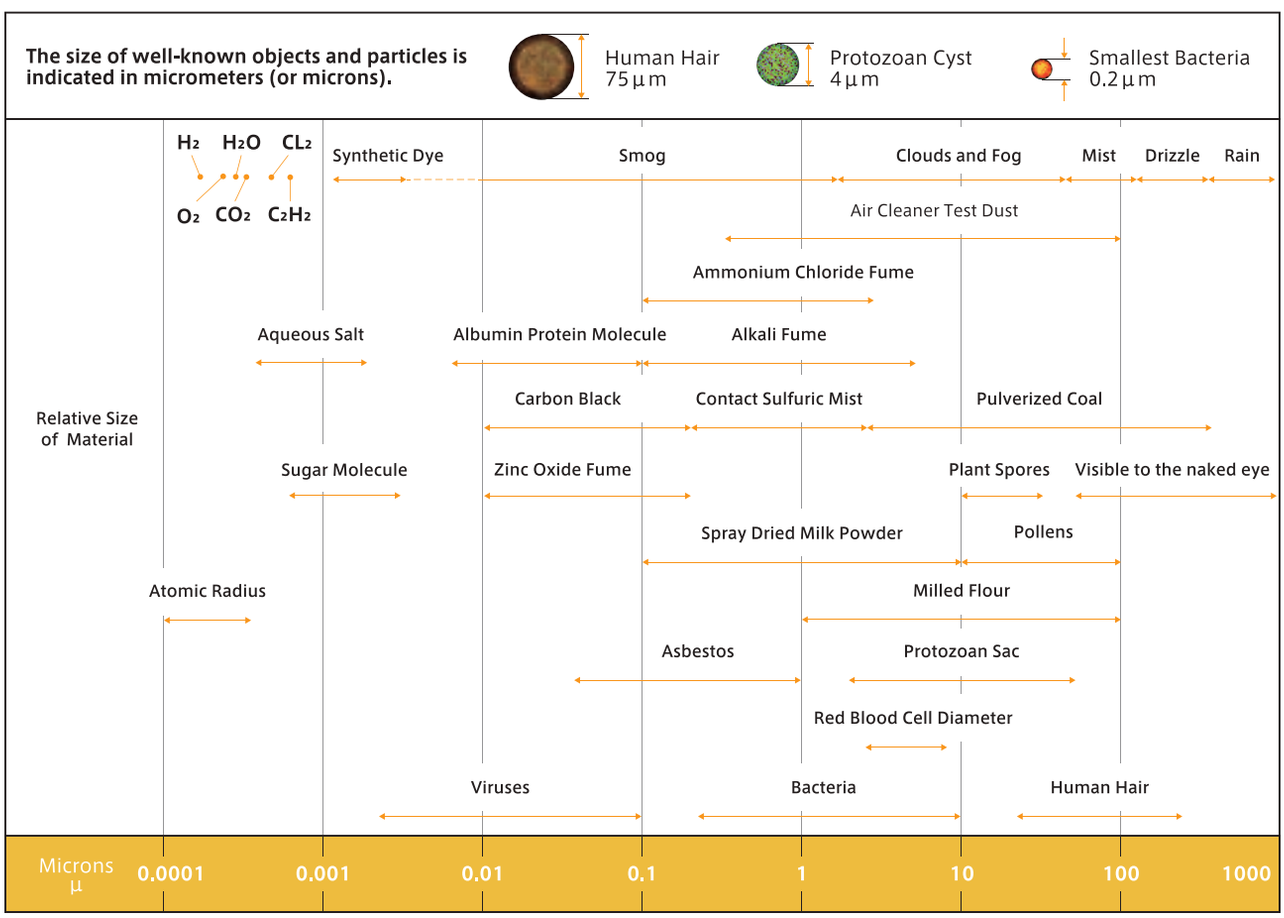
Detection Accuracy

Our high voltage pinhole inspection machine has technology that can reliably detect even as small as 0.1µm holes. These tiny holes cannot be found by human eyes or visual inspection. Our pinhole machines assure container closure integrity by targeting 0.1µm holes which are even smaller than those Φ 0.2µm of the filling filter mesh.

An example of hole detected by using our high voltage system
= Pinhole 0.5µm photomicrograph







0.2µm particles pass through the clean room filter.
Our machines can detect 0.1µm hole, which is smaller than the particles.

Features of High Voltage Leak Detection System

Various inspection methods are used to inspect pinholes, cracks and seal defects in food and pharmaceutical packaging products.
High voltage leak detection is the most reliable and productive among these methods.
It has the following features;

- 0.1µm micro-hole detection capability.
- Non-destructive inspection.
- Prevents secondary contamination to products.
- High-speed reliable processing makes it suitable for 100% inline inspection applications.
- 1µS/cm of WFI, Dextrose and other low conductivity products can also be inspected.
- High voltage leak detection system achieves optimal performance in response to the increasing demand for CCIT (Container Closure Integrity Testing) of pharmaceutical products.
- 21CFR Part11 Compliance
- EU GMP Annex 1 Compliance
- USP1207 Recommended

HMI (Human Machine Interface)

Visually recognizable icons

Storage and display with excellent visibility of production data

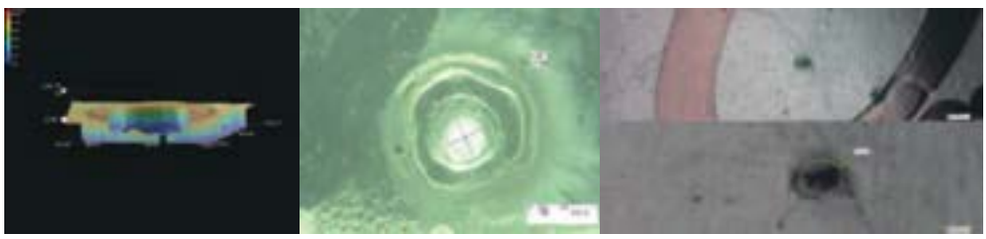
Inspection result data and signal trend

Compatible with 21CFR Part11 and GAMP

Inspection Performance Validation

Based on more than 50 years of experience and collective expertise as the pioneer of high voltage leak detection systems, Nikka Densok is not only able to propose optimal inspection solutions but also validation of such systems.

Example of Laser Drill Hole

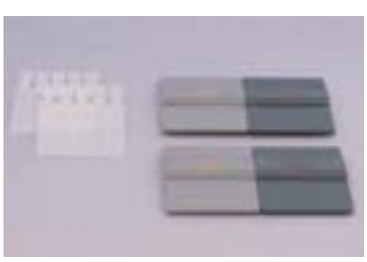


Nikka Densok cooperates with domestic and overseas laser processing service companies to support customer validation. Samples of 0.1µm holes can also be created using special tools.

Test Kit

The test kit is a daily challenge support tool that allows the user to check the machine readiness before production.
They are created based on the shape of the customer's container. Resistance whose value is changed for good and defective products is arranged according to the electrode configuration of the machine. By passing them through the machine, it is possible to confirm that sensors from infeed to discharge, circuit and component for judgement, sorting and signal display function properly.

Test Kit for Ampoule



Test Kit for BFS Strip

Elemental Experiment

Upon receiving samples with an inquiry, we can provide testing and full report with results.

HDB Series

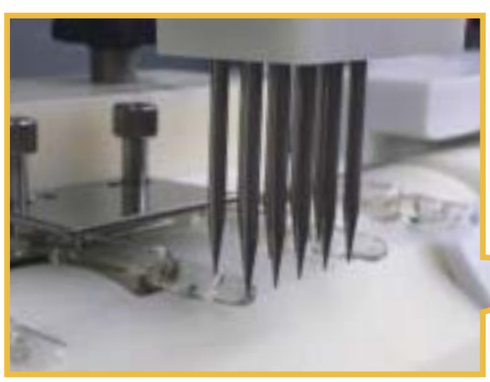
For Glass Ampoule / Vial

- Inspection machines for cylindrical containers such as glass ampoules and vials.
- Infeed is applicable for both inline and offline by tray feeding, upstream and turntable connection.

