ND Dome Switch Design Validation Report

**Projects: Dome Switch Supplier ChangeProtocol: ENG-PRT-660**

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| **REVISION** | **DATE** | **SUMMARY OF CHANGE** |
| A | 1/15/20 | Original Release |

Approval List:

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| --- | --- | --- | --- |
| **Function** | **Name** | **Signature** | **Date** |
| Lifecycle Design Engineer | Gracie Brooks | Esig in Mastercontrol | Esig in Mastercontrol |
| Quality Engineer | Steven Kuykendall | Esig in Mastercontrol | Esig in Mastercontrol |
| Lifecycle Design Engineer | Brain Taylor | Esig in Mastercontrol | Esig in Mastercontrol |

1. **executive summary**

The purpose of this study was to evaluate a new dome switch design (M101900) in the ZIP, ACE, Rally, and Rally GEM products with representative users to determine the acceptability of the buttons for use in their procedures.

The evaluation was conducted in a market research facility with twelve surgeons in Boston, MA on December 17 and 18 (see **Table 3** for location details). For specific demographic breakdown of respondents see section 2.4 Summary of Surgeon Background.

1. **Evaluation execution**
   1. **Devices used in Evaluation**

See **Table 1** below for the devices used in this evaluation. See table X below comparison between devices used in this validation and final production devices.

**Table 1: Products used in Evaluation**

| **Product Code** | **Device Name** | **Lot Number** | **Comparison to Production Device** |
| --- | --- | --- | --- |
| X252510N | Zip pen, electrosurgical pencil w/e-z clean, holster, 10 ft. Tubing | SM1910009 | These devices are production equivalent except for using the new M101900 dome. Records can be found as an attachment to ENG-PRT-594. |
| XME725M1CN | Ace blade 700, 2.5 modified zip pen, "c"connector, 10 ft. Tubing | SM1910010 | These devices are production equivalent except for using the new M101900 dome. Records can be found as an attachment to ENG-PRT-594. |
| X251010JN | Ultra vac 2, electrosurgical pencil w/e-zclean, holster, 10 ft. Tubing | SM1910018 | These devices are production equivalent except for using the new M101900 dome. Records can be found as an attachment to ENG-PRT-594. |
| XME725M1STN | Megadyne ace blade 700, 2.5” blade, modified, smoke evacuation telescoping pencil, 10 ft. | SM1910019 | These devices are production equivalent except for using the new M101900 dome. Records can be found as an attachment to ENG-PRT-594. |

* 1. **Protocol Deviations**

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| **Table 2: Deviations from Protocol and Study Artifacts** | |
| **Deviation** | **Effect on Study** |
| The products were not connected to a smoke evacuator or energy generator for the evaluation. The protocol specified this as an option if the surgeon was unable to evaluate tactile feedback of the buttons without activating on tissue. | This is not believed to impact the study because surgeons were able to evaluate the tactile feedback of the buttons without connecting the devices to capital equipment. Connection to a generator or smoke evaluator does not affect the tactile feedback of the buttons. This deviation is considered acceptable. |
| Excess suction tubing and power cable were trimmed on the prototypes to ease handling of the devices in the study. | This is not believed to impact the study because surgeons were evaluating the tactile feel of the buttons which operate independently of the suction tubing and power cable. This deviation is considered acceptable. |

* 1. **Study Location**

Table 3: Study Location

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| --- | --- | --- |
| Location | Date | Facility Address |
| Boston, MA | December 17th and 18th, 2019 | Focus on Boston Rowes Wharf 30 Rowes Wharf, Boston, MA 02110 |

* 1. **Summary of Surgeon Background**

A total of twelve (12) surgeons completed this evaluation which meets the ENG-PRT-660 requirement for a minimum of 10 surgeon evaluations. Surgeon background information is captured in **Table 4** below.

