**VERIFICATION & VALIDATION PROTOCOLS & FINAL REPORTS**

**LAPARODOME: LOW-COST LAPAROSCOPIC TRAINING DEVICE**

April 2020

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# Inspection & Measurement Verification for *Laparodome*

***Purpose:*** to confirm measurements and materials specified in design outputs and required by users

***Subjects:*** protocol should be completed on 15 complete *Laparodome* devices to confirm consistency throughout manufacturing processes

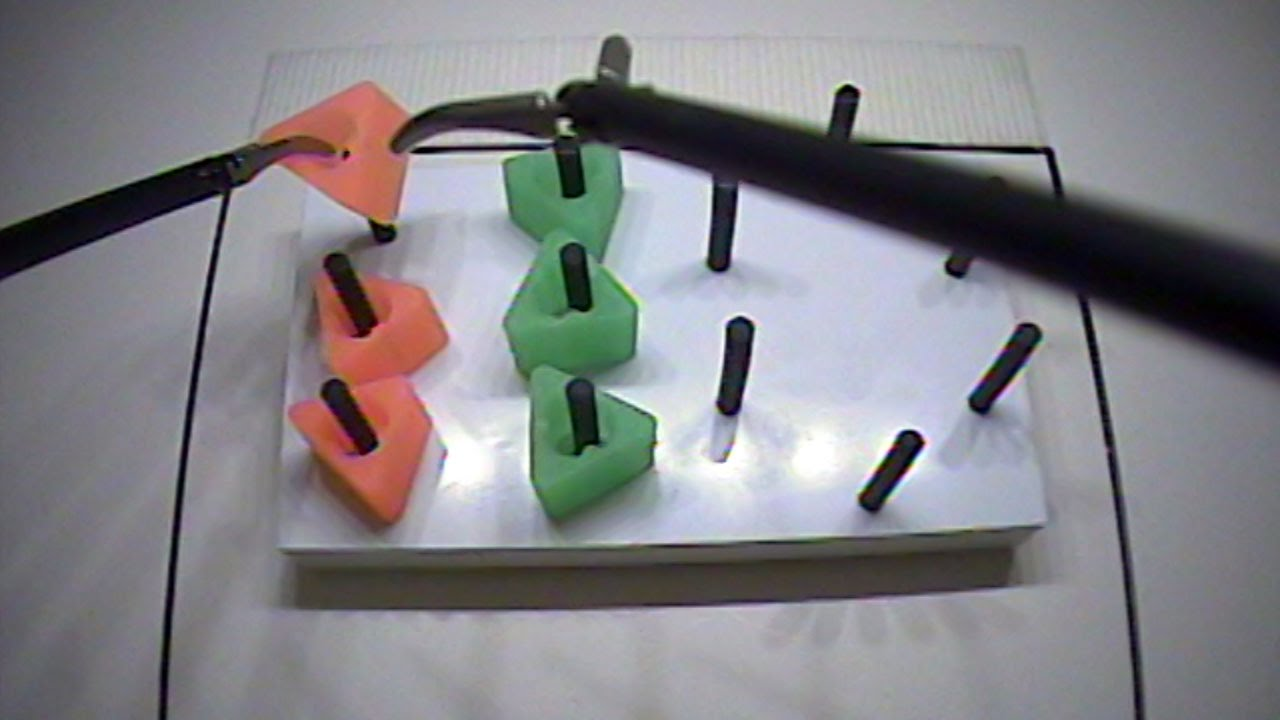
***Materials Needed:***

* 1 complete laser cut *Laparodome* cardboard sheet
* 1 set of [Instructions for Assembly and Use](https://drive.google.com/a/rice.edu/open?id=19Q5CJREaWgDdlPXzJ1c85lGabbMjl61EQiv8zzHnHcI)
* Either 1 webcam and monitor OR 1 mobile phone with camera ability
* 4 grommets
* 5 strips of velcro
* 4 suction cups
* 1 complete set of laparoscopic tools, including:
  + 1 pair of endoscissors
  + 1 grasper with locking ability
  + 2 needle drivers
  + 2 Maryland dissectors
  + 1 open-ended knot pusher
  + 1 closed-ended knot pusher
* 1 complete set of tasks, including:
  + 6 pencil grips
  + 1 cardboard peg board
  + 1 cardboard task platform
  + 12 pegs
  + 1 chip clip with velcro strip
  + 1 sheet of gauze with pattern drawn
  + 2 penrose drains (prepared with dots)
  + 2 silk or sofsilk suture at least 90cm in length, taper SH or V-20 curved 26mm needle

***Protocol:***

1. One complete *Lapardome* device will be assembled using the cardboard sheets and all provided materials. See [Instructions for Assembly](https://drive.google.com/a/rice.edu/open?id=19Q5CJREaWgDdlPXzJ1c85lGabbMjl61EQiv8zzHnHcI) for details.
   1. Device must be able to be assembled in less than 20 minutes (design input 3A)
2. User will verify the following in each device setup. Device must meet all criteria to be considered passing:
   1. Device includes all components required to complete all FLS tasks (see Materials list) (design input 2B)
   2. Device task platform and base provide sufficient space for completion of tasks (e.g. entire task fits within base) (design input 2D)
   3. Device includes port for camera insertion and provides full view of task platform (design input 2D)
      1. If device includes > 1 camera view, meets optional design input 7B
   4. Device includes at least 2 ports for tool insertion
      1. If device includes > 2 ports, meets optional design input 7A
   5. Instrument ports allow for frictionless insertion and range of motion to complete FLS tasks (design input 2G)
