

Performance Verification of AER Connection Sets

By Bryan Griffin, Emer Stone & Ross Sherwood

Medical Physics and Bioengineering Department, St James's Hospital, Dublin 8

1. Introduction:

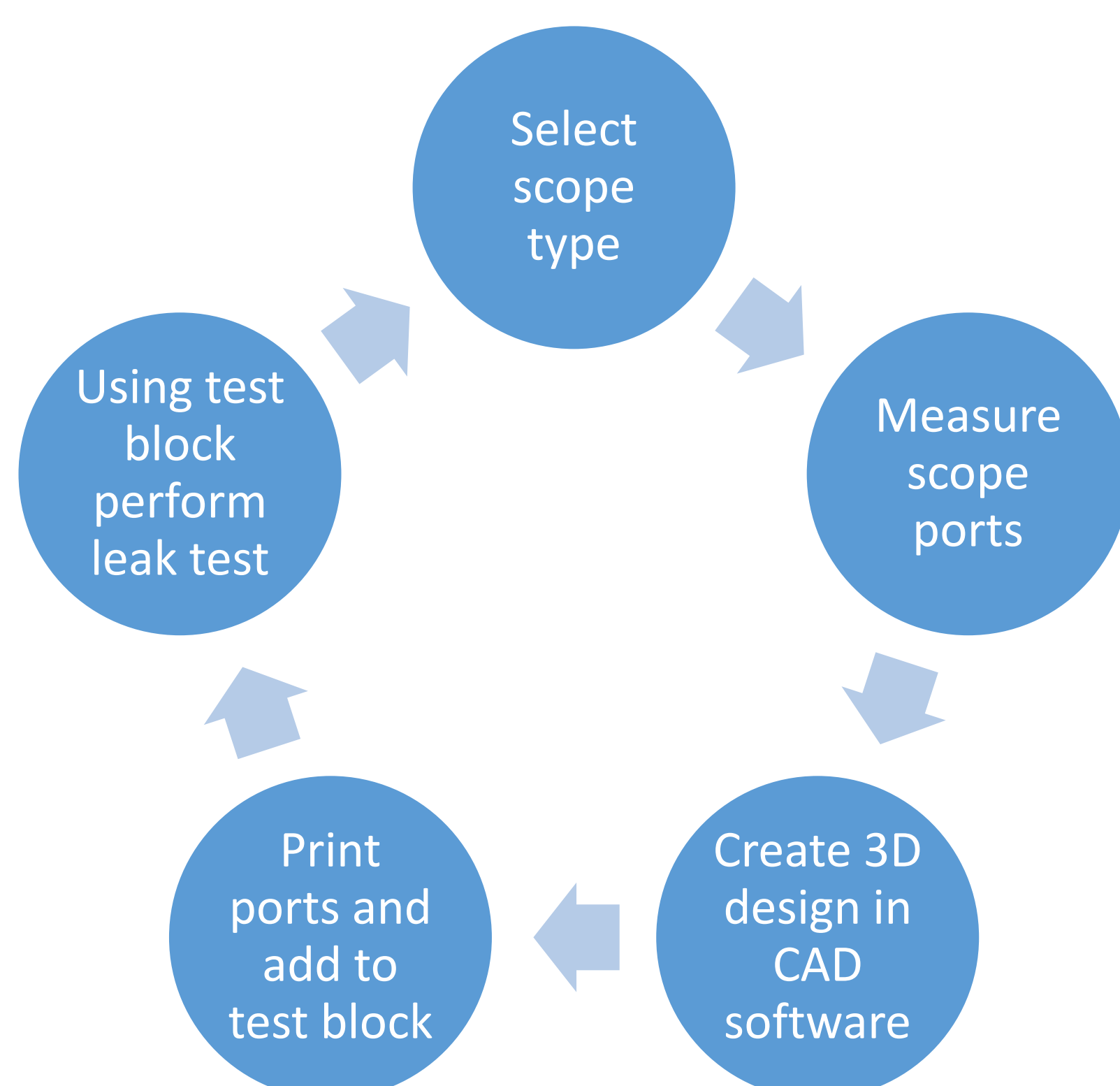
AER connection sets are a vital part of a channelled endoscope decontamination process, ensuring that the endoscope are adequately flushed with detergent and disinfectant during reprocessing. Currently there are no approved or recommended methods to test that AER connectors make an adequate seal. If a connector is damaged or has missing O-rings the scope channel may not be adequately irrigated. Resulting in less detergent, PAA and rinse water flowing through the contaminated scope during a wash cycle. Air purge will also be affected.