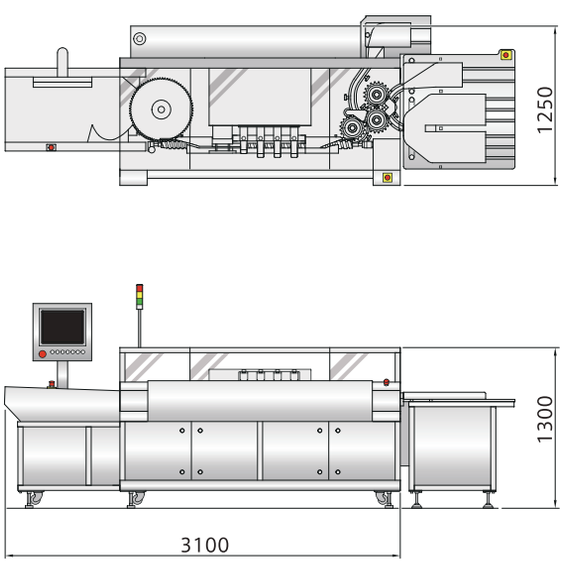
HDB-II-ASR

Stand type HMI is available.

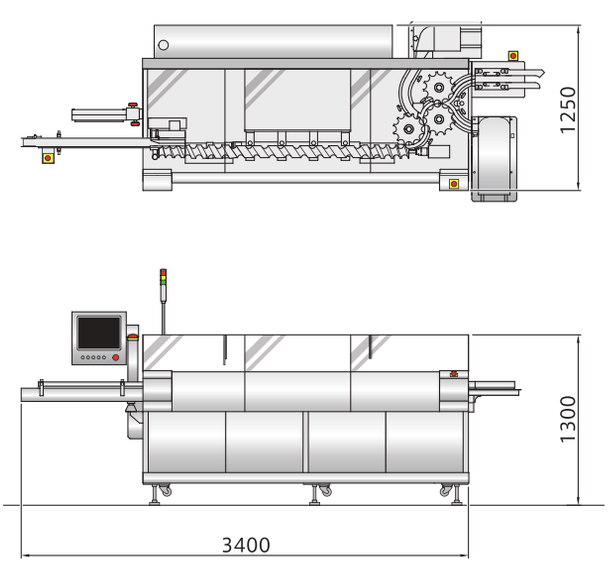
Inspection Section



HDB-II-AST/HDB-II-ASR for Ampoule

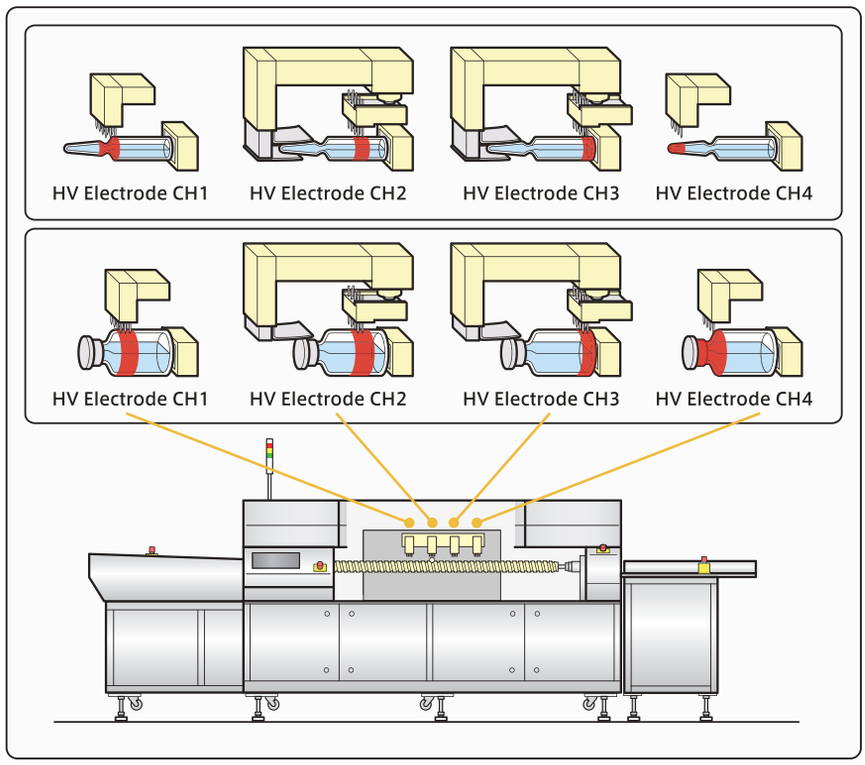


HDB-204V for Vial

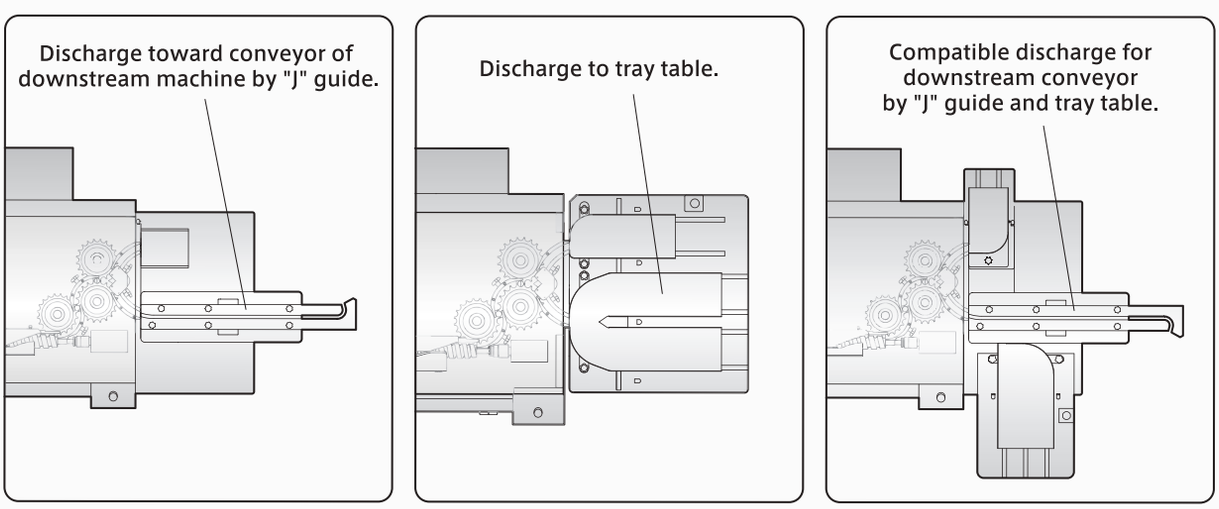


Unit : mm

Inspection Area



Optional choice for discharge method to meet line specifications.



