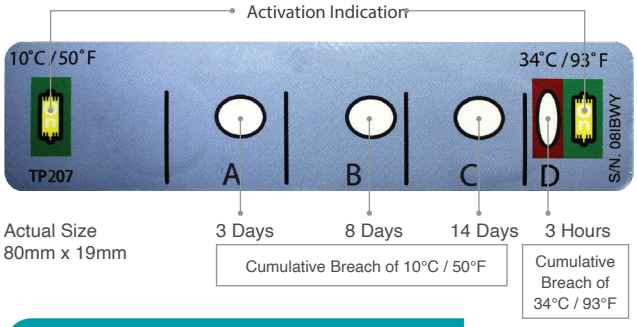
Product Specifications

TempDot® Plus Duo

A temperature abuse indicator for vaccines



Item#:17010032 Model 51063

How long has this vaccine been kept above its maximum recommended storage temperature? Has it also been exposed to excessively high temperatures?

TempDot® Plus Duo provides a low cost and accurate answer to both questions. Duo is a small and self-adhering double temperature indicator. It monitors two ascending temperature thresholds in one label and indicates:

- If cold chain conditions have been compromised (breached 10°C/50°F) and if this abuse has lasted for 3 days (A), 8 days (B) or 14 days (C).
- The vaccine has been exposed to very high temperatures (34°C/93°F) and irreversibly records when this abuse has lasted for 3 hours.

Duo's technical specifications follow World Health Organization (WHO) recommendations for monitoring vaccine temperature and reflect the tolerances allowed for different vaccines. Duo can also be used to monitor supply chains for medicines or other products for which the specified time and temperature thresholds are relevant.

Duo is inert until activated so it can be stored safely at room temperature and can be activated in the field. Duo can be ordered from stock via our distributors, including small order sizes for samples/trials. Duo can be customized to combine different temperature thresholds or different time markers. Custom projects are subject to minimum order size, minimum technical specifications and additional cost. Please contact us for more information.



Flexible Use and Storage	Duo is inert until activated, so it can be stored at ambient temperatures and activated when required in the field.
Reliable Evidence	Duo is single use, irreversible, and accurate to within +/-1°C/2°F.
Targeted Decision Making	Duo is small, light, and cost effective enough to support the monitoring of many packs within a consignment; pockets of temperature abuse can be identified.
Easy to Read	Duo is visually clear and easy to interpret so handlers can quickly and confidently recognise temperature abuse. Clear and visible monitoring may also encourage a greater duty of care.
Quality Assured	Duo is manufactured to ISO9001:2015; is process and batch validated, and each indicator has a unique serial number. It is patented, safe, and disposable.
Cost	Duo is a low cost solution that requires no power. It is a cost effective and practical replacement for data loggers.

DeltaTrak®

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Product Specifications

How duo works

All TempDot® Plus Duo indicators work as follows. A mixture will melt from solid to liquid form when an ascending temperature threshold is breached and return to solid form if the temperature falls again to its freeze point (STOP temperature). When in liquid form, the mixture will move laterally through a porous membrane at a known rate. The progress of the liquid will be visible through a viewing window.

Once TempDot® Plus Duo is activated, if the temperature being monitored remains below the STOP temperature, the blue colour will not move. If the threshold is breached, the blue colour will progress to a viewing window with time markers. Each movement is irreversible so the cumulative time of any temperature breach is shown by how far the blue colour has moved along the time markers.

With Duo, the blue colour will completely fill window A after 3 days of a breach of 10°C, window B after 8 days, and window C after 14 days. A different blue formulation is contained in the 34°C indicator. It will melt and completely fill window D three hours following a breach of 34°C.

Specification

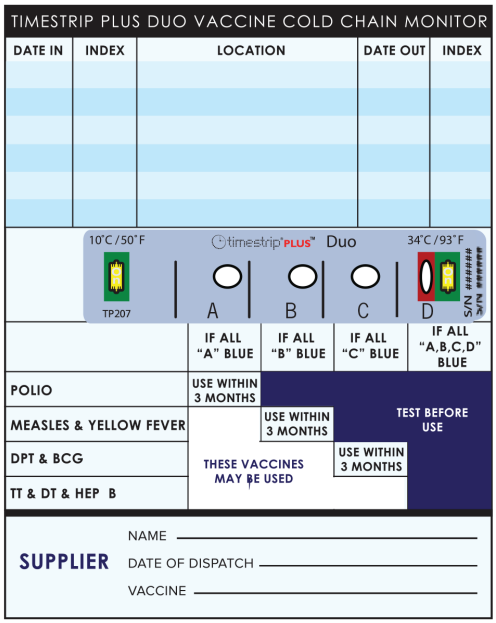
Type	Irreversible, single use
Activation Feature	2 manual activation buttons on the back – 1 for each temperature threshold. Both 'On' windows turn green.
Indication	Windows A, B, C or D turn blue if thresholds are breached for the time thresholds indicated.
Temperature & Time Thresholds (A-C)	Threshold of 10°C/50°F and STOP of 8°C/46°F. Time markers; 3 days (A), 8 days (B) and 14 days (C).
Temperature & Time Thresholds (D)	Threshold of 34°C/93°F and STOP of 30°C/86°F. Time marker; 3 hours.
Accuracy of Temperature	+/-1°C/2°F
Accuracy of Time	+/- 15% in isothermal conditions
Size	80 mm x 19 mm
Quality Assurance	Produced under ISO 9001:2015