   6. Instrument ports allows for insertion of four (4) different manufacturers’ laparoscopic tools (design input 4A)
3. User will measure the following in each device setup. Device must meet all criteria to be considered passing:
   1. Distances in fully assembled configuration (design input 2H):
      1. Between standard tool ports - **passing criteria:** 7 in. ± 0.50 in.
      2. Camera to task platform - **passing criteria:** field of view matches that of FLS training

***Example:***

* + 1. Tool ports to talk platform - **passing criteria:** 8.5 in. ± 0.50 in.
    2. Diameter of tool ports - **passing criteria:** 5 mm ± 1.0 mm
  1. Weight of device - **passing criteria** (design input 3C)**:** <10 lbs

1. Upon completion of measurements, user will disassemble the device
   1. Device must be able to be disassembled in less than 20 minutes (design input 3A)
2. Capture all results in the [Data Capture Sheet](https://drive.google.com/a/rice.edu/open?id=1zHTKs7wit4744poBSfIM6dWNUQ9smyKZaqCts7-iqic) to document passing or failing of verification testing.

***Testing Results:*** Results to Inspection & Measurement testing performed by Ellie Reynolds on 29 March 2020 can be found [here](https://drive.google.com/a/rice.edu/open?id=1zHTKs7wit4744poBSfIM6dWNUQ9smyKZaqCts7-iqic). The protocols were performed on one current version (V12) of the device and one previous version (V10). Creation of additional devices was significantly limited due to closure of resources in response to COVID-19 outbreak.

* Device #1 (V12) passed all design criteria, including optional design criteria, resulting in overall passing the verification testing.
* Device #2 (V10) did not pass required design input 2H (camera field of view similar to FLS) and optional design input 7B (multiple camera ports), resulting in overall failure for the verification testing. However, this older design version has been adjusted to meet these criteria as demonstrated by later versions (V12) passing the testing.

***Testing Conclusion:*** In conclusion, the final version of the design meets all required design inputs that can be tested through inspection & measurement. This indicates that the design mimics FLS standards for relevant laparoscopic skill training and assessment, can be easily and cheaply assembled, and is portable and durable for multiple uses. The previous versions were assessed based on these criteria during design iterations and adjusted until they were able to meet all required and optional criteria as indicated by the failure of previous designs.