- The AER connection sets are classified as reusable machine accessories.
- They are not individually CE marked and are sold under the CE mark of the AER; this allows the AER manufacturer to develop and modify connectors without the need for regulatory approval.
- They are sold without a defined lifetime or recommended number of cycles.
- They are not tested during the validation of an AER.
- There are no recommended routine functional tests.
- An AER will not always alarm if a connection set is missing an O-ring.
- An AER will not always alarm if a connection set is damaged.

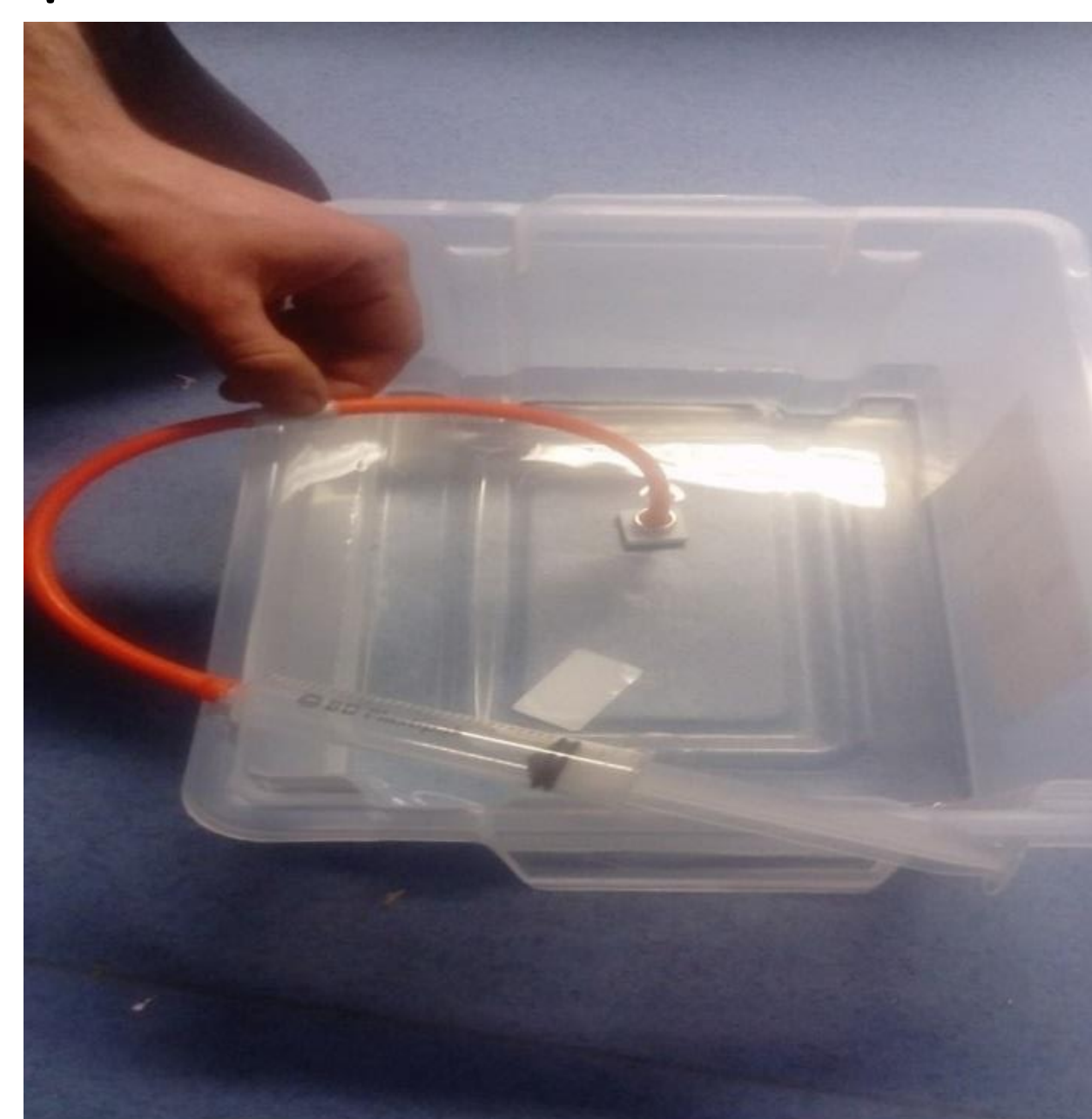
We have developed method to functionally test AER connection sets.



