TestingProtocol

Timestrip®3 Month RT BOT TS-172

### External validation of progress rate

Introduction:

This test has been designed in order to validate the progress rates of test products by matching the actual progress to a predictive isotherm curve, allowing for an accelerated accurate validation of the progress rate. Timestrip have a wide range of products available, each designed for specific controlled conditions. These conditions need to be simulated during the test in controlled environments, constantly monitored via temperature data loggers. When the actual progress follows the predicted curve at the early stages of progress (4mm – 6mm) it will continue with minimum deviations providing the temperature remains constant. Timestrip is committed to supply products within their acceptance criteria as claimed, therefore for external evaluation of the progress rate the products performance must be tested as referred to in the recommended usage mode.

Goals:

This external test should provide an accelerated accurate indication of the actual versus the predicted progress.

Tools:

- Controlled environment matching the product designated temperature by ±1 °C (other conditions if required).
- Temperature probe data logger.
- Caliper or other accurate measuring instrument.
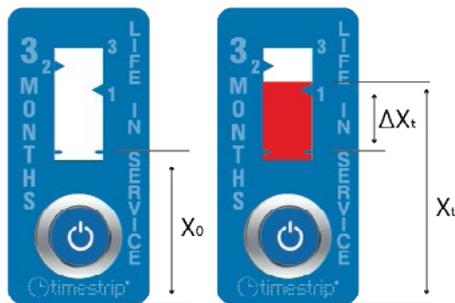
Method:

1. Number the tested products.

2. Activate all products at the same time by firmly squeezing the button. Make sure the activation line appears within 2 minutes in each activation window. If the line does not appear, re-squeeze the button immediately. This activation line is the start point of the window and its position should also be indicated via print marking (e.g. triangle mark, line mark, etc…).

3. Note the time and date of activation. The time of activation will be defined as elapse time zero.

4. In order to reduce inaccuracies in the measured progress it is advised to monitor each product X0 immediately after activation. X0 is defined as the distance of each product activation line from the product's bottom edge. Log this measurement with the time and date.

5. Place all products in the designated controlled environment within 5 minutes from activation and make sure that the temperature data logger is in close proximity to the products. Avoid any direct exposure to sun light and/or very high humidity (>85% R.H).

6. Daily measure each product progress (in millimeters), measure the Xt progress and subtract X0 from it. (See attached scheme). Monitor the exact date and time of each measurement. ΔXt is the actual measured progress for each product. $\Delta Xt = Xt - X0$.
   When removing products from the controlled environment for measurements they should be returned to the environment within 5 minutes.

7. If the product has segmented time marks (e.g. a 6 month product may have marks for 1, 2, 3 & 4 month besides the 6 month end mark) it is advisable to monitor the progress at these elapsed times.

8. When the products have progressed approximately 4mm-6mm (millimeters) plot the product's progress at different elapse times (remember that elapse time zero is defined as the activation time).

9. Confirm that the actual progress of the products match the predicted curve within the anticipated tolerances. The predicted isotherm curve is provided by Timestrip for test purposes. (See Appendix A).

Once the actual progress follows the predicted curve during the early stages (~4mm– 6mm) it will continue to do so with minimum deviations as long as the temperature is kept constant.

10. Download the temperature profile from the temperature data logger and confirm that the average temperature throughout the test period is within the tolerance (±1°C) of the designated temperature. If the actual average temperature is out of tolerance, contact Timestrip for the predicted shift to match the temperature change.

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Appendix A
3 month RT BOT- Progress Isotherm @ +22°C

Progress isotherms (in deg C)
3 month RT LIS BOT
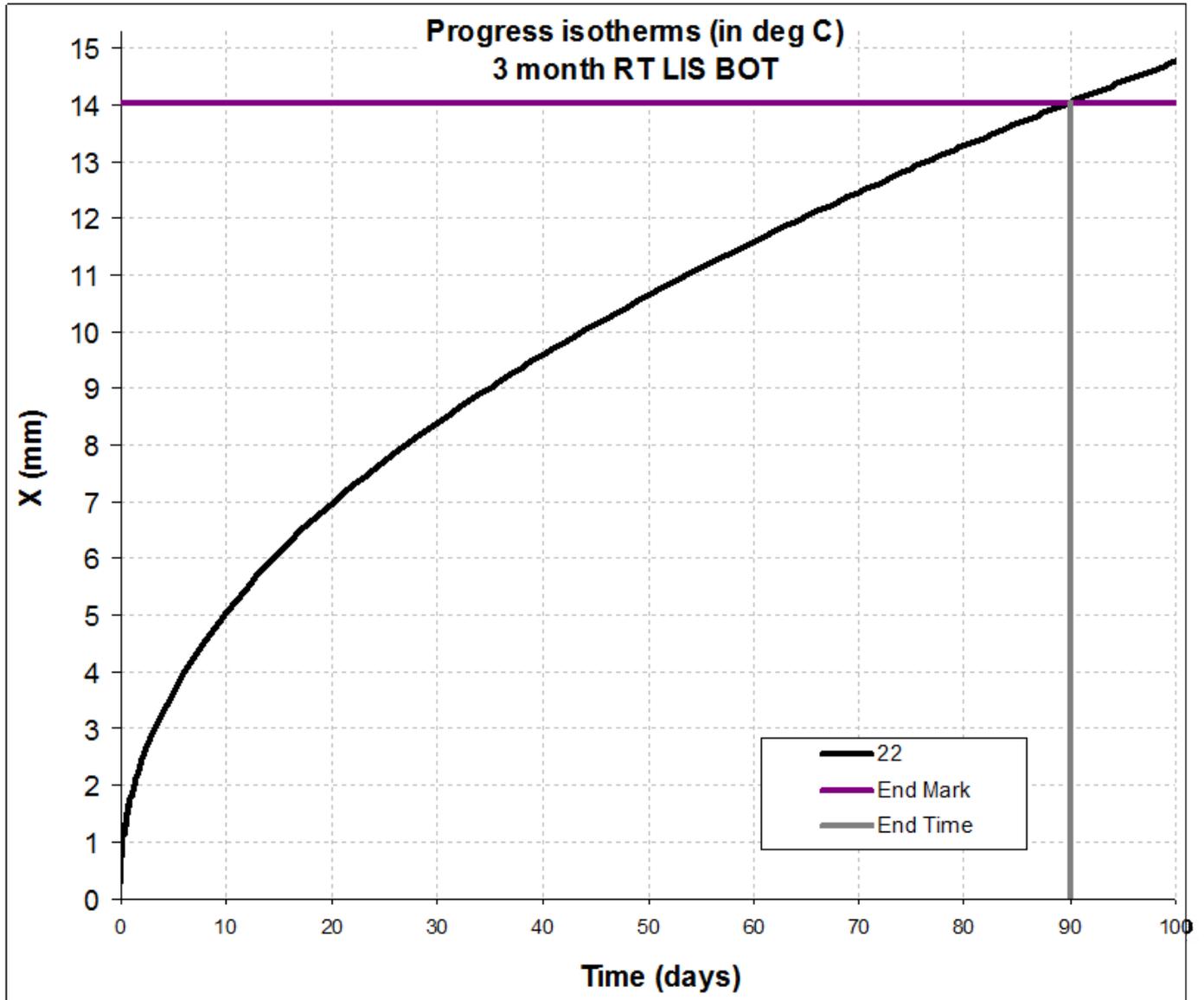
The progress after	90	days, is -->	14.05	(mm)
	60		11.59	
	30		8.39	
	14		5.91	
	7		4.27	