***Future Work:*** Because of the severely limited access to resources due to the COVID-19 outbreak, the complete verification testing for inspection and measurement could not be completed for 15 final devices. In the future, additional testing on future replicas of the design should be performed to demonstrate consistency within the production processes. This testing should also be completed if manufacturing scale-up occurs and the production changes from laser cutting to die cutting in order to verify consistency within those processes as well.

# Preclinical Testing & Usability Study for *Laparodome*

***Purpose:*** to test objective and subjective measurements of usability of *Lapardome* device both independent of and as compared to traditional FLS-based training curriculum

***Subjects:***

* 15 users who are not familiar with the assembly and use of the *Laparodome* device, the use of laparoscopic tools or the Fundamentals of Laparoscopic Skills (FLS) training curriculum
* 15 physicians who have been certified or are currently training to be certified in the Fundamentals of Laparoscopic Skills (FLS) curriculum but who are not familiar with the assembly and use of the *Laparodome* device

***Materials Needed:***

* 1 complete laser cut *Laparodome* cardboard sheet
* 1 set of Instructions for Assembly and Use
* Either 1 webcam and monitor OR 1 mobile phone with camera ability
* 4 grommets
* 5 strips of velcro
* 4 suction cups
* 1 complete set of laparoscopic tools, including:
  + 1 pair of endoscissors
  + 1 grasper with locking ability
  + 2 needle drivers
  + 2 Maryland dissectors
  + 1 open-ended knot pusher
  + 1 closed-ended knot pusher
* 1 complete set of tasks, including:
  + 6 pencil grips
  + 1 cardboard peg board
  + 1 cardboard task platform
  + 12 pegs
  + 1 chip clip with velcro strip
  + 1 sheet of gauze with pattern drawn
  + 2 penrose drains (prepared with dots)
  + 2 silk or sofsilk suture at least 90cm in length, taper SH or V-20 curved 26mm needle

***Protocol:***

1. Using the Instructions for Assembly and Use, subject will be asked to assemble one complete *Laparodome* device using the cardboard sheets and all provided materials
   1. Subject will be timed during the assembly process
   2. Subject will be asked to evaluate ease of assembly using a standardized survey
   3. **Assembly passing criteria:** assembly of device in less than 20 minutes +/- 5 minutes
   4. **Survey passing criteria:** surveys will be scored according to Systems Usability Scale scoring for questions 1-10:
      1. For each of the odd numbered questions, subtract 1 from the score.
      2. For each of the even numbered questions, subtract their value from 5.
      3. Take these new values which you have found, and add up the total score. Then multiply this by 2.5.
      4. Scores > 68 will be considered passing
      5. Questions beyond #10 will be averaged and scores > 3 will be considered passing
2. Following completion of assembly, subjects will be asked to perform each of the following tasks according to instructions outlined in the official FLS curriculum:
   1. Peg transfer
   2. Pattern cut
   3. Intracorporeal suture
   4. Extracorporeal suture
   5. **Untrained Users Passing Criteria:** ability and resources available to perform all tasks *(completion of tasks is not necessary for completely untrained users)*
   6. **Trained Users Passing Criteria:** completion of all tasks according to FLS standards
   7. **Training Users Passing Criteria:** completion of all tasks according to current self-reported performance
   8. **Passing Criteria:** the device did not need to be readjusted during completion of tasks
3. After engagement in or completion of all 5 tasks, subject will be asked to fill out a standardized survey regarding the performance of the device compared to expectations (untrained users) or standard FLS trainers (trained/training users) and the ability of the device to increase interest in developing laparoscopic skills
   1. **Survey passing criteria:** surveys will be scored according to Systems Usability Scale scoring for questions 1-10:
      1. For each of the odd numbered questions, subtract 1 from the score.
      2. For each of the even numbered questions, subtract their value from 5.
      3. Take these new values which you have found, and add up the total score. Then multiply this by 2.5.
      4. Scores > 68 will be considered passing
      5. Questions beyond #10 will be averaged and scores > 3 will be considered passing