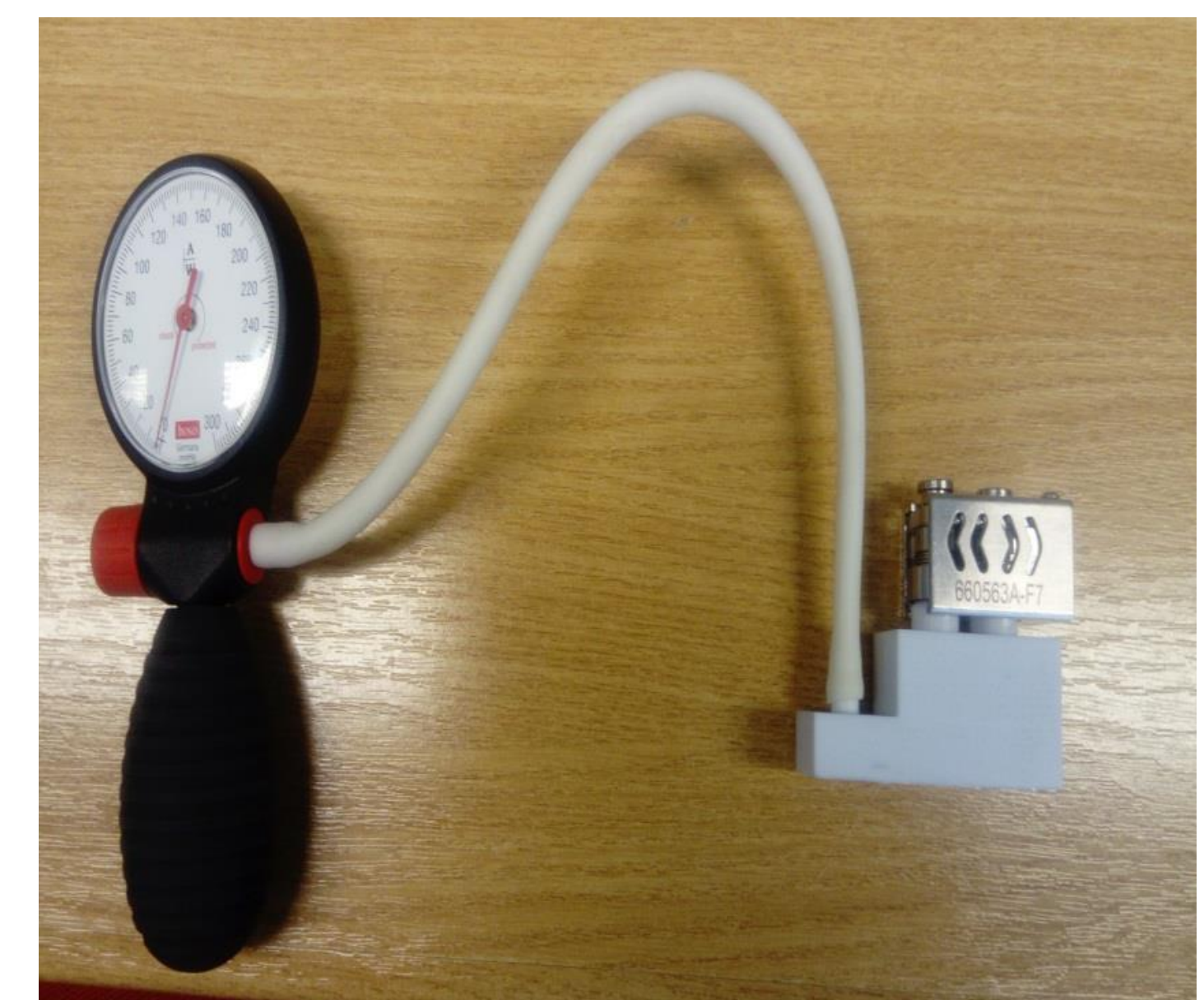
2. Design and test process



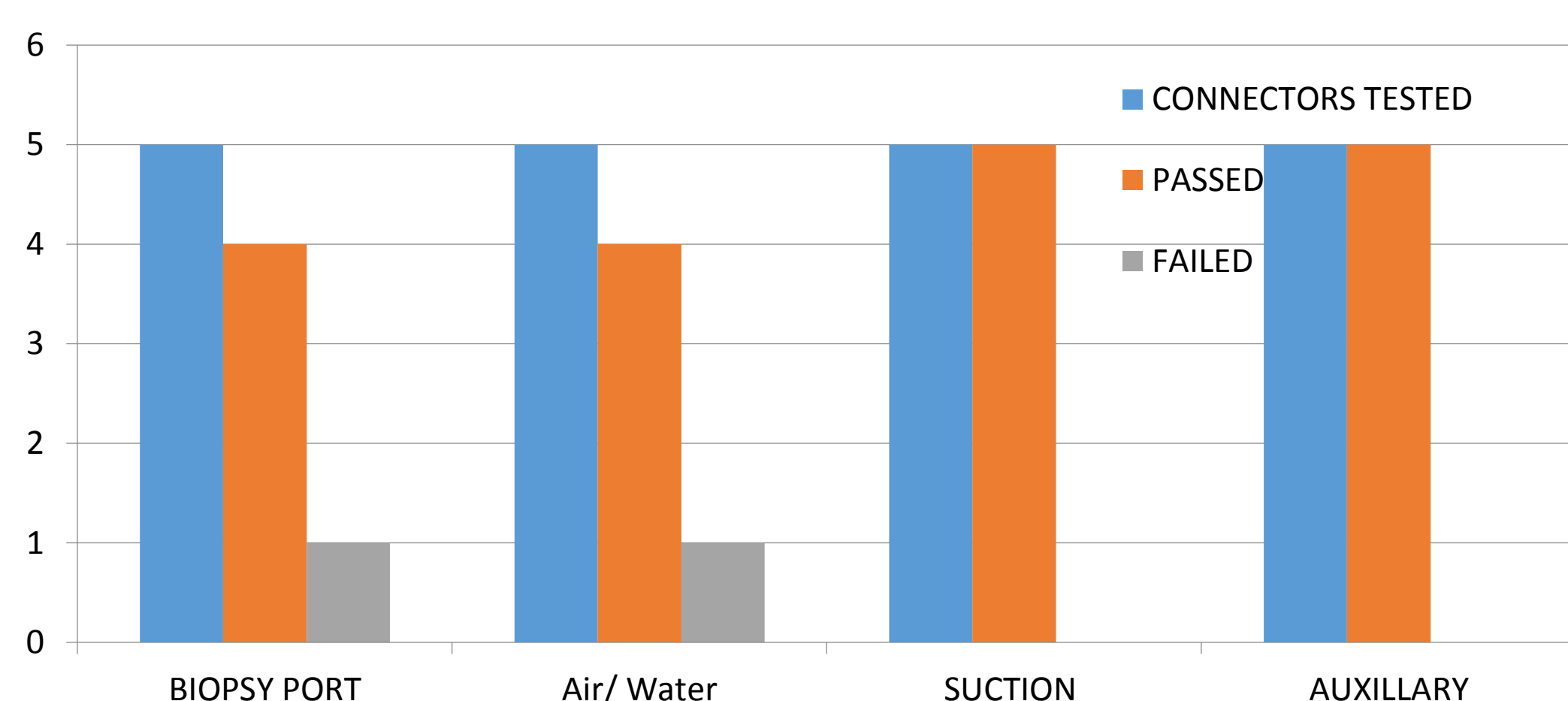
Biopsy port connector connected to 3D biopsy replica port and wet leak test is performed. If any air is leaking from the connector this connector would be deemed faulty