Specifications

Model	HDB-II-AST/HDB-II-ASR	HDB-20X
Inspection Station	4 Channels	4+ Channels
Processing Capacity	Up to 600 pcs/min (diameter Φ 10 – 11.75mm)	Up to 400 pcs/min (diameter Φ 15 – 26mm)
	Up to 400 pcs/min (diameter Φ 11.76 – 18.75mm)	Up to 200 pcs/min (diameter Φ 27 – 32mm)
	Up to 300 pcs/min (diameter Φ 18.76 – 22.5mm)	Up to 150 pcs/min (diameter Φ 33 – 39.85mm)
Power Consumption	5.0kVA	5.0kVA
Air	0. 5MPa, 200NL/min	0. 5MPa, 200NL/min
Power Supply	200 – 480VAC, 50/60Hz	200 – 480VAC, 50/60Hz

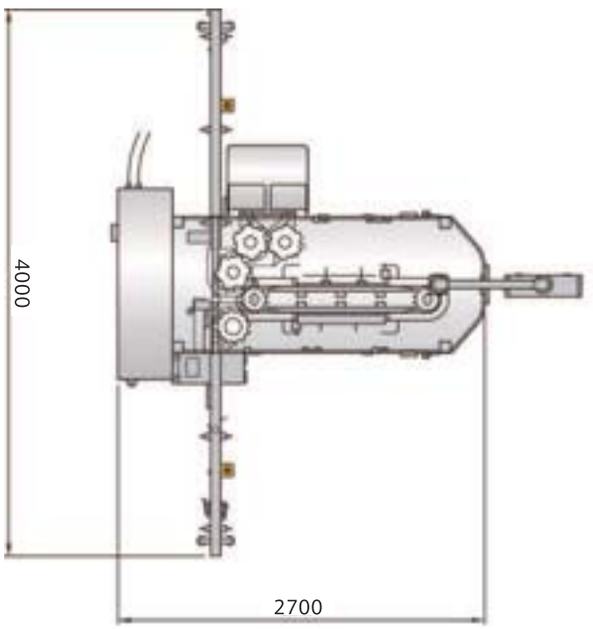
PINHOLE INSPECTOR

HDV-AT Series

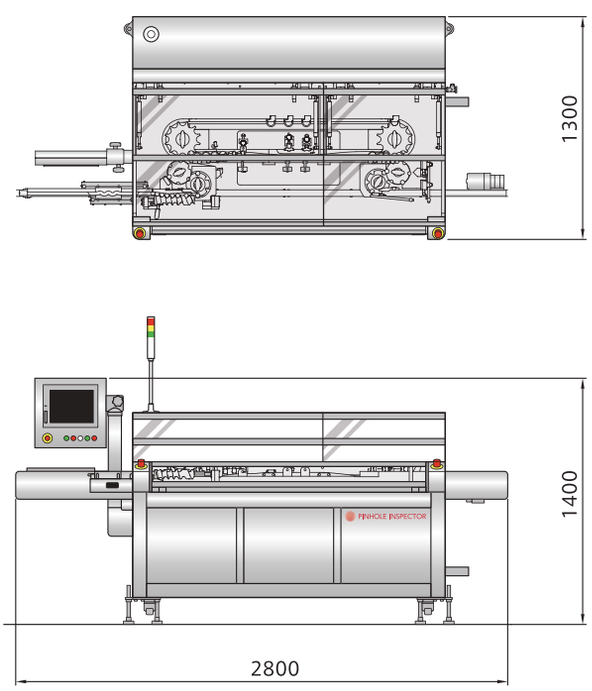
For Vial / Small Bottle

- Optimal for inspection of glass vials and small bottles.
- Smooth transport by ACE-trac™ (Continuous Carrier System).

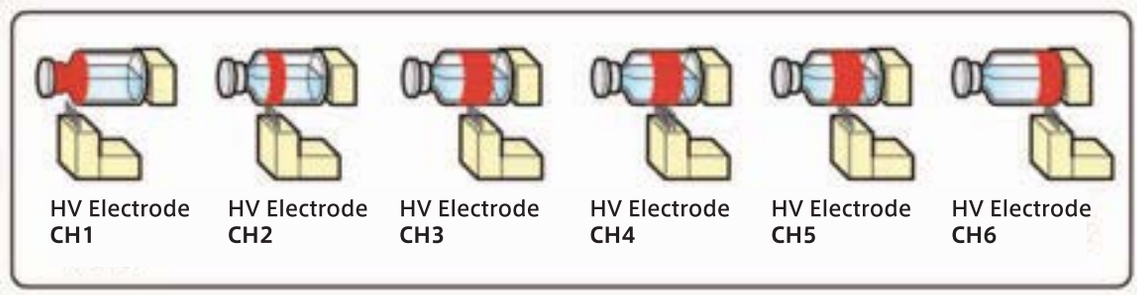
HDV-AT6



HDV-AT3



Unit : mm

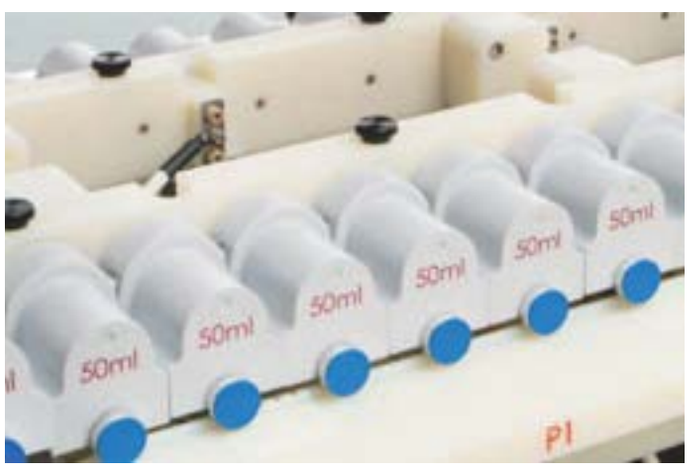


Uninspected Product Discharge Tray

Reject Product Discharge Tray

Good Product Discharge Conveyor

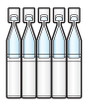
ACE-trac™
(Continuous Carrier System)
for Stress-Free Transportation



Specifications	
Inspection Station	6 Channels
Processing Capacity	Up to 400 pcs/min (2mL)
	Up to 300 pcs/min (5 – 10mL)
	Up to 200 pcs/min (20 – 50mL)
Power Consumption	7.0kVA
Air	0.5MPa, 60NL/min
Power Supply	200 – 480VAC, 50/60 Hz

HDI Series

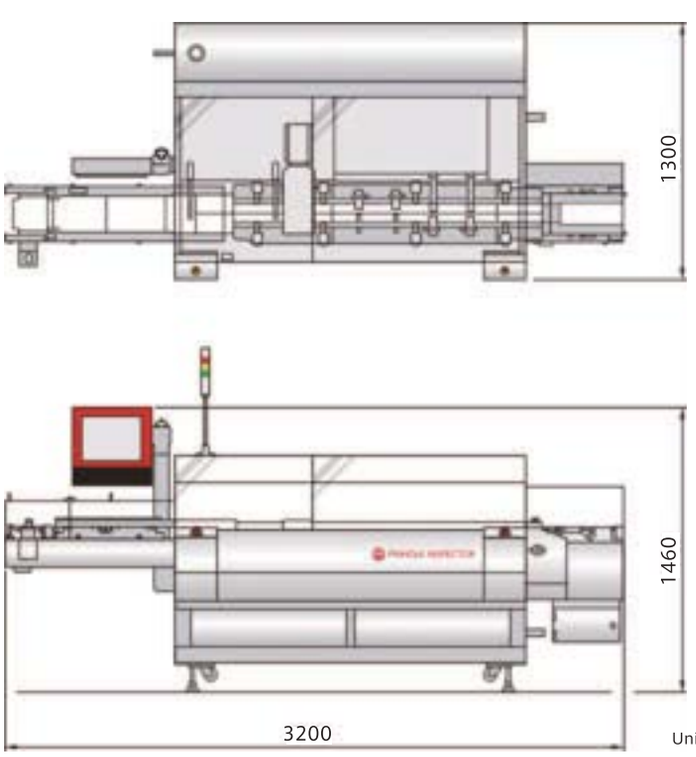
For BFS Strip



- Optimal for inspection of eye drops and other BFS strips.
- Configured and designed according to the size and characteristics of each product.

