

REY	ECO	DESCRIPTION	ENGR	DATE
061	--	INITIAL RELEASE	MJG	1/21/13
002	--	Added Validation Steps checklist.	MJG	2/18/14

Validation Plan

This Validation was designed to test the UNDs generated by the Use Cases written for CRL 4485. This Validation will give evidence that the needs identified at the beginning of CRL 4485 have been met by the final implementation.

Design validation shall ensure that devices conform to essential user needs/intended uses and require s:

- Clearly defined pass/fail criteria (necessary to support a conclusion).
- Testing be performed under defined operations conditions
- Testing be performed on initial production units, lots, batches, or their equivalents
- Actions being carried out under actual or simulated use conditions
- Methods applied, dates, and person(s) involved in activities be documented

1. Need an airway filter for spirometer to meet recommendations during COVID-19.

Goal - Validate User Needs:

1448	Need an airway filter for spirometer to meet recommendations during COVID-19.
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Method: ATS and Human Testing

Perform the following steps in compliance with the pass/fail criteria outlined below. Provide a conclusion based on the results of this test with respect to that criteria. All criteria must be satisfied for successful completion of this test.

Validation Steps		
STEP	DESCRIPTION	Comments
1. <input checked="" type="checkbox"/>	Perform ATS Testing on Spirometer 80024 with no airway filter. 80024 performs nominally within spec.	
2. <input checked="" type="checkbox"/>	Perform ATS Testing on Spirometer 80024 with the Pulmoquard II filter.	
3. <input checked="" type="checkbox"/>	Compare results of the two tests and confirm they pass.	PEF Volume 20 and 23 are ok to Fail
4. <input checked="" type="checkbox"/>	Perform ATS Testing on Spirometer 80333 with no airway filter. 80333 performs at the lower end of spec	
5. <input checked="" type="checkbox"/>	Perform ATS Testing on Spirometer 80333 with the Pulmoguard II filter.	
6. <input checked="" type="checkbox"/>	Compare results of the two tests and confirm they pass.	PEF Volume 20 and 23 are ok to Fail
7. <input checked="" type="checkbox"/>	Have human subject 1 perform a spirogram and alternate maneuvers with no filter and with the filter.	
8. <input checked="" type="checkbox"/>	Compare the results of the two tests and confirm there is marginal difference in the graphs.	

CRL 4485 - Validation Plan

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Pass/Fail Criteria:

1. This Validation fails if there are any unexpected results above that cannot be resolved in the Comments section.

Involved Person(s):

PSK, JRB

Dates of Activities:

10/22/2020 and 10/23/2020

Traceability to Equipment:

Spirometers 80024 and 80333

Results:

PASS

Conclusion:

This validation is complete and distributors can order the SDI Pulmoguard C filters and fittings.

Signature: 

References

1. *Design Control Guidance for Medical Device Manufacturers*, Pg. 33.
2. *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, Pg. 1.4