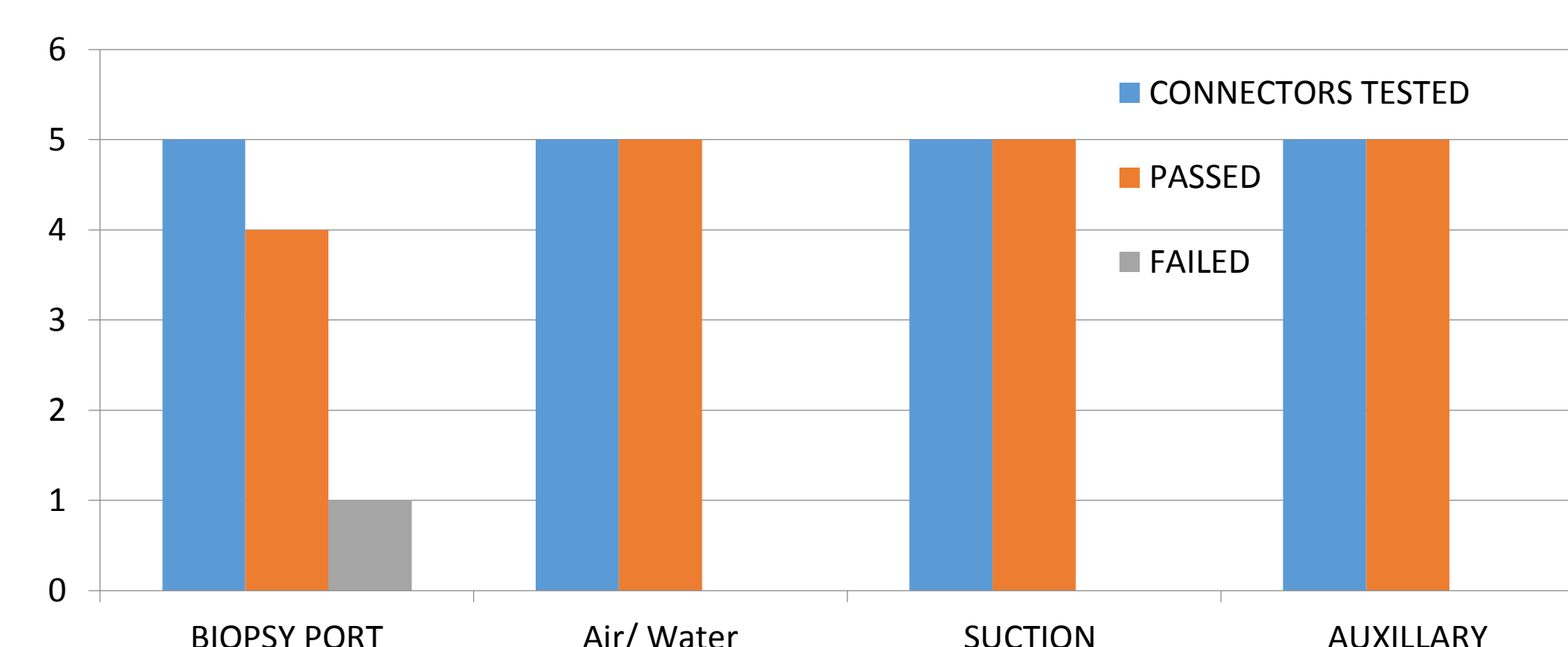
Channel separator fitted to 3D printed air/water and suction test ports. Pressurise test ports to .3 bar, no pressure drop should occur.



3. Testing connection sets from 2 different AER manufacturers



Scope connection set manufacturer A



Scope connection set manufacturer B

4. Conclusion:

- We have demonstrated a simple method to test connection sets.
- We found a number of failures across in seal integrity for biopsy port AER connectors and air/water port AER connectors across AER manufacturers.
- The 3D printed test blocks will allow endoscopy departments to test connection sets before they go into use and periodically during the life time of the product.