HDI-14-ER

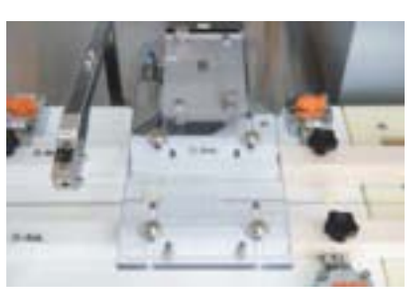
Inspection Section

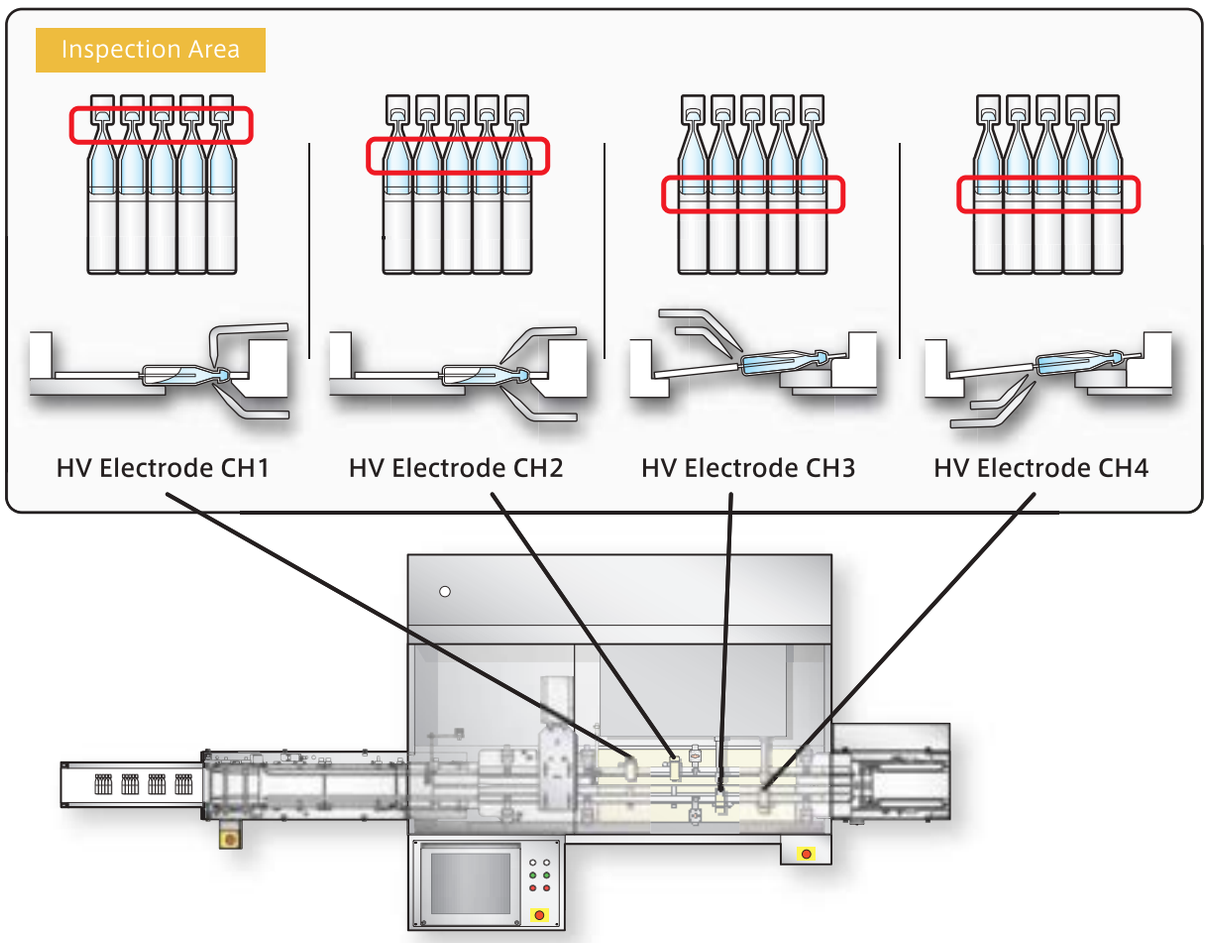


Unit : mm

Liquid Distribution Device

Before inspection, the container is vibrated to equally distribute the liquid to help ensure inspection accuracy.





Specifications

Inspection Station	4+ Channels
Processing Capacity	Up to 150 strips/min (50 – 160mm width)
Power Consumption	5.0kVA
Power Supply	200 – 480VAC, 50/60Hz

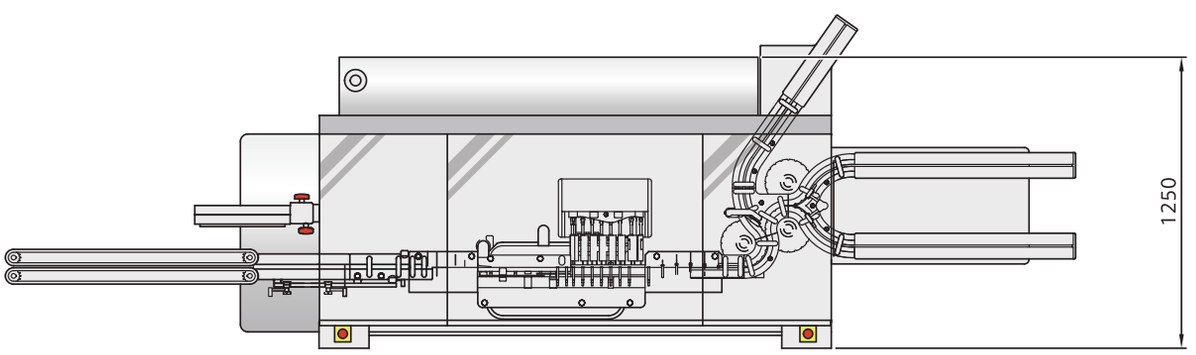
PINHOLE INSPECTOR

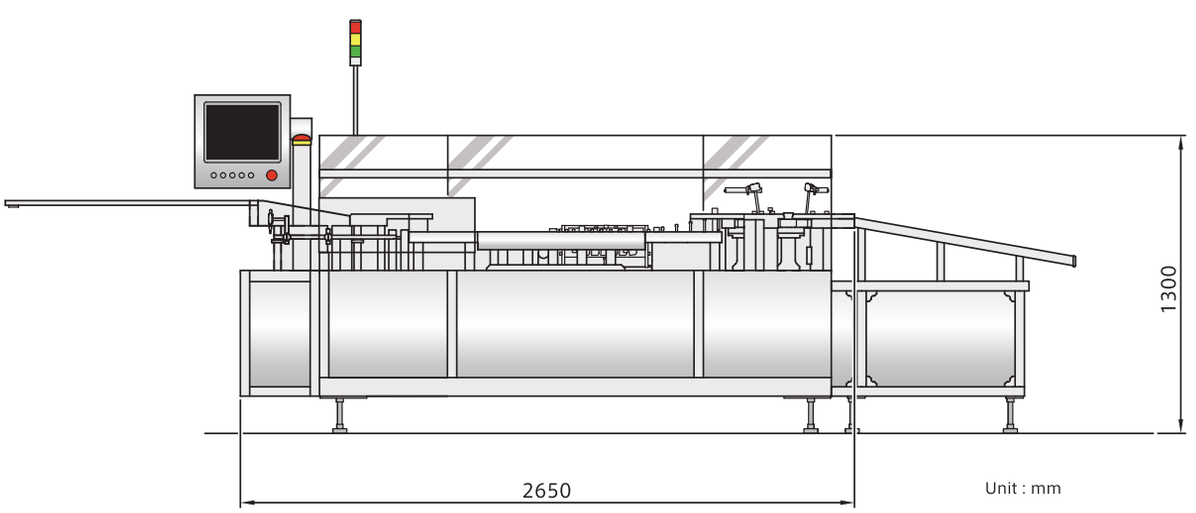
SLD Series

For Pre-filled Syringe

- High-speed pre-filled syringe inspection.
- Needle shield and stopper inspection capability.

