System Design Validation of Stryker Digital Capture and it's accessories for use in Endoscopic surgeries

A dissertation Report

Submitted in Partial Fulfillment of the Requirements

for the Award of the Degree of

Master of Technology in Biotechnology

by

Samriti Singh Thakur

601704005

Under the supervision of

Mrs. Manila Batra, Associate Manager

Stryker, Gurugram

And

Dr. Manoj Baranwal

Associate Professor

Department of Biotechnology,

Thapar Institute of Engineering & Technology, Patiala

July, 2019

CERTIFICATE

This is to certify that the dissertation work entitled "System Design Validation of Stryker Digital Capture and its accessories for use in Endoscopic surgeries" submitted by Samriti Singh Thakur (Roll No. 601704005) in partial fulfillment for the award of degree of Master of Technology in Biotechnology from Thapar Institute of Engineering and Technology, Patiala Punjab is the record of the candidates own independent work carried out under our supervision and guidance. The matter embodied in this dissertation has not been submitted in part to any other University/Institute for the award of any degree or diploma in India or Abroad.

Manila
17th June 2019

Dr. Manoj Baranwal

Department of Biotechnology

TIET, Patiala – 147004

Punjab, India

Mrs. Manila Batra

Associate Manager (Endoscopy)

Stryker Global Technology

Gurugram, India

DECLARATION

I hereby declare that the work being presented in the dissertation report entitled " System Design Validation of Stryker Digital Capture and its accessories for use in Endoscopic surgeries" submitted by me for the award of the degree of Master of Technology in Department of Biotechnology, Thapar Institute of Information & Technology, Patiala is true and original record of my own independent work carried out under the supervision of Mrs. Manila Batra. Further, I declare that no part of this dissertation has been submitted to any other University/Institute for the award of any degree in India or abroad.

Dated: 25th Sept. 2019

(Samriti Singh Thakur)

ACKNOWLEDGEMENTS

I would like to thank Stryker Corporation, Gurugram and Thapar Institute of Information & Technology, Patiala for giving me an opportunity to undertake this internship. It is my great pleasure and privilege to work under the guidance of **Mrs. Manila Batra** (Associate Manager, Endoscopy) as my project manager who has been motivating and encouraging me throughout the project and has put in every possible effort to make the project a success.

I would like to thank **Dr. Manoj Baranwal** (Associate Professor) as my mentor for helping me during the internship with their valuable guidance and motivation which is the key to the successful implementation of this internship.

I would like to extend my sincere gratitude towards **Dr. Maushmi Ghosh**, HOD, Biotechnology department, for being cooperative to the students of the department and providing relevant guidance in their endeavors.

I would also like to acknowledge **Mr. Arjan Singh** (Quality Engineer) for helping me learn the basics of Quality Engineering since the very first day of my internship and has been guiding me throughout my project.

I would like to express my gratitude to **Mr. Rohit Chaurasia** (Senior Quality Engineer) and **Mrs. Pragya Rastogi** (Quality Engineer) for not only being good mentors but also creating a friendly environment by being there for me whenever I was in need.

Samriti

(Samriti Singh Thakur)

LIST OF ACRONYMS

OR	-	Operating Room
SDC	-	Stryker Digital Capture
GUI	-	Graphical User Interface
TP	-	Test Protocol
IFU	-	Instructions for Use
OSD	-	On-Screen Display
LCD	-	Liquid Crystal Display Screen
SFB	-	Stryker Firewire Backbone
DUNs	-	Defined User Needs
FS	-	Functional specifications

LIST OF FIGURES

LIST OF TABLES

ABSTRACT

An endoscopy is a procedure where a surgeon uses a special instrument called an endoscope to examine the inside of a human body. It can also be used for biopsy purposes where a small sample of tissue is removed from the body for analysis. Endoscopic surgeries are also known as Minimally Invasive surgery. In this technique, the surgeon makes small incisions in patient's body and introduces an instrument called an endoscope onto which a camera is inserted which enables the surgeon to visualize during the intervention.

The current study reports the System design validation of Stryker Digital Capture and its accessories intended to be used in endoscopic surgeries. The Stryker Digital Capture (also referred to as SDC) is a comprehensive OR documentation system. It is a network-compatible hardware platform on which software functionality can be added to tailor the product features to the customer needs. In the present study, the production equivalent units of SDC along with other devices and accessories to be required for the system design validation were obtained from the Production unit in San Jose, USA which were then assembled in the iSuite lab in SGTC, Gurgaon where the validation cycles were performed. The company's Design Controls were followed for the purpose to ensure that the resulting product is safe and effective for its intended use.