Shipping & Handling

Recommended Storage	Room temperature: 22°C/72°F at 20-80% humidity. Cool, dark environment
Shipping Package Requirements	No special requirements as inert until activated
Protection	Splash proof
Traceability	Unique serial number on each indicator
Shelf Life	Inert: 3 years from manufacturing date. Post activation: Until shows breach/ 1 year.

Application - Duo

Duo can be applied directly onto product packaging or a vaccine monitoring card which clearly explains to the end user how to interpret the display windows. The example provided shows how the usage requirements of different vaccines can be accommodated by a single Duo label.



Duo on a vaccine monitoring card

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How to Use TempDot® Plus Duo

1. Storage- Inactive

Ideally, store at room temperature, 20-80% humidity & in a cool, dark environment. Duo is inert prior to activation. All the windows are white. Discard before use any indicator that does not have all its windows white.

2. How To Activate

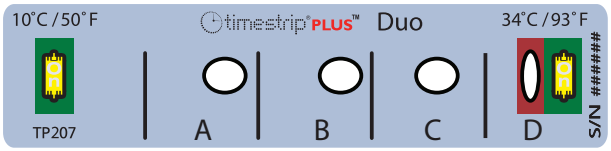
Activate the 34°C indicator first. Raise the temperature above 35°C (and not greater than 60°C) and fully press the button above D. The activation window on the right should turn green and reveal 'ON'. In the event that it doesn't, re-heat and press the button fully.

Then press the 10°C indicator button fully until the left side activation window turns green and 'ON' is revealed.

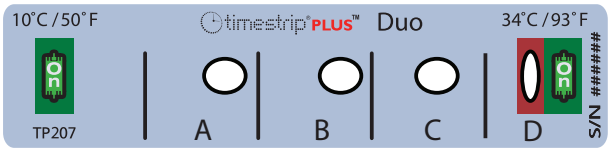
Within 5 minutes of activation, place Duo below 8°C for a minimum of 1 hour to ensure the liquid freezes again. Duo is then ready to use. You can adhere the indicator immediately to a package or carrying card, which is already below the STOP temperature of 8°C. Alternatively, place the activated indicator in an environment much colder than the STOP temperature for a short period of time and then attach it to the carrying card or package.

3. Review

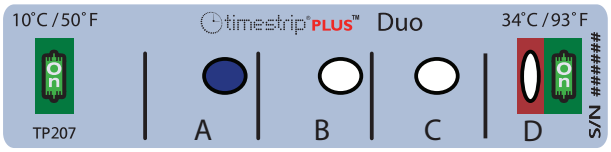
Once correctly activated, Window A will completely fill with blue if the threshold temperature of 10°C has been breached for 3 days, window B for 8 days, and window C for 14 days. D will completely fill with blue if 34°C has been breached for 3 hours. Duo shows clearly if vaccines or medicines have been exposed to temperature abuse, and for how long.



Inactive

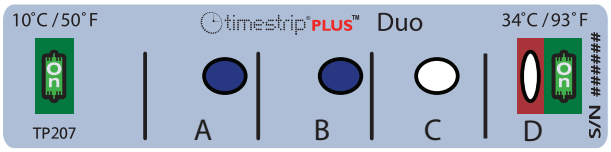


Activated and N OT breached



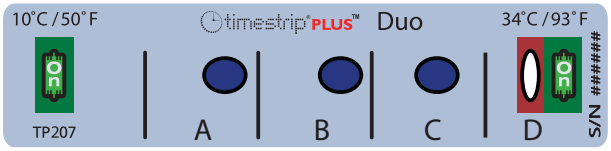
Breached 10°C

Breaches of 10°C occurred for 3 days, but less than 8 days



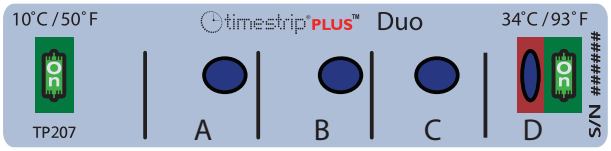
Breached 10°C

Breaches of 10°C occurred for 8 days, but less than 14 days



Breached 10°C

Breaches of 10°C occurred for at least 14 days.



Breached 34°C

Breaches of 34°C occurred for at least 3 hours.

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