Product Specification Sheet

BST Trace-It® Detectable Pen | TRACE*

The BST Trace-It® Detectable Pen

These Trace-It® pens are an economical alternative to our premium pens which feature a metal detectable and x-ray visible plastic body and insert which is made from our specially formulated xdetect® Polypropylene compound. With a blue or red body for visual identification and blue, black and red ink options, as well as clipped and looped models available, these pens are designed to be the perfect addition to your food production areas. They are compliant with EU and FDA food contact legislation and the ink conforms with ISO 12757-2 for documentary use.

The BST Trace-It® Detectable Pen Advantages

- ✓ Detectable by in-line metal detection systems and x-ray inspection systems
- ✓ Available in two body colours for easy visual identification (Varies per model)
- ✓ The ink complies with ISO 12757-1 for general use and ISO 12757-1 for documentary use
- ✓ Strong, durable, shatter resistant, and chemically resistant
- ✓ Compliant with EU and FDA, including mandatory EU migration test standards
- ✓ Can be used as part of HACCP and BRC procedures
- ✓ Write out length of 9,000m +/- 30%
- ✓ Clipped and looped* versions are available and bespoke printing can be added if requested
- ✓ Displays due diligence in the prevention of foreign body contamination

**Looped models are only available in blue body*

Product and Packaging Information

Product Code	TRACE*	**Cartridge**	Stainless Steel
Pack Size	50	**Cartridge End Plug**	Detectable POM
Pack Weight	0.55kg	**Write Out Length**	9,000m +/- 30%
Body Colour(s)	B,R	**Detectability**	Metal & X-Ray Visible
Ink Colour(s)	B,K,R	**Country Of Origin**	Britain
Housing Material	BST XDETECT®	**Commodity Code**	96081010

Ink Specification

- ✓ Temperature Range 5 ~ 30°C
- ✓ Unpressurised ink
- ✓ ISO 12575 - 2 DOC G2
- ✓ ISO 12575 - 2 DOC H
- ✓ ISO 12575 - 2 G2
- ✓ ISO 12575 - 2 DOC A2
- ✓ ISO 12575 - 1 A M
- ✓ TSCA Listed (USA)
- ✓ ISO 12757 - 1
- ✓ ISO 12757 - 2
- ✓ Conforms to REACH standards

Safety Certificates / Approvals

FDA Approved	BRCGS Compliant	ISO 9001:2015
EU Compliant	Made In Britain	

Food Contact Status (EU)

Hereby we declare that the material XDETECT® in various colours is manufactured in line with the relevant requirements of 2023/2006/EC as amended by Commission Regulation (EC) 282/2008, on good manufacturing practice (GMP) for materials and articles intended to come into contact with food.

The raw materials used in the manufacturing process of the above mentioned materials (XDETECT® in various colours) can be considered suitable for food contact applications in terms of compliance with European regulations. The raw materials used meet the relevant requirements of EU Framework Regulation 1935/2004 on materials and articles intended to come into contact with food.

All monomers, starting substances and additives used to manufacture these grades are listed in Commission Regulation (EU) No. 10/2011 as amended by (EU) 321/2011, (EU) 1282/2011, (EU) 1183/2012, (EU) 202/2014, (EU) 2015/174, (EU) 2016/1416, (EU) 2017/752, (EU) 2018/79, (EU) 2018/213, (EU) 2018/831, (EU) 2019/37, (EU)2019/1338, and (EU) 2020/1245 respectively, related to Plastic Materials and Articles intended to come into contact with foodstuffs.

Colourants used are compliant with European Council Resolution AP(89) 1 on the use of colourants in plastic materials coming into contact with food, and also with German BfR Recommendations (IX).

BST Detectable Products hereby declare that articles manufactured from BST XDETECT® are, according to EU regulations, authorised to come into direct contact with all types of foodstuffs at a maximum temperature of 40°C for a maximum time period of one hour.

Food Contact Status (FDA)

The polypropylene base resin used in XDETECT® meets the FDA (Food and Drug Administration) requirements contained in the Code of Federal Regulations in 21 CFR 177.1520 (a) (3) (i) , (b) and (c) (3.1a). At the same time this base resin grade meets the FDA criteria in 21 CFR 177.1520 for food contact applications, excluding cooking, listed under conditions of use C through H in 21 CFR 176.170 (c), Table 2., and can be used in contact with all food types as listed in 21 CFR 176.170 (c), Table 1. Also the mineral additives and the pigments used are GRAS (Generally Recognized As Safe) or are FDA cleared under specific FDA citations.

