

Tom Thumb Devices

Benefits of the device against residual risks.

01/09/15

See DOC ID 14193 Post Market Surveillance / Risk assessment 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 occurring,

Risk

11 : is special intervention necessary in the case of failure of the medical device

59 : Patient Environment 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.

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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 45cmH2O 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

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

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