| **Table 4: Surgeon Background** | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **P ID** | **Specialty** | **Glove Size** | **# Years in Role (post residency, including fellowship)** | **Surgical Procedures per month** | **% Lap** | **% Open** | **Does the user have smoke evacuator experience?** | **Which smoke evacuator has participant used in the past?** |
| FD | General, ENT (including thyroid) | 7 | 4 | 30-35 | 10-20% | 80-90% | yes | Neptune S3 - primarily for Suction |
| TS | HPB | 7 | 8.5 | 15-20 | 50% | 50% | yes - have used before | Zimmer |
| EB | OBGYN | 6 | 26 | 15 | 67% | 33% | yes - For C-Sections - bovie with smoke evac | Neptune S2 - not sure |
| BS | General, Trauma | 7.5 Brown | 20 | 20-30 | 50% | 50% | yes | honestly, I don't look at the equipment - use Neptune for suction only |
| BK | General | 7.5 | 21 | 45-55 | 70% | 30% | yes | Neptune S2 |
| AS | General, Bariatric | 7.5 | 15 | 40 | 60-65% | 35-40% | yes | Neptune S3 |
| DB | Colorectal | 7 | 20 | 20 | 80% | 20% | a little | Medtronic Rapidvac Airflow - has been demoed - seen at meetings |
| PM | Colorectal | 8 | 22 | 22 | 60% | 40% | yes | Medtronic Rapidvac |
| RA | GYN | 9 | 6 | 6 | 50% | 50% | yes | Megadyne MegaVac |
| BA | GYN | 10 | 30 | 30 | 50% | 50% | yes | Neptune S3 |
| HI | Head and Neck | 11 | 21 | 21 | 0 | 100% | some, but not significant | n/a |
| CF | HPB | 12 | 15 | 15 | 60% | 40% | yes | Medtronic Rapidvac |

1. **Design Validation Results**

All raw data sheets for this evaluation are captured in **Attachment 1**. See **Attachment 2** for completed moderator and data recorder training records. **Table 5** summarizes the design validation results, for a more detailed discussion please refer to **Table 6**.

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| --- | --- | --- |
| Table 5: Dome Switch Design Validation Results Summary | | |
| **Validation Question:** | **Acceptable** | **Acceptable w/ Comments** | **Unacceptable** |
| **(Zip) X252510N**: Rate the tactile feedback of the device buttons | 12 | 0 | 0 |
| **(Ace 700) XME725M1CN**: Rate the tactile feedback of the device buttons | 12 | 0 | 0 |
| **(Rally) X251010JN**: Rate the tactile feedback of the device buttons | 10 | 2  (EB, DB) | 0 |
| **(Rally GEM) XME725M1STN**: Rate the tactile feedback of the device buttons | 11 | 1  (EB) | 0 |

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| --- | --- | --- | --- |
| Table 6: Detailed Nurse Validation Results | | | |
| P ID | Rating | Comments | Risk Assessment / Team Response |
| **(Rally) X251010JN**: Rate the tactile feedback of the device buttons | | | |
| EB | AC | Surgeon commented that it had “more spring - would use if someone handed to her she would use it, but doesn’t like how it feels - would catch her attention because it has a different feel, unfamiliar - feels less reliable - doesn't feel right” | Surgeon would prefer that the buttons felt less “springy.” This is a tactile feel preference, but the surgeon would be able to use it in her procedures. Button reliability will be evaluated in a separate design verification study (ENG-PRT-594).  This comment is considered acceptable. |
| DB | AC | feels a little clunky - sticks a little bit | Surgeon does not prefer the feel of the button but could use it in their procedure. Button sticking and reliability will be evaluated in a separate design verification study (ENG-PRT-594).  This comment is considered acceptable. |
| **(Rally GEM) XME725M1STN**: Rate the tactile feedback of the device buttons | | | |
| EB | AC | Better than [Rally]\* -surgeon questioned if it was supposed to be the same - still not as good as [Zip]\* - would not pick - would pick one with more standard feeling button  *\*Note: Surgeons did not use the project name when referring to the products, rather, they pointed to the product.* | Surgeon preferred these buttons compared to the Rally buttons- the two devices share identical components, the only difference between the Rally and Rally GEM devices is the electrode. The electrode type does not affect the tactile feedback of the buttons. The perceived difference may be due to a study artifact (surgeon may be trying to find a difference between the devices because of the study environment). Although the surgeon did not prefer this button feel over the other designs tested (Zip and Ace 700), the surgeon would be able to use it in their procedures.  Button reliability will be evaluated in a separate design verification study (ENG-PRT-594).  This comment is considered acceptable. |

1. **Conclusions**

This study demonstrates the overall acceptability of the M101900 switch tactile feel in the Rally, Rally GEM, Zip and Ace 700 products. The new dome switch design (M101900) received no “Unacceptable” ratings and all “Acceptable with Comment” ratings were acceptable clarified (see Section 3). It is recommended that the M101900 dome switch pass Customer Design Validation.

1. **Attachments**

* Attachment 1: Nurse Data Sheets
* Attachment 2: Completed Training Records