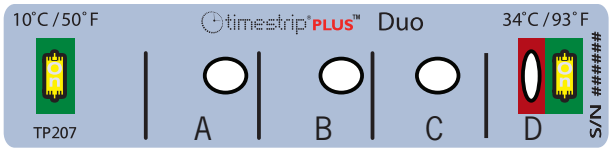
the smart way to measure time & temperature

Timestrip® PLUS Duo FAQ



What is Duo?

Timestrip® PLUS Duo puts two temperature threshold indicators side by side into one handy label format.

The indicator on the left shows if temperatures have breached the cold chain threshold of 10°C/50°F and for how long, with time markers for 3, 8 or 14 days. It is activated by pressing the blister on the back underneath the activation window. The indicator on the right shows if temperatures have breached an extreme of 34°C/93°F and for how long, with one time marker for 3 hours. It has its own activation blister, again on the back.

How can I use Duo?

Duo has been engineered to comply with World Health Organisation recommended monitoring requirements for Vaccines. That is why it combines a threshold indicator of 10°C/50°F with 3, 8, and 14 day time markers and a 34°C/93°F indicator showing 3 hours of breach. However, there is nothing to prevent Duo being used to monitor other products if these time markers and threshold temperatures are suitable. It is also possible to manufacture Duo for other temperature thresholds. (See FAQ on customising Duo).

What are the key advantages of Duo?

Duo indicators require no power, are single use, record temperature abuse irreversibly and can be instantly read by the end user. They have unique serial numbers to ensure the traceability of each unit and can be used at the carton or single unit level. Using Duo at multiple points within a shipment or container can isolate unacceptable temperature pockets.

They are lower cost, more immediate and can operate at smaller unit levels than electronic data loggers. Data loggers provide a full history of temperature from the time of activation. Duo records how long a vaccine has been above its threshold temperature (up to 14 days for the 10°C threshold) but cannot tell you when the breach or breaches occurred.

How does Duo work?

A blue dye housed in a blister is held adjacent to a micro-porous membrane. Upon squeezing the activation button the liquid dye comes out of the blister and into contact with the membrane. If the temperature of the product is below the stated 'STOP' temperature, the blue dye changes state to solid form, and it is unable to move through the membrane. If the temperature rises to or above the threshold temperature, the dye changes to liquid form and moves at a precise rate through the membrane. Its progress is irreversible and the distance it travels through the viewing window indicates the cumulative time the indicator has been exposed to the threshold temperature or above.

The 10°C and 34°C threshold indicators use different liquid dyes which melt and solidify at different temperatures. The liquid dye in the 10°C blister has a STOP of 8°C/46°F and the liquid dye in the 34°C blister has a STOP of 30°C/86°F.

Why is there a start/threshold temperature and a STOP temperature?

The melting point of a solid is the temperature at which it changes state from solid to liquid. The freezing point (or crystallization point) is the temperature at which a liquid changes to a solid. For certain substances the melting and freezing point are not the same and the freezing point is lower than the melt point. This behaviour is called hysteresis. At the STOP point (freezing point) the dye can't move. At the melt point the dye moves and indicates a threshold breach.

Do I need to condition the products prior to activation?

No. Unlike some other threshold temperature products, Duo indicators do not require pre-conditioning.

However, you need to activate above the highest threshold temperature, as you cannot squeeze the dye out of the blister if it is in solid form. The temperature of Duo needs to be raised to 35°C/95°F to be able to activate both indicators and then dropped to the lower of the two STOP temperatures (8°C/46°F) to stop the progress of both liquid dyes. The fastest way to do this is by placing Duo in an environment much colder than the STOP temperature (8°C/46°F) for a short period of time.

Does Duo have any special storage requirements before activation?

No, unlike some other threshold temperature products, they can be held at ambient temperatures.

Is the liquid safe?

Yes. Please see our MSDS for further information. In the unlikely event that the liquid leaks from the Timestrip® and comes into contact with skin, simply wash with soap and water. If the liquid comes into contact with eyes, rinse immediately with plenty of water and seek medical advice

What's the shelf-life for Duo?

Duo has a shelf-life of 2 years from date of manufacture and a 1 year shelf-life once activated. An expiry date is provided for each batch of products supplied.

How accurate is Duo?

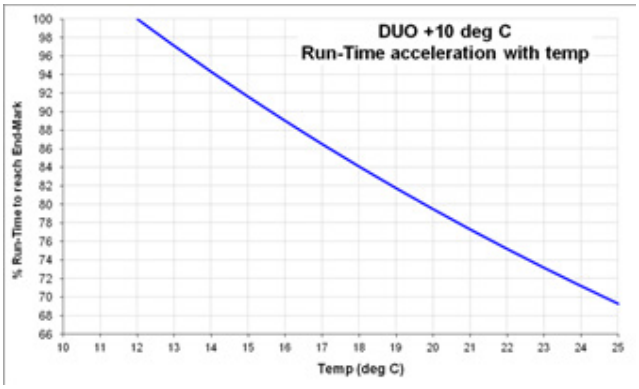
+/- 1°C for each temperature component and +/- 15% for each time component.

The run rate of the blue dye across the time markers is calibrated to a temperature of 2°C above the stated threshold temperature. For example, the time markers for the 10°C threshold indicator in Duo are calibrated to a temperature of 12°C/54°F. If the vaccine being monitored breaches its threshold temperature and is held at a constant temperature (i.e. isotherm) of 12°C, the blue mixture will reach the 3 day print mark within 3 days (+/- 15% in time).

