Tom Thumb

Clinical Evaluation Risk assessment August 2015

Benefits of the device against residual risks.
See DOC ID 14193 Post Market Surveillance / Risk assesment Carried out August 2014,

Residual Risks,

10,30,52,53,54,102,103,108,110,129,154,156,158,160,198,223,276,278,279,280,285,287

are minor harm rated and remote possibility of occuring,

Risk
11 : is special intervention necessary in the case of failure of the medical device
59 : Patient Enviroment with regard to pressure

Both the Main value and the safety value would have to fail and the user would have to revert to a bag and mask resuscitator, or find a replacement resuscitator.

Routine maintenance of the device this likely hood of either value failing is unlikely.
DOC ID:15008
DOC ID:2209

Risk
105 : Factors that should be considered include any restrictions placed upon users in their selection of accessories.

Using a circuit with the T Occluder, Maximum pressure would be 45cmH20 as required by ISO 10651-4,
Operator should immediately be aware they are using the device incorrectly as there will not be the T Occluder for them to use the resuscitator

Risk
153 : Is the medical device used in an environment where distractions can cause use error Factors that should be considered include the consequence of use error :

Used in maternity, level environment distractions will be High, however the number one patient will be the infant if the Tom Thumb is in use.

T - Occluder devices are still the recommended method of infant resuscitation as compared to the other Bag and Mask method of resuscitation for newborns

See Documents / Journals

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The Benefits of the Tom Thumb system still out weigh the limited residual risks

Signed

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