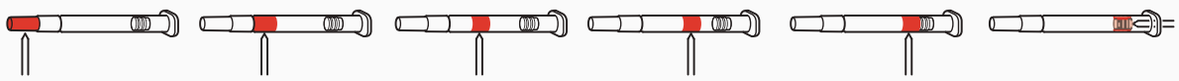
SLD-4-ER



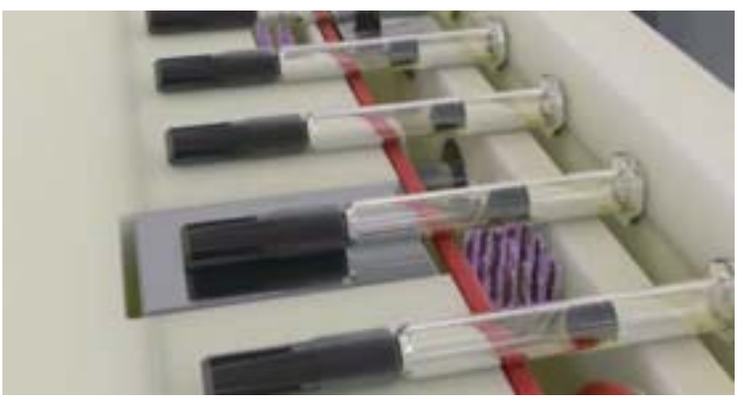


Unit : mm

Inspection Area



HV Electrode **CH1** | HV Electrode **CH2** | HV Electrode **CH3** | HV Electrode **CH4** | HV Electrode **CH5** | HV Electrode **CH6**



Syringe Barrel Inspection

Needle Shield Inspection

Specifications

Inspection Station	4+ Channels
Processing Capacity	Up to 600 pcs/min (diameter Φ 8.2 – 11mm)
Power Consumption	3.5kVA
Air	0.5MPa, 60NL/min
Power Supply	200 – 480VAC, 50/60Hz

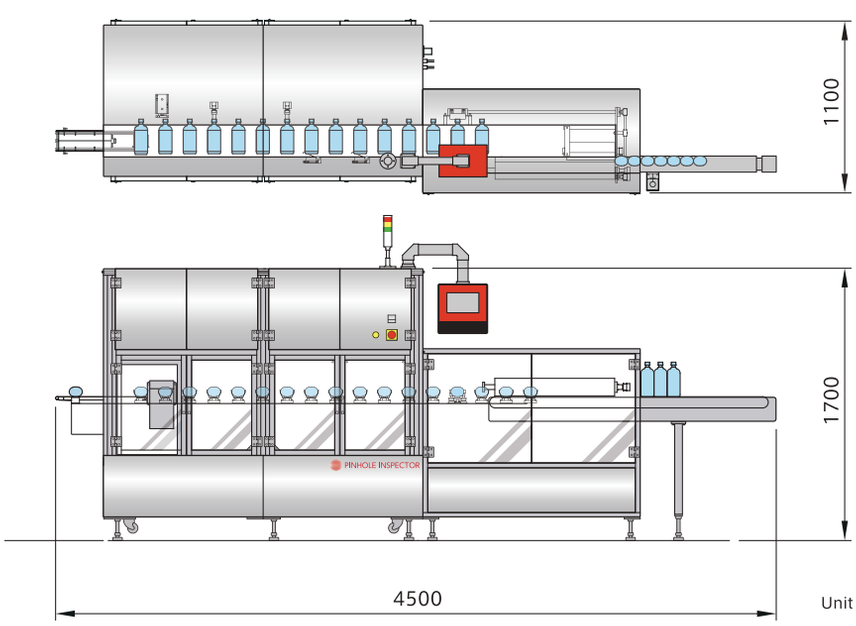
PINHOLE INSPECTOR

HDC Series

For Large Plastic Bottle

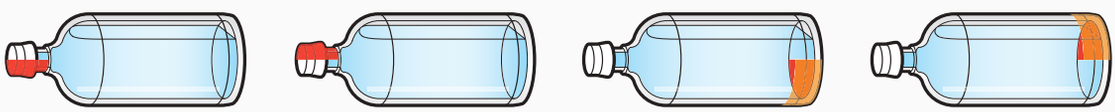
- High voltage leak detection for large plastic bottles from 100 to 1000mL.
- Inspection of cap seal welding and bottom areas including any hanger tabs.
- Customized infeed and discharge design to fit to product's posture.

HDC-4-ER



Unit : mm

Inspection Area

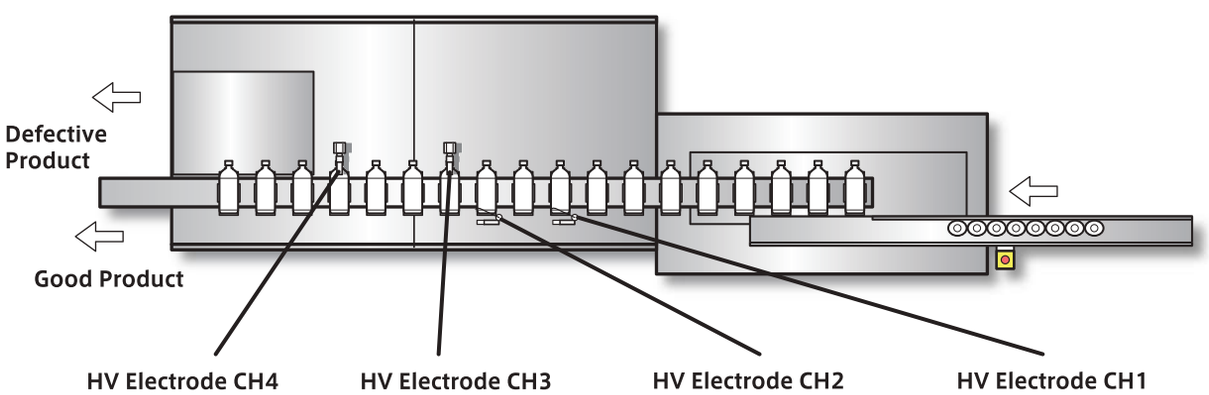


CH4
Cap (Lower)

CH3
Cap (Upper)

CH2
Bottom (Lower)

CH1
Bottom (Upper)



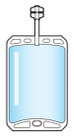
Specifications

Inspection Station	4+ Channels
Processing Capacity	Up to 100 pcs/min (100 – 1000 mL)
Power Consumption	7.0kVA
Air	0.5MPa, 200NL/min
Power Supply	200 – 480VAC, 50/60Hz