The device and relevant accessory packages were used as intended within a simulated use environment for two different scenarios: laparoscopic surgery design validation and arthroscopic surgery design validation and for two different software versions. These were 1.2.0 and 1.2.1 i.e Cart Limited release and Cart Full release respectively. Cart Limited release refers to the release of the SDC along with the Base package, Voice package, Device package and whereas the Cart full release refers to the release of the SDC along with all the required packages, 1688 Camera and L11 Light source. The simulated environments were set up as similarly as possible to the real use environment. The validation consisted of testing in a simulated cart where the SDC was placed on a surgical cart with all the relevant devices used for endoscopic surgeries. All products within scope of this system design validation were production or production equivalent, with appropriate measures of traceability to the manufacturing process. The system design validation for both the releases was performed in multiple evaluations until the product passed almost all the defined user needs. The product was then released (limited launch) in the market and following this, the User data was obtained from the surgeons regarding the feedback of the product

TABLE OF CONTENTS

Chapter 1

INTRODUCTION

System design validation is basically of two types: User design validation and System design validation. This study is in support of System design validation which was required to test against an approved design validation test protocol, production equivalent IFU's and production equivalent equipment (both primary and secondary, where applicable). It evaluates the DUNs under simulated user conditions in a surgical cart-type and iSuite (with arthroscopic or laparoscopic devices) settings. Design Controls govern the process of design and development to ensure the resulting product is safe and effective for its intended use.

Phase	Theme	Objective
I	Concept and Plan (Design and Development Plan, Design Inputs)	Confirm that product concept and plan are well-defined and approved. Design Inputs and Risks are well defined.
II	Design, Build, Verification and Validation (Design Outputs, V&V, Design Changes, Design Transfer)	Confirm that product and process design is verified and validated. Confirm that product is safe and effective for use.
III	Limited Launch and Stock Build (Design Changes)	Confirm that product will be successful in the market through a limited launch of the product. This will provide confidence to commit to production.

Fig.1: Design Control Phases

Laparoscopy is keyhole surgery that is used to examine and operate on the interior of the abdominal or pelvic cavities. It is performed under general anaesthesia, usually by a surgeon. During laparoscopy, a small cut is made in the abdomen through which a laparoscope is inserted to look inside the abdomen and pelvis. Gas is used to inflate the belly so the surgeon can see the organs properly whereas an arthroscopy is by the doctor when he wants to inspect the inside of a joint. This is done using an arthroscope. Arthroscopy can be used to help

diagnose a problem in a joint, and can also help guide surgical repair of a joint problem. The surgery is done with narrow, pencil-shaped surgical implements.

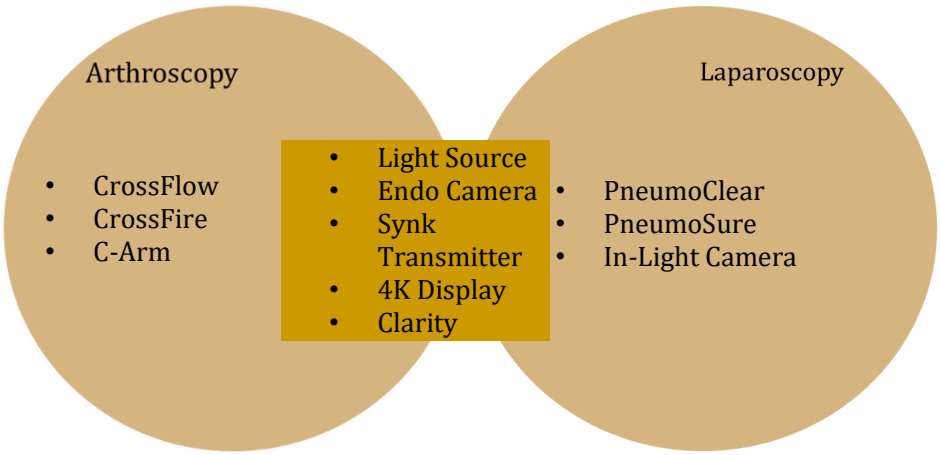

Fig.2: Arthroscopy v/s Laparoscopy

Figure 2 depicts the devices used in arthroscopy and laparoscopy surgeries. The light source (L10 light source/ L11 Light source), Endo camera (1488 camera/1588 camera/1688 camera), Synk Transmitter, 4K Display and clarity being common in both the surgeries whereas the Crossfire being replaced by Pneumosure/ Pneumoclear in Laparoscopy surgeries.

