

Product Specification

Item Code: Product Name:

TP464 Timestrip® Blood 10+



General:

The Blood 10+ blood bag indicator is a temperature—sensitive indicator that can be used by blood banks and transfusion services to maintain quality control in blood transportation and temporary storage.

When applied to a pre-chilled blood bag, Blood 10+ can now either be transported right away or returned to the refrigerator temporarily, for future use*.

Blood 10+ senses the blood temperature. Any breach of the blood temperature above 10°C will be indicated on the breach window by the appearance of blue colour. The breach period is correlated to the printed time marks (1/2, 1, 2, & 3 Hrs.).

* Blood 10+ may remain on a stored blood bag as long as no indication is observed.

Instructions for Use:

- Select a Blood 10+ indicator and implement a QC visual test: make sure that the indicator is not activated - the arming window should be yellow and the breach window should be white.
 Blood 10+ does not require pre-conditioning.
- 2. Note: the activation button can only be squeezed when the Blood 10+ is at or above 10°C.
- 3. Remove the pre-chilled blood bag from the controlled refrigerator $(2^{\circ}C/36^{\circ}F 6^{\circ}C/43^{\circ}F)$. Select a suitable location on the blood bag for the Blood 10+ (for example, the lower 1/3rd of the blood bag, if stored upright). Ensure this area is oil & moisture free.
- 4. Firmly squeeze the button located on top of the indicator, between thumb and forefinger. Verify that the arming window changes colour immediately from yellow to dark green.
- 5. Immediately after activation, peel off the liner and firmly adhere the Blood 10+ to the prepared location. Verify full adhesion to the blood bag.

Monitoring has begun!

Blood 10+ does not need post- conditioning once on a pre-chilled blood bag, which can now either be transported right away or returned to the refrigerator for future use. Blood 10+ may remain on a stored blood bag as long as no indication is observed.

Date: January 15, 2020

I) Performance Specifications:

• Threshold temperature 10°C/50°F

• Temperature Accuracy: 9° - 10°C /48°F - 50°F

• Display: Irreversible

• Breach Time Periods: 1/2, 1, 2 & 3 Hrs.

II) Product Specification:

• Blister Position: Button on Top (BOT)

Colour of breach window
 Blue

during a breach event:

• Adhesive: DuploCOLL® 3720 – for reverse coating of labels

employed for labelling blood bags - see Appendix 1

Product drawing: See Fig. 1Graphics: See Fig. 2

• Other: Not suitable for immersion in water

III) Product Construction:

The indicator is constructed of polymeric assembly multilayer and aluminium-plastic laminate. It encapsulates coloured liquid chemicals*.

- * Maximum weight of colorant is <0.5 mg.</p>
- ** Liquid chemicals are listed in the Food Chemicals Codex and/or approved by the Food and Drug Administration (FDA) under Title 21, and/or considered generally recognized as safe (GRAS).
- *** All materials are non-toxic, latex and PVC free.

IV) Packaging & Presentation:

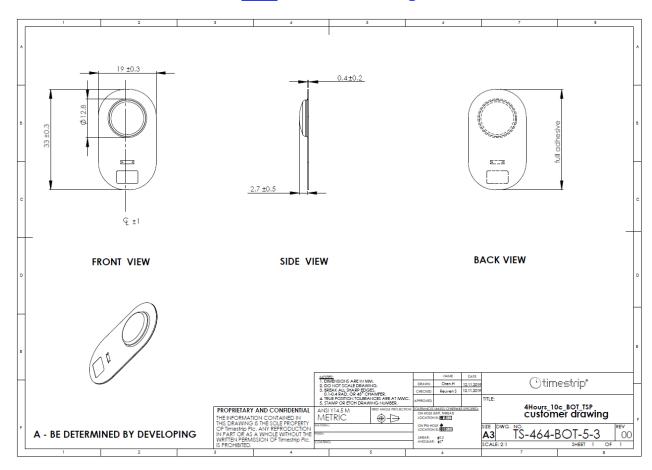
Singles in a box of 100 products.

V) Storage Conditions (un-activated):

• Store indoors, at room temperature up to 30°C.

VI) <u>Shelf-life</u>:

• 2.5 Years from date of manufacture.



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Fig 1: Product Drawing

Fig 2: Graphics



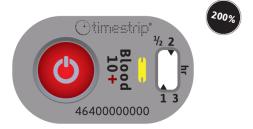




After





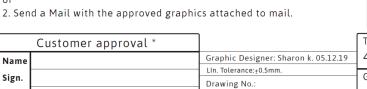


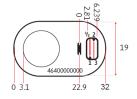


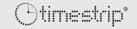
*For Approval:

1. Print out, sign and Fax to +972-9-8991347

Date







Title:		
4Hours_10c_BOT_TSP		
Graphic no.	Rev. 5	
800-464	SH. 1 OF. 1	

Printing DWG: TSP2-L-00000

Appendix 1

DuploCOLL® 3720

Art. No. 11 01 15

Double-sided adhesive tape with special paper carrier for universal applications

Specific technical data* Temperature range -40 °C to +150 °C** Peel strength on polypropylene after 24 h at room temperature 21 N/25 mm Peel strength on polyethylene after 24 h at room temperature 17 N/25 mm Certified and recognized according to UL 969

^{**} Reached temperature in a rising heat test according to the internal test method PM-211 following DIN EN 1943 at 1 kg strength, beginning at 30 °C, increasing of temperature every 30 minutes by 10 °C

Technical Data			1
Shear strength	on steel according to DIN EN 1943, edition 1996, at +23 °C +/- 2°C	40 N/625 mm ²	
Peel strength	on steel according to DIN EN 1939, edition 1996, at +23 °C +/- 2°C	30 N/25 mm	, M

Product features		Applicability on	
Initial adhesion Final adhesion Dimensional stability Adhesion on even surfaces Adhesion on rough surfaces Ageing resistance Weathering resistance Chemical resistance Resistance to plasticizers • • • very suitable • • suitable • •	 • • ○ • • ○ • • • ○ • • • • • • ○ • suitable with reductions 	Foam Rubber Fabric Glass/Ceramics Wood High energy plastics: PVC, PC, ABS, Low energy plastics: PE, PP, Metal Paper/Cardboard O O not suitable	

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Document information

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Graphics	800-464	05	05.12.19
Product Drawing	TS-464-5	00	12.11.19
Adhesive	DuploCOLL 3720		04/2019
Product Specification Sheet		01	15.01.20

^{*} Specific test results, statistically not approved.