PINHOLE INSPECTOR

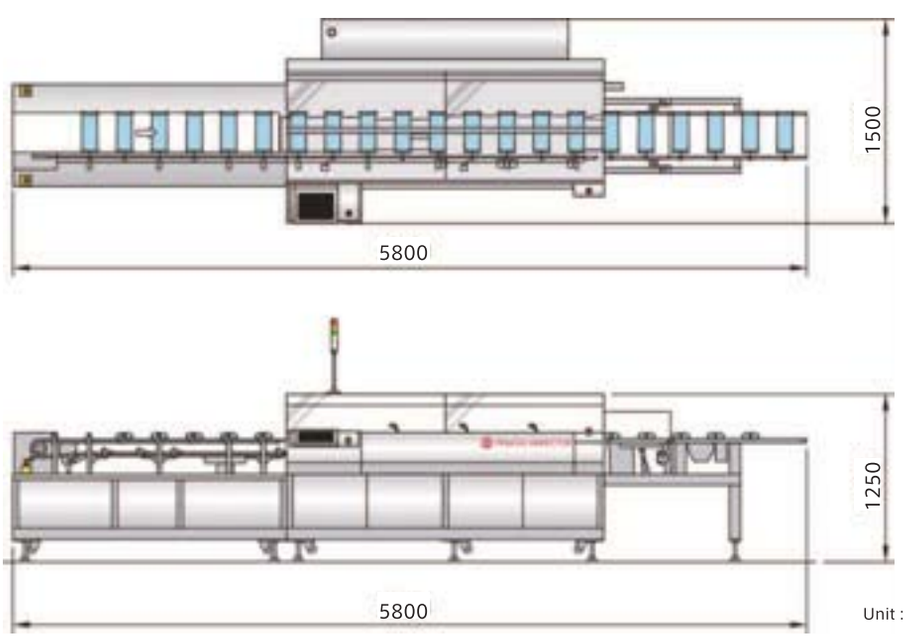
HDK Series

For Bag



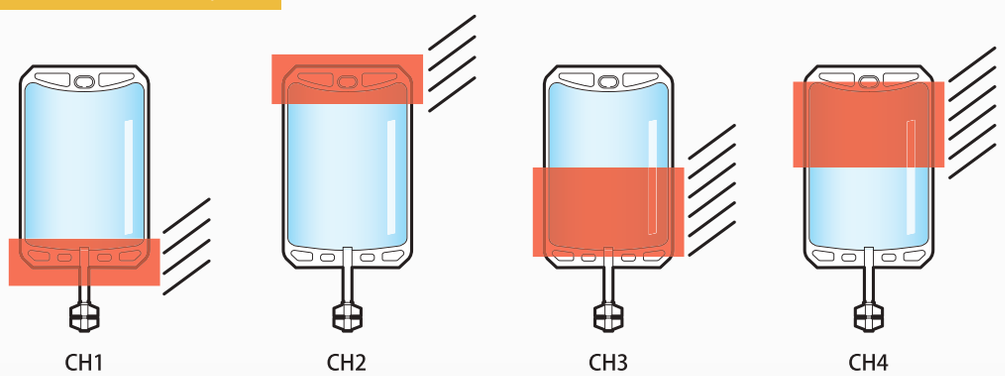
- High-speed processing machine.
- Inspects entire body evenly.
- Detection at key points such as sealing and port welding with inspection electrodes that fit to product shape.

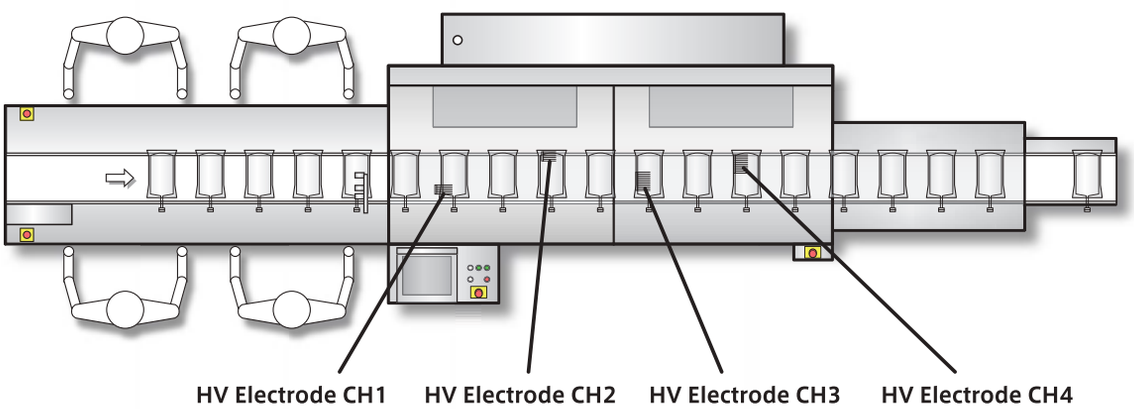
HDK-4-ER



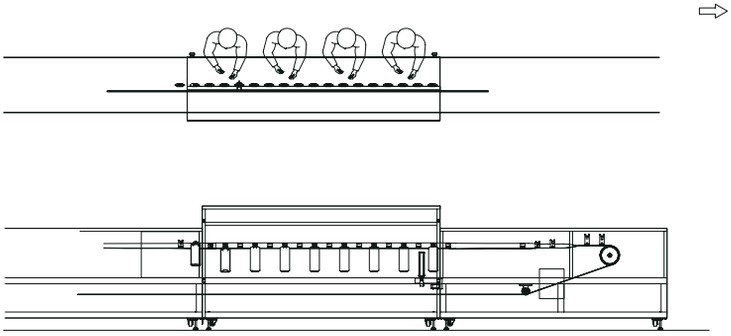
Unit : mm

Inspection Area (Example)

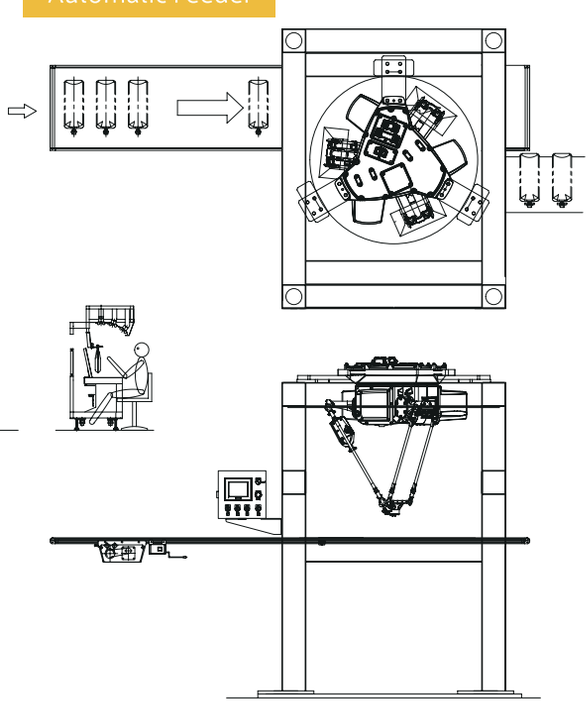




Visual Inspection Station



Automatic Feeder



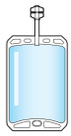
Integration of pinhole inspection machine
with visual inspection station.
It saves space and cost.

Specifications

Inspection Station	4+ Channels
Processing Capacity	Up to 100 pcs/min (100 – 1000 mL)
Power Consumption	5.0kVA
Power Supply	200 – 480VAC, 50/60Hz

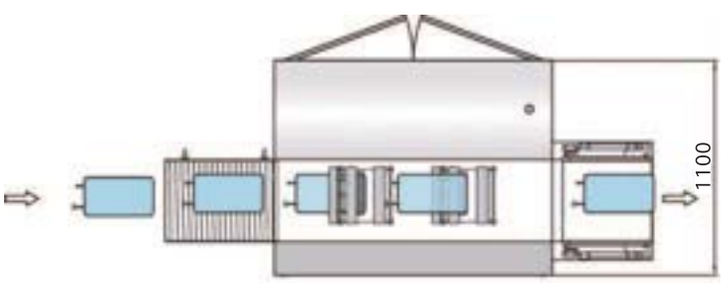
HDG Series

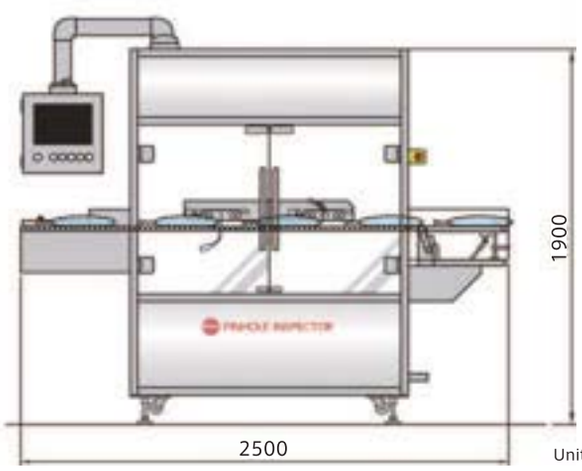
For Bag



- Versatile bag inspection.
- Small footprint.
- Customizable for both inline and offline applications.