The SDC is a comprehensive OR documentation systems. It is part of the Stryker 4K visualization platform (i.e. 4K camera, 4K endoscopes, 4K display, 4K routing, 4K Clarity video processing, 4K image capture and video recording) as well as legacy hardware platforms that will enable surgeons to further distinguish anatomy across minimally invasive specialties, while providing a simplified experience to the surgical team. The SDC comes with a 4K visualization platform. This innovation in the advanced imaging and OR connectivity has been driven to allow the surgeon to see and do more. It is intended to be used for electronic transfer, storage, and display of medical device data independently of the functions or parameters of any connected medical device. It is also intended to convert the data of the medical device from one format to another according to the preset specifications.

These documentation systems have additional packages:

- The SDC Base Package refers to the SDC console that has only the base software installed and contains no additional accessories.

- The SDC Device Control Package includes a software upgrade that enables SDC to control connected compatible devices and a remote control that is used by the nurse or O.R. technicians to issue commands to the attached devices.
- The SDC Voice Package consists of a software upgrade that includes the voice device control and voice annotation features as well as a microphone headset worn by the surgeon to give voice input to the system.
- The SDC DICOM Package is a software upgrade that enables SDC to convert digital images to the DICOM format, obtain patient schedule information through the Modality Worklist, and retrieve prior case images through Query/Retrieve. DICOM is a communications standard that enables the transfer of information between devices produced by different manufacturers.
- The SDC Video Editing and Telestration Package is an optional upgrade that allows the user to edit (Trim, Cut & Stitch) the captured Videos and add graphical annotation over Live Video preview to highlight the intended region. The annotated live video preview is displayed on surgical monitors and can be streamed over network. The SDC Video Editing And Telestration Package cannot be used as a standalone software activation package and must be used in conjunction with the activation of SDC Workflow Software.
- The SDC Routing Package integrates the SPI3 routing capabilities through router control. An external Touch Panel Display connected to the SDC will allow the user to view the UI via a larger viewable and controllable area instead of the current smaller built-in LCD screen on the SDC.
- The Connected OR 4K Recording Package is only available as a package is a software upgrade that enables SDC to record a 4K video in the highest quality.
- Accessories to the SDC includes:
  1.) The SDC iPad application- MyPatient SDC is an optional accessory that provides for storage and review of surgical video and images from the SDC, Studio3 and PowerShare onto an Apple iPad. The application also allows the surgeons to - edit/add annotations used for images saved from the SDC, create notes and PDF Templates directly on the iPad, share the videos, images, and/or notes via email, generate PDF reports from templates, merge PDF's and print.
  2.) The SDC Stryker Surgeon Profile Manager is a convenient software tool (web application) only available to Stryker Sales Representative is an optional software accessory to SDC system that provides ability to electronically transfer preset settings and surgeon profile to the SDC. The web application also allows Stryker Representative to -

create surgeon profile out of the SDC, create /edit / arrange annotations, create OpNotes, create Device Presets, search and create profiles of surgeons with PowerShare and ProCare accounts, create Messaging Contacts

3.) The SDC EMR Connectivity and PowerShare packages are optional software accessories to the SDC System that enables archival and sharing of case asset to compatible hospital EHR systems and Nuance's PowerShare Image Sharing Platform.

Project Management tools used:

1.) Agile: It is a project management tool that is used for documentation purposes.
2.) JIRA: It is also a project management tool that is used for tracking of issues and bugs related to the software

Chapter 2

REVIEW OF LITERATURE

Minimally invasive surgery

Minimally invasive surgery is a surgical technique in which the surgeon makes little/small incisions in the patient's body, through which a special instrumental called trocar is inserted. A camera is inserted to the trocar which allows the surgeon to visualize during the intervention. In the others trocars, the rest of the instruments are introduced based on the surgeon's requirements. These surgeries (may be laparoscopy, arthroscopy, thoracoscopic etc.) offers great advantages over traditional methods. These include making little incisions in the body, low probability of infection and no necessity of future interventions (López-Mir F et al.,2011). This provides the benefits of a short hospital stay and a quick recovery period. Drawbacks of this technique include lack of direct vision and the lack of perception by the surgeon. The development of various devices and platforms in the recent years have allowed the surgeons to carry out such procedures in a safer and efficient manner. This platform has also enabled the surgeon to simulate surgical tasks (e.g., suturing and dissection) in a much better way. For example, the recent natural orifice transluminal endoscopic surgery technique enables the resection of abdomen without necessitating any skin incision. Endoscopic surgeries are becoming popular among surgeons because the surgeons are capable of performing flexible endoscopy in many Asian countries.(Daniel Jin Keat Lee et al.,2015).