***Testing Results:*** Results to Preclinical & Usability testing with *untrained* users was performed by Ellie Reynolds on 29 March 2020 can be found [here](https://drive.google.com/a/rice.edu/open?id=1zHTKs7wit4744poBSfIM6dWNUQ9smyKZaqCts7-iqic). The protocols were performed on one current version (V12) of the device and one previous version (V10). Creation of additional devices was significantly limited due to closure of resources in response to COVID-19 outbreak. Furthermore, Velcro was intentionally left out of the testing as this component results in nearly permanent securing to the device and would be destructive to the only finalized version of the design remaining.

* Untrained User #1 performed the testing on Device #1 (V12). Assembly was completed in 25 minutes and disassembly was completed in 11 minutes. All tasks were able to be performed although completion was not a requirement for untrained users. On the usability survey, the user rated the device an overall SUS score of 90 (excellent) and an average usability score on other elements of 4.67.
* Untrained User #2 performed the testing on Device #2 (V10). Assembly was completed in 22 minutes and disassembly was completed in 10 minutes. Due to the limited resources available, the device was not a complete set of all materials necessary to fully assemble the device. However, all tasks with components available were able to be performed. On the usability survey, the user rated the device an overall SUS score of 75 (good) and an average usability score on other elements of 3.83.

***Testing Conclusion:*** In conclusion, the final version of the design allows for the full completion of all necessary FLS tasks (peg transfer, pattern cut, and intracorporeal and extracorporeal suturing). Additionally, assembly and disassembly were able to meet the criteria of 20 +/- 5 minutes for each process, indicating ease of assembly and clarity of instructions. Feedback provided by users about the instructions was incorporated into the document. While the untrained users were not expected to be able to meet the standards of FLS for task completion, they had the materials available to do so.

Furthermore, the Systems Usability Scale results indicated that the device meets the criteria of exceeding a score of 68, representing good or excellent usability. On additional usability metrics, each user scored the device an average > 3, indicating overall positive impressions of the device, its assembly and its purpose.

Finally, user and device failures were documented as anecdotal failures in the [FMEA](https://drive.google.com/a/rice.edu/open?id=1PF8PTMy4GR0f5m9Fwol2LsdncniktOETmxBpH6NxX9I) as part of the post-market surveillance process. These failures were largely associated with the assembly process resulting in tears of the material or unstable structures if the instructions were not followed correctly.

***Future Work:*** Because of the severely limited access to resources due to the COVID-19 outbreak, the complete verification testing for preclinical testing could not be completed with 15 untrained users. Additionally, we were unable to have any FLS-trained / training physicians test the final design of the device. We were also unable to test the final version of the device with more than 1 individual because of the lack of resources available. In the future, additional testing on future replicas of the design should be performed to confirm the results seen in untrained users as well as further validate the design, its similarities to formal FLS training and certification and its ability to improve laparoscopic skills with physicians who have gone through formal FLS training. This expanded testing would allow for more robust verification and validation that the design meets the criteria, particularly as related to its similarities to FLS and its ability to increase interest and skill level of training medical students and residents.

# Durability Study for *Laparodome*

***Purpose:*** to assess durability of *Laparodome* device in simulated use conditions

***Subjects:*** protocol should be completed on 16 complete *Laparodome* devices to confirm consistency throughout manufacturing processes

***Materials Needed:***

* 1 complete laser cut *Laparodome* cardboard sheet
* Either 1 webcam and monitor OR 1 mobile phone with camera ability
* 4 grommets
* 5 strips of velcro
* 4 suction cups
* 1 complete set of laparoscopic tools, including:
  + 1 pair of endoscissors
  + 1 grasper with locking ability
  + 2 needle drivers
  + 2 Maryland dissectors
  + 1 open-ended knot pusher
  + 1 closed-ended knot pusher
* 1 peg transfer task, including:
  + 6 pencil grips
  + 1 cardboard peg board
  + 12 pegs