Food Contact Status (Japan)

The base resin (PP copolymer) used in the manufacturing process of the above mentioned compounds is listed in the Positive List of Base Polymers (Table 1). The additives used in the manufacturing process of the PP-C resin are listed in the Positive List of Additives (Table 2) authorised for use in this base resin.

ISO Standards

This ink conforms with ISO 12757-2. For documentary use, to assure the legibility of lettering and for the handling and storage of documents during long periods of time. Testing of light resistance to a minimum of 5 years.

Animal Derivatives

To the best of our knowledge there are no ingredients in the formulation of this material that is of animal origin. As such, this material should not pass on any animal derived disease like BSE (Bovine Spongiform Encephalopathy) or other TSE (Transmissible Spongiform Encephalopathy).

Migration Testing

The following overall migration results for XDETECT® were obtained using a UKAS accredited laboratory, with overall migration simulants and conditions as detailed in EU Regulation No 10/2011 as amended, on plastic materials and articles intended to come into contact with food.

Sample: PP-C-2013/393
Test conditions: Simulants A, B and 95%v/v ethanol: 10 days at 40°C. Iso-octane: 2 days at 20°C

Method	EN-1186-3 Migration into 10% v/v Ethanol (Simulant A)	EN-1186-3 Migration into 3% w/v Acetic Acid (Simulant B)	EN-1186-14§ Migration into Iso-octane (Substitute test)	EN-1186-14§ Migration into 95% Ethanol (Substitute test)
Replicate #1	0.2 mg/dm2	0.5 mg/dm2	19.4 mg/dm2	0.8 mg/dm2
Replicate #2	0.3 mg/dm2	0.5 mg/dm2	21.0 mg/dm2	0.9 mg/dm2
Replicate #3	0.0 mg/dm2	0.3 mg/dm2	20.8 mg/dm2	0.6 mg/dm2
Mean Result	0.2 mg/dm2	0.4 mg/dm2	20.4 mg/dm2	0.8 mg/dm2
EU Limit	10.0 mg/dm2	10.0 mg/dm2	#20.0 mg/dm2	10.0 mg/dm2
Tolerance			#6.0 mg/dm2	

#Limit and tolerance are quoted after the application of a fatty food reduction factor of 2 as quoted in EU Regulation 10/2011. To summarise the overall migration test results, the PP-C-2013/393 complies with the overall migration requirements given in EU Regulation 10/2011, as amended, with regards to use with all non-fatty foods, aqueous foods and fatty foods that require a reduction factor of 2 (or greater), as given in EU regulation 10/2011, as amended.

Metal Detectability Testing & Results

BST DetectaPens® are made using XDETECT®, an electromagnetically detectable and x-ray visible plastic compound. Within the pen housing is a stainless steel ink cartridge. The metal detectability of this product will vary based on, but not limited to:

- Calibration Levels
- Product Type (E.g. Wet, Dry, Frozen, Liquid)
- Aperture Dimensions
- Orientation

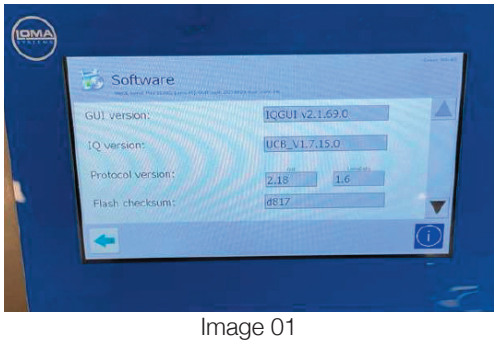


Image 01


(Product H)

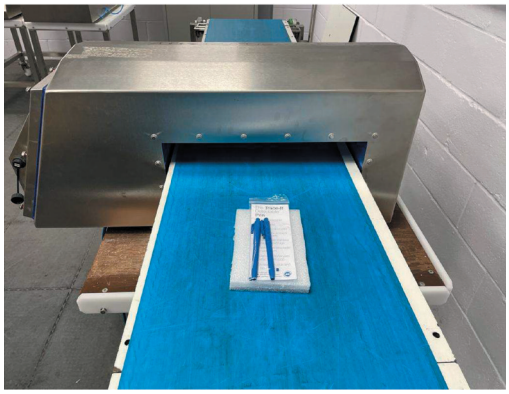
Orientation is a highly influential factor for the metal detectability of a contaminant that is non spherical, i.e. it will be easier to detect the contaminant when passing in one orientation compared to another - this is known as the orientation effect. During testing of the BST DetectaPen® we used a worst case scenario which is through the geometric centre of the aperture and in the worst case orientation. We used a piece of form and set it up in the machine as the main product (H), in order to pass the contaminant on top. The product (H) has been set up in the IQ4H 100mm aperture height metal detector (image 01 indicates the version of the software used) at 25 m/min belt speed. Please note, the following results are applicable only to the product (H) or similar and that detection performances vary with the main product and packaging type.

