BS EN 62366-1:2015

With zero negative feed back, and the normal use established use since 1993 there has not been the need to revisit the usability of the device in line with BS EN 62366-1:2015.

In Light of BSI Non Conformance:**1511824-201709-M4**

The Tom thumb was design 1993, prior to BS EN62366.
The Tom Thumb is a very simple device with a single pressure relief function - that is generally pre-set by local trust guide lines. no user / patient contact to the device itself is require to use the device, With the whole user patient interaction taking place by the T-Occluder device which is CE Marked and controlled by the original manufacturers of such devices.

The Tom Thumb has a single display gauge. Addressed in the risk analysis document
C.2.29.5 Does the medical device display information
– reference questions 174,175,176,178 and 179.

With regard use error / abnormal use, there is one adjustable component on the device to adjust the Pressure Relief, even at the maximum settings the device will perform within its maximum specifications of 45cm2ho as per BS EN ISO 10651-4:2009 B.6.7.2 Pressure limitation
“Experience with infant resuscitation suggests that a maximum inspiratory pressure of 4,5 kPa (45 cmH2O) will not produce lung damage and will permit adequate tidal volumes in most patients weighing under 10 kg. “
*as referenced in Tom Thumb Risk analysis reports Risk assessment DOCID21003 Reference Question 333