***Protocol:***

1. Each device will be subjected to preconditioning in one of the following settings (4 devices per conditioning scenario, 2 unassembled and 2 assembled):
   1. Accelerated aging: representative of 3 months at 75°F and 85% humidity
      1. 15 days in environmental testing fixture
      2. Temperature: 55°C (122°F), Humidity: 85%
   2. No preconditioning
   3. If resources allow, testing high heat (75°F), ambient humidity
   4. If resources allow, testing ambient temperature, high humidity (85%)
2. For unassembled devices: using the Instructions for Assembly and Use, complete device will be assembled using the cardboard sheets and all provided materials
   1. Assembly process will be timed.
   2. **Assembly passing criteria:** assembly of device in less than 20 minutes
3. Following completion of assembly, subjects will be asked to perform the ***peg transfer task*** according to instructions outlined in the official FLS curriculum
   1. **Passing criteria:** ability to perform task *(completion of tasks is not necessary for completely untrained users)*
   2. **Passing criteria:** the device did not need to be readjusted during completion of tasks
4. After attempting the peg transfer task, each device will be subjected to the most extreme use cases. This will entail the user rotating and moving the laparoscopic instruments across the entire range of motion allowed and in all directions for 5 minutes.
   1. The device will then be inspected for any rips or tears in the cardboard or compromised structural integrity (e.g. tabs cannot be inserted, device cannot stand up on its own, etc.)
   2. Any deviations in structure will be remedied prior to assessing passing criteria.
   3. **Passing criteria:** device can still stand up on its own with all components remaining securely in place after reinsertion / reassembly required
   4. **Passing criteria:** device experiences no rips or tears in material after extreme movement exercise

***Testing Results:*** Results to Durability testing performed in the Richards-Kortum lab over the course of a week in March 2020 can be found [here](https://docs.google.com/document/d/1vgzu0zxsp6h86LbBRUIz5kTt4NLR2i_mj7j7_sRUb5A/edit). The protocols were performed on one version (V11) of the device. Creation of additional devices was significantly limited due to closure of resources in response to COVID-19 outbreak. Because of these limitations, only the condition with high heat and temperature was able to be simulated. Furthermore, due to size restrictions of the available testing equipment, the device was only able to be tested in its assembled format. The device was also only able to be kept in the chamber for 1 week due to building closures in response to COVID-19.

* The device was left in the environmental chamber for 7 days at a humidity of 85% and a temperature of 55°C, representing 1 month of storage in similar humidity and a temperature of 25°C (75°F). Upon removal from the environmental chamber, the device was visually inspected for any obvious signs of damage or deterioration. The device experienced slight warping on the base, but the overall structure remained intact and did not demonstrate any sagging or compromise to its integrity.
* The device then underwent verification testing including performance of the peg transfer task and extreme use scenario. The device held up to performance and withstood all the extreme movements during the peg transfer exercise.

***Testing Conclusion:*** In conclusion, the material was able to withstand simulated aging of 1 month at an ambient temperature of 25°C and 85% humidity. The integrity of the device was maintained and did not experience any damage during the course of the accelerated aging process.

During verification testing on the aged device, the device stayed intact during the peg transfer exercise. There was only slight warping of the cardboard on the base, but it did not affect the performance of the task. It was able to stand on its own and exhibited no damage after extreme movements in the peg transfer exercise. The device also passed all the verification inspection and measurements testing after use.

***Future Work:*** Because of the severely limited access to resources due to the COVID-19 outbreak, the complete durability testing could not be completed with 16 devices. Additionally, we were unable to simulate 3 months of aging as the protocol states due to building closures. In the future, additional and more complete testing on future replicas of the design should be performed to confirm the results seen with this device and its ability to withstand extreme use and extreme environmental conditions.