What happens to the liquid viscosity at elevated temperatures?

Due to the nature of liquids, higher temperatures reduce the viscosity of the liquid dye in Duo. The correlated result is faster/shorter run-times (the progressing blue dye will reach each printed time-mark sooner than intended). This behavior matches most drugs, medicines and foods as they inherently degrade faster at higher temperatures.

The following graph is a generic representation of the run-time acceleration of the 10°C/50°F indicator in Duo.



The y-axis represents the actual run-time of the liquid at different temperatures, and is expressed as a percentage of the specified run-out time at an isotherm of 12°C/54°F. So, at an isothermal temperature of 12°C, the liquid dye will reach each time-marker (3, 8, 14 days) within these times +/-15% in time. However, if for example the product is exposed to an isotherm of 21°C/70°F the dye will reach each time marker within only 77% of the intended run-time. In other words, it will reach the;

- 3 day time-marker within approximately 2.3 days (77% of 3 days)
- 8 day time- marker within approximately 6.16 days
- 14 day time-marker within 10.78 days.

This run-out acceleration closely matches the WHO recommendation for the 10°C indicator of any vaccine temperature indicator. (see WHO/PQS/E06/IN02.1).

At a less extreme temperature elevation, say 15°C/59°F the blue dye will reach the 3 day time-marker at 91% of that time, or 2.73 days.

Why are there so many windows on the Duo?

The two yellow activation windows provide assurance that each of the indicators is armed. The four white run-out/breach windows are completely separate so it is clear if a temperature breach has occurred and for how long.

How are Duo indicators evaluated for their time accuracy?

Duo are polymeric multi-layer indicators. They are based on spontaneous lateral wetting by a blue liquid inside a porous substrate and not a chemical reaction. Each production batch (7000 – 8000 products) undergoes strict quality control tests to validate its time accuracy.

This is conducted via a computer vision software (TSCV) which analyses scanned photos of seven randomly-selected products from each batch (roughly 0.1% of the population). The photos are taken at different elapsed times and the tested products are placed at their designated temperature through the entire test period. The software automatically analyses the lateral progress and the elapsed time of each product tested and the data is presented numerically and graphically in a specific file which is labelled by batch. This data is translated into a final release report which is attached to the outgoing product batches.

What are your Acceptable Quality Limits?

The Accepted Failure Rate is based on ANSI/ASQC Z1.4 (formally MIL-STD-105E) Level II Normal Inspection. For Duo the AQL is 0.65%. Packs are over shipped by 2-3 units per 100 to cover this AQL.

Duo indicators go through extensive quality checks before they are shipped. Central to this process are tests against defined specifications for; run-time accuracy (how quickly the dye progresses through the membrane), environment sensitivity (high heat and vacuum tests to check resilience to harsh conditions during shipping) and also the accuracy of the threshold melting point. A full pack of release reports is provided with each shipment. Further details are available on request.

What if one of the indicators in my pack has got a green activation window or the indication window is already blue, before I've pressed the activation button?

If stored under the correct conditions, there is very little risk of auto-activation, but occasionally, this can happen, and the built-in activation window lets you know it. If a Duo indicator has auto-activated before use the arm window will already be showing green.

If this happens, discard the indicator and select another. There is no need to contact us, as we ship a few extra products per hundred anyway.

Can I get a false positive indication?

If the indicator is correctly activated false positives are extremely unlikely as the blue dye can only melt at or above certain temperatures. It is important to lower the indicator to its STOP temperature after activation and only attach it to a product, carrying card or material that is already at or below the STOP temperature to avoid premature indication.

Customising Duo FAQ

Can Duo be customised for different time markers and temperature thresholds?

Yes. The temperature thresholds and time marker specifications can be adjusted. It also possible to change the graphic to incorporate customer colours and logos. All custom orders are subject to a minimum volume and the cost and specification will depend on what is required and feasible. Please contact us for more information.

For a custom Duo, what temperature thresholds could be included?

Our single indicator range Timestrip® PLUS extends from -20°C/-4°F to 38°C/100°F. Many different pairings could be combined into a Duo. Please contact us for more information.

Our products have been tested at maximum and minimum temperatures between -30°C/-22°F and 60°C/140°F. Our products should not be exposed to temperatures outside of this range.

For a custom solution what are the minimum and maximum run-time windows that Duo can offer?

In theory, a minimum run-out of 5 minutes and a maximum of several years is feasible. However, there are many parameters that affect what combinations are feasible or appropriate. The required threshold, run-out markers and the size and shape of the indicator will all need to be taken into consideration in designing a custom solution.

Can you provide customised instructions with Duo?

We can provide a quote for printing custom carrier cards and backing labels for Duo.

Further Information FAQ

Do you make any other temperature indicators?

Yes. In addition to Duo and single indicator Timestrip® PLUS products we have three products designed for specific markets; Seafood, Food and Blood Temp 10 (for blood bags).

Do you make any other type of indicator?

Yes, we make Timestrip® timers. These are handy self-adhesive labels that monitor any elapsed time within the range of 5 minutes to several years.

Durations of 1, 3, 6 or 12 months can be ordered from stock or Timestrip® can be fully customised to suit your needs. They can be stuck directly onto a product or device and act as a simple visual reminder to replace an expired product or carry a task, like maintaining a machine or checking results from a test.

How can I find out more?

A full range of technical documents is available for each of our products including; a general information sheet with instructions for use, a test protocol, a specification and an MSDS. All these documents are available on our website.

Who do I contact to place a stock or custom order?

Many of our products are sold through distributors. Please contact us for more information.