Metal Detectability Testing & Results Cont.

Machine Settings:

Belt Speed	Head Gain Settings	Frequency	Threshold	Phase Angle
25 m/min	I Gain = Low Q Gain = Max RF Gain = Med Head Drive - Max	625kHz	100	121.7

Product passes through the centre of the aperture:



(Length 140mm Width 35mm Height 18mm)

(Product A)

Please refer to the below table for results of the full product sample and the smallest peice detected an signals:

Complete Product	Reject Signals	Samllest Piece Detected	Reject Signals
Trace-It DetectaPen (Product A)	I / Q Saturated (Very Good Reject Signals)	5mm in length and width	1400-1700

X-Ray Visibility Testing & Results

In contrast to metal detection, x-ray visibility is determined by material density. For this reason, XDETECT® contains an additional, evenly dispersed, food safe, high density additive.

Based on our experience and testing, positive readings should be consistent both for whole pens and XDETECT® fragments as small as 3mm. X-ray detection performance will be reduced when small fragments are buried in deeper, denser products - detection will depend on product type and density. We highly recommend that all our products be thoroughly tested on your x-ray inspection systems by a trained and certified professional. It may be the case that your equipment needs to be recalibrated in order to reliably detect this product. Such a professional should be available by contacting the manufacturer of your x-ray inspection system.

We calibrated and set up the product (G) as the main product, in order to pass the contaminant on the top, to see whether we were able to detect it. The product (G) has been set up in the X5 Mark IV Space Saver machine with the standard lightweight curtians and equiped with a 4.0mm diode detector set to FINE AAT at 25 m/min belt speed. Please see the following page for the machine settings and results.

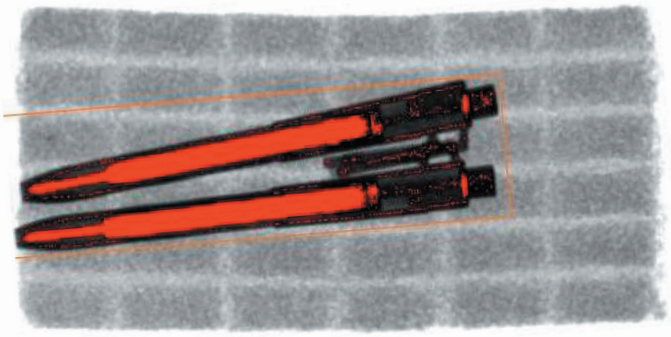
(Product G)

X-Ray Visibility Testing & Results Cont.

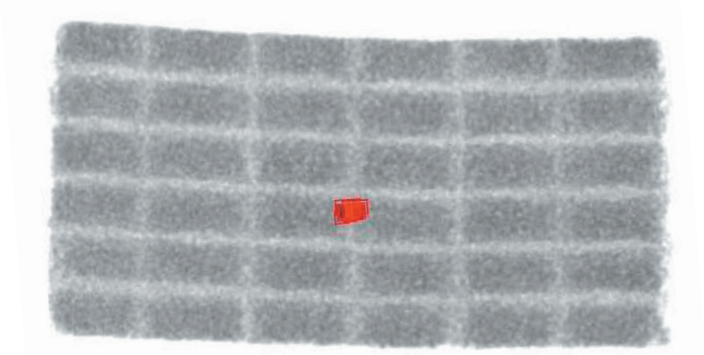
Machine Settings:

Scan Settings	Image Processing	Basic	Explorer
CalKV = 4.0 CalMA = 2.0 RunKV = 40 RunMA = 2.0 Gain = High Sensitivity = High Belt Speed = 25 m/min	Gamma = 80 Lower Range = 10 Upper Range = 90	Auto Learn	Auto Learn

Please refer to the below images for results of the full product sample and the smallest peice detected:



Complete Trace-It DetectaPen (Product A)
Length 150mm Width 35mm Height 18mm



The smallest piece detected from Product A is 3mm

Please note that the pen clip cannot be detached from the pen without extreme force or the use of tools. Generally speaking, the only circumstances where by such a small pen component could be introduced to food product would be through deliberate action or the pen going through an extreme process such as crushing, blending, mincing etc.

All of the above results are based on our own testing, and is supplied purely for customer convenience. Different detector systems will feature different sensitivity settings, as well as settings for different product types (E.g. Wet, Dry, Frozen, Liquid).

For this reason BST recommend that all our products be thoroughly tested on your metal detection systems by a trained and certified professional. It may be the case that your equipment needs to be re-calibrated in order to reliably detect this product. Such a professional should be available by contacting the manufacturer of your metal detection system.

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