# USABILITY SURVEY: ASSEMBLY & USE

1. I think that I would like to use this system frequently.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 |
| Strongly Disagree | Disagree | Neutral | Agree | Strongly  Agree |

1. I found the system unnecessarily complex.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 |
| Strongly Disagree | Disagree | Neutral | Agree | Strongly  Agree |

1. I thought the system was easy to use.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 |
| Strongly Disagree | Disagree | Neutral | Agree | Strongly  Agree |

1. I think that I would need the support of a technical person to be able to use this system.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 |
| Strongly Disagree | Disagree | Neutral | Agree | Strongly  Agree |

1. I found the various functions in this system were well integrated.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 |
| Strongly Disagree | Disagree | Neutral | Agree | Strongly  Agree |

1. I thought there was too much inconsistency in this system.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 |
| Strongly Disagree | Disagree | Neutral | Agree | Strongly  Agree |

1. I would imagine that most people would learn to use this system very quickly.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 |
| Strongly Disagree | Disagree | Neutral | Agree | Strongly  Agree |

1. I found the system very cumbersome to use.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 |
| Strongly Disagree | Disagree | Neutral | Agree | Strongly  Agree |

1. I felt very confident using the system.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 |
| Strongly Disagree | Disagree | Neutral | Agree | Strongly  Agree |

1. I needed to learn a lot of things before I could get going with this system.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 |
| Strongly Disagree | Disagree | Neutral | Agree | Strongly  Agree |

1. Assembly of the device was intuitive and the instructions were clear.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 |
| Strongly Disagree | Disagree | Neutral | Agree | Strongly  Agree |

1. I would be willing to practice at home if I had access to one of these devices.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 |
| Strongly Disagree | Disagree | Neutral | Agree | Strongly  Agree |

1. The device is comfortable to use.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 |
| Strongly Disagree | Disagree | Neutral | Agree | Strongly  Agree |

1. The device feels stable and could withstand up to 100 uses over a few months.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 |
| Strongly Disagree | Disagree | Neutral | Agree | Strongly  Agree |

1. The device would engage me to practice the skills learned in order to meet the standards.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 |
| Strongly Disagree | Disagree | Neutral | Agree | Strongly  Agree |

1. The device increases my interest in wanting to learn and develop laparoscopic techniques.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 |
| Strongly Disagree | Disagree | Neutral | Agree | Strongly  Agree |

**TRAINED / TRAINING USERS ONLY:**

1. The device matches expectations for FLS training standards and would improve my skills necessary to meet certification.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 |
| Strongly Disagree | Disagree | Neutral | Agree | Strongly  Agree |

1. I would be able to consistently meet the FLS standards and times set to determine proficiency with the use of this device.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 |
| Strongly Disagree | Disagree | Neutral | Agree | Strongly  Agree |

1. The device would increase my familiarity with the skills and movements necessary to complete typical laparoscopic procedures.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 |
| Strongly Disagree | Disagree | Neutral | Agree | Strongly  Agree |

1. The tool arrangement feels similar to traditional or anticipated laparoscopic setup.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 |
| Strongly Disagree | Disagree | Neutral | Agree | Strongly  Agree |

1. The range of motion of the tools feels similar to traditional or anticipated laparoscopic setup.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 |
| Strongly Disagree | Disagree | Neutral | Agree | Strongly  Agree |

1. The camera display / visualization resembles traditional or anticipated video feed from a laparoscope.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 |
| Strongly Disagree | Disagree | Neutral | Agree | Strongly  Agree |

1. The device setup and design reasonably mimics patient anatomy / abdomen.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 |
| Strongly Disagree | Disagree | Neutral | Agree | Strongly  Agree |

# REFERENCES

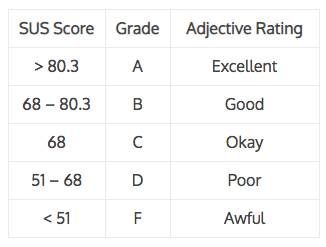
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**Usability Score Translation:**

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