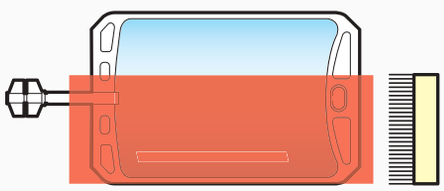
HDG-2-ER





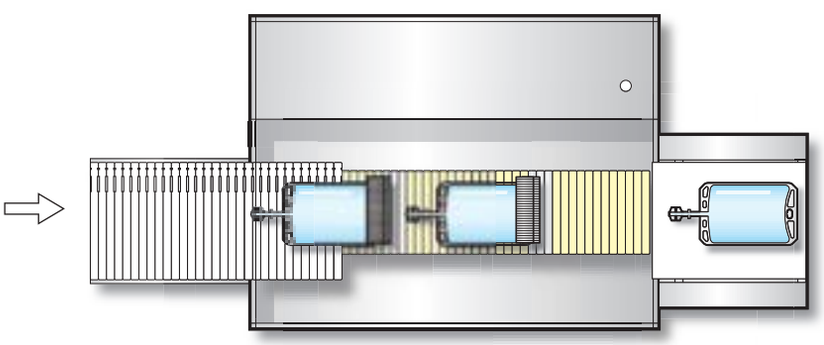
Unit : mm

Inspection Area (Example)



HV Electrode CH1

HV Electrode CH2

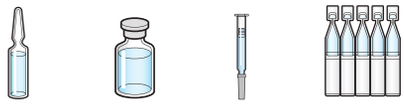


Specifications

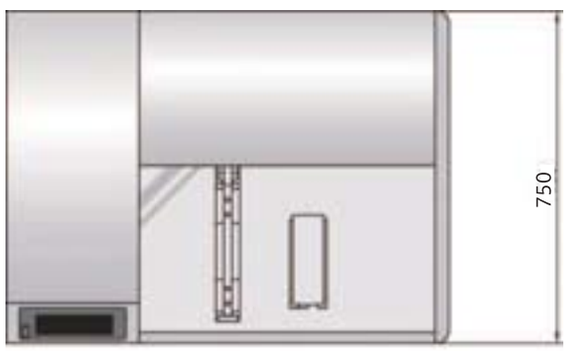
Inspection Station	1 – 2 Channels
Product Volume	100 – 1000mL
Processing Capacity	Up to 70 pcs/min, specific speed by request
Power Consumption	3.0kVA
Power Supply	200 – 480VAC, 50/60Hz

HDL Series

Semi-automatic Type



- For sample inspection and laboratory use.
- Compatible with different containers.
- Inspection area is customizable.
- Optimal for AQL testing.



Unit : mm

Specifications

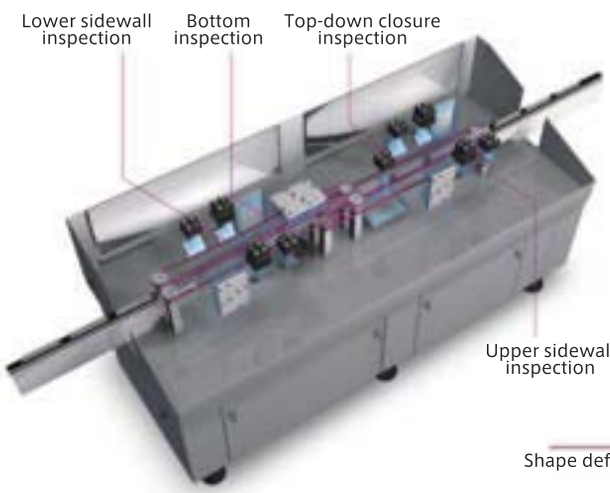
Inspection Station	1 channel
Power Consumption	0.5kVA
Power Supply	200 – 480VAC, 50/60Hz

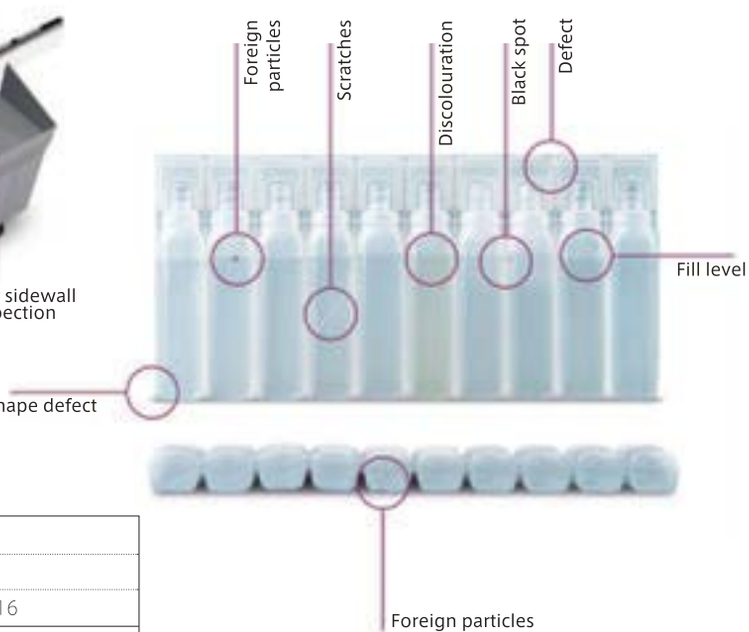
BLOW FILL SEAL AMPOULE INSPECTION

HEUFT *spotter*^{II} *BFSA*

100% complete inspection and integrity testing of Blow Fill Seal ampoule cards

- Identification and rejection of BFS ampoule cards with the illustrated quality and integrity issues – see picture
- State-of-the-art optomechanics and sophisticated transport design for full coverage during optical inspection.
- Full detection and rejection reliability thanks to adaptive lighting and intelligent image processing, filtering and subtraction technologies developed in-house and tailored to specific inspection tasks.
- Automatic programme and format changes with self-adjusting sensors, cameras, LED units and conveyors.
- Space-saving linear system with no format parts for reduced wear and maintenance.
- Future-proof network connectivity, e.g. for full audit trail documentation and online remote maintenance.
- Compliance with FDA, GMP, GAMP5 and 21 CFR Part 11 requirements.





Specifications	
BFS Strip Size	Height: 50mm to 130mm
	Length: up to 300mm
	Single ampoules / strip: 1 – 16
Processing Capacity	Single ampoules / hour: up to 70,000
Power Supply	400V ± 10%, 50/60Hz

Headspace Gas Analyzer

GASPOROX
LASER SENSOR PACKAGE SOLUTIONS

- Headspace gas analyzer for non-intrusive measurements in vials.
- Non-destructive during production, storage or laboratory quality testing.
- GASPOROX sensors allow fast and reliable inspection of parenteral pharmaceuticals in vials.
- Test results will be presented instantly.
- An infrared light passes through the gas headspace of the container and precisely measures the concentration of oxygen.
- The laser light is completely eye-safe.
- The method is non-destructive, deterministic and recommended by USP1207.

Advantages

Reliable Oxygen Sensing
Non-destructive testing
Low headspace measurement
Instant inline spot-check
Easy to operate

CCIT approach for lyophilized vials

- Vials are sealed under near vacuum conditions that result in low oxygen concentration.
- Poor seal or pinhole draws air into the container which results in the increase of oxygen concentration.
- By measuring headspace oxygen concentration, the leaking vials will be identified.

Defective product

High oxygen concentration

Good product

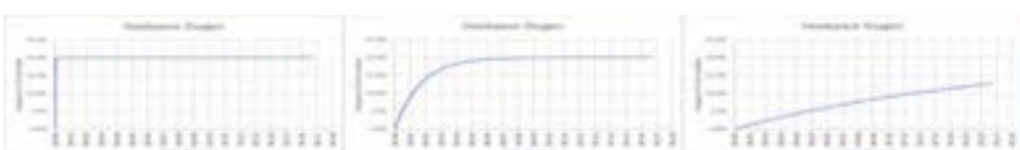
Near zero oxygen concentration

Leak size and oxygen concentration with respect to time

LARGE LEAK

MEDIUM LEAK

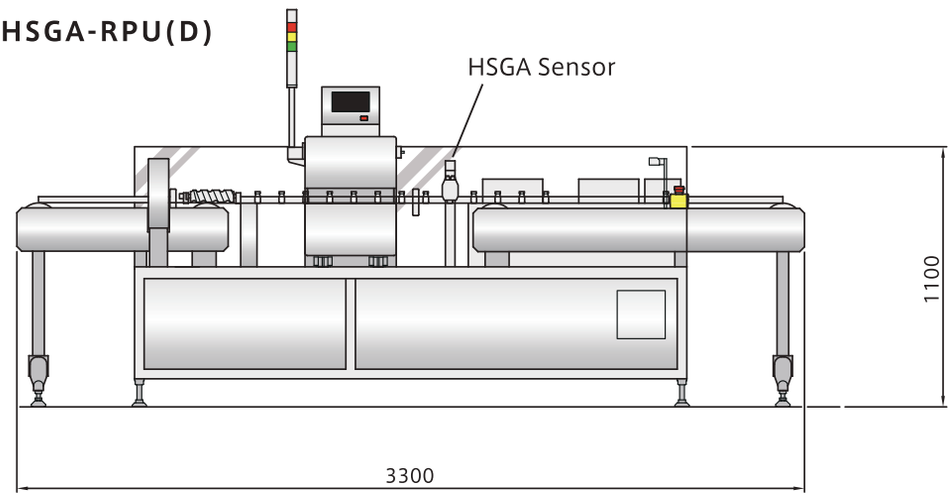
SMALL LEAK



Combination of HSGA with Magnetized Metal Detector and HVLD for Vial

Combination of HSGA with Magnetized Metal Detector

NMDV-8B+HSGA-RPU(D)

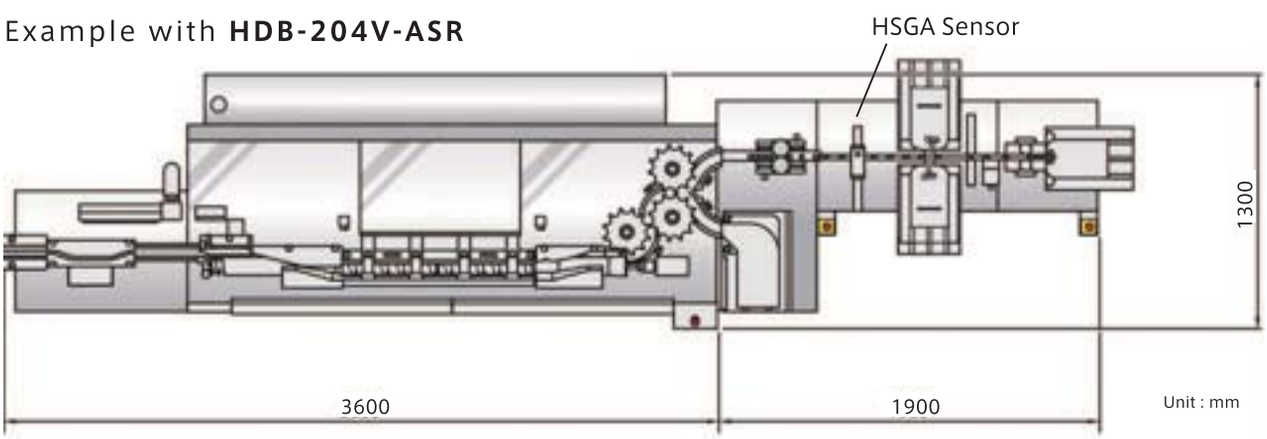


- Metal detector and HSGA combination machine detects metal particles in a Lyo product and inspects the integrity of the vial closure.
- It is capable of detecting SUS304 ϕ 0.2㎜× 2㎜ metal particles and speed up to 300 vials/min.
- Vial sizes up to 30mL can be inspected.
- Such a combination is a suitable way to ensure product safety.
- After passing through the magnetic field, magnetic material such as stainless steel in vial will be detected by the special magnetic sensor, while aluminum cap that is not magnetic material does not affect the inspection.

Specifications	
Processing Capacity	Up to 300pcs/min
Vial Size	Up to 30mL
Power Consumption	5kVA
Power Supply	200 - 440VAC, 50/60Hz

Combination of HSGA with HVLD

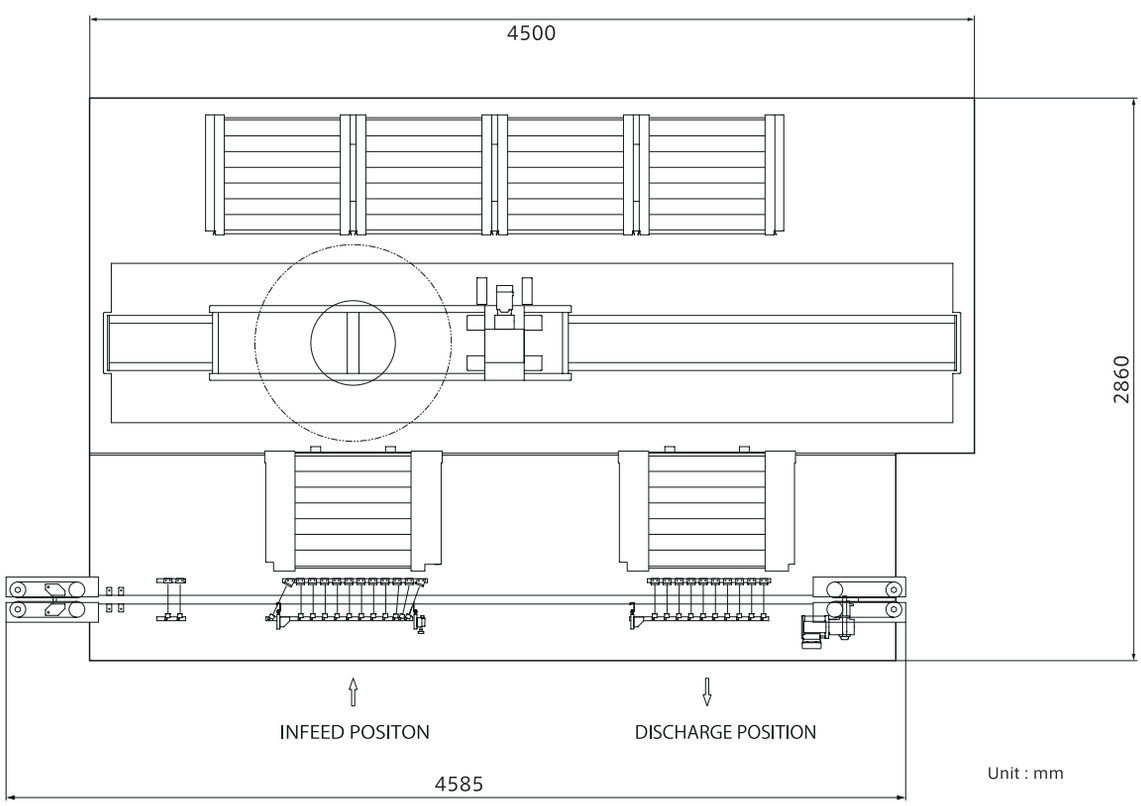
Example with **HDB-204V-ASR**



- Combination of HDB-204V pinhole inspector and HSGA is a perfect solution as CCIT for vial products. It can detect leak of vial filled with both liquid and lyophilized product.

BFS Buffer System

- BFS buffer unit is available with HDI series pinhole inspector.
- This system allows you to continue production by running the upstream BFS machine in case any machine in the downstream packaging line stops.
- This unit can hold up to 8,100 cards.
- Made in Japan by KOYO Automatic Machine Co., Ltd.



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Product Lineup by Nikka Densok

- Metal Detector
- Check Weigher
- Check Weigher with Metal Detector
- Magnet System
- X-Ray Inspection System
- Pinhole Inspector
- Seal leak Inspector
- Security System
- Optical Measuring Instruments
- Rejector
- BFS Cosmetic / Particle Inspection Machine
- Headspace Gas Analyzer
- BFS Buffer System

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