Comparison between Open surgery and Minimally Invasive Surgery

Minimally invasive surgery (MIS) is being used increasingly for a number of procedures since the last decade. This approach holds the advantages of better cosmesis, fewer wounds, a short hospital stay, and a quick return to the functional status. Although all of these benefits have not been proven completely successful in studies examining MIS versus open approaches, patients however remain interested in the MIS approach (Aslam Ejaz et al,2014). The advantages of MIS might cause octogenarian and high risks of operative morbidity and mortality in older patients who then become willing to receive surgery instead of conservative treatment(Chien-An Liu et al,2017). Recently, a study had been conducted that compared MIS with open surgery for octogenarian and older gastric cancer patients. The result thus obtained from the study concluded that MIS for gastric cancer may be performed safely in octogenarian and older patients relative to open surgery due to the advantages such as significantly less blood loss, lower consumption of

analgesic, and a shorter postoperative hospital stay. More recently, the use of MIS approach complex abdominal operations has been increasing over time and it is particularly gaining acceptance for urologic, bariatric, gynecological ,colorectal procedures and complicated HPB operative procedures and major hepatic resections

Use of documentation systems in the operating room

Nowadays, documentation systems are becoming popular for use in the operating rooms. Surgeries are being filmed for teaching purposes and also for publications. Since the evolution of digital recording, patient records has become increasingly popular .It offers various advantages such as allowing long-term storage and retrieval of patient data and more importantly it is playing a major role in database organization. In addition to this, sharing of the digital contents has also become easier due to the internet that has various video sharing sites and social networks where the content can be uploaded. These documentation systems has created a simple and a very economical system for the surgeons to record surgeries in high definition under sterile conditions without any interference. The SDC comes with a 4K visualization platform. This platform has enabled the surgeons to distinguish anatomy across all minimally invasive procedures, while providing a simpler experience. This innovation in the advanced imaging has been driven to allow the surgeon to see and do more. It is meant to be used in general laparoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy and plastic surgery wherever a laparoscope/endoscope/arthroscope is indicated for use. It is intended to be used for electronic transfer, storage, and display of medical device data independently of the functions or parameters of any connected medical device..

Due to the increasing requirements for documentation and communication capabilities of medical devices in the operating room, their integration and modular networking has become very important. Commercial integrated operating room systems poses a certain limitation of integration of devices from different vendors. In order to overcome these limitations, there has become a need for the introduction of a standardized architecture that is based on standard protocols and interfaces that enables the integration of devices from different vendors based on heterogenous software and hardware components (Benzko J et al,2012). The SDC comes with a standardized hardware and software platform that enables the integration of devices from different vendors in one operating room thus eliminating this limitation.

Recently, a digital video editing system that is ideal to produce video documentation and still images has been introduced. It allows the mixing of different streams of video input from all the devices that are in use in the operating room with the application of filters and effects that produces a final end-product (Perrini Pet al,2017). The SDC gives an advantage of recording and saving

onto an iPad, DVD, CD, USB drive that provides an inexpensive, portable and easy-to-use medium to store. It also provides a system for storing onto the Hospital servers through which the data, high-quality, still images can be retrieved by the surgeon at any point of time.

Chapter 3

OBJECTIVE

System Design validation of SDC and it's accessories for two software releases:

- Software version 1.2.0 (Cart Limited release)
- Software version 1.2.1 (Cart Full release alongwith 1688 camera and L11 light source)

Chapter 4

MATERIALS AND METHODS

4.1 Procurement and maintenance of SDC and its accessories

The post production units of SDC along with other devices and accessories to be required for the system design Validation were obtained from the Production unit in San Jose, USA which were then assembled in iSuite lab in SGTC, Gurgaon where these devices were maintained within a simulated use environment in the lab. The simulated environment was set up as similarly as possible to the real use environment for the purpose of Design Validation.

For 1.2.0 Cart Limited Release, Post Production units of SDC alongwith Voice package, Device package and 4K recording package were obtained whereas for 1.2.1 Full Release, the post production units of 1688 camera Capture Unit and L11 light source along with EMR Package, DICOM package, PowerShare license, Data Mediator,Stryker surgeon profile manager, & iSuite media management system were obtained.

4.2 Requirements for Validation:

- The System Design Validation was carried out by following a Test Protocol that establishes the procedures to validate applicable defined user needs (DUNs) of the SDC and it's accessories. Appendix A tab of the Test protocol lists all DUNs under evaluation for System Design Validation and indicates the minimum number of device samples, number and type of users required for evaluation of each DUN within scope of the design validation, as well as rationale for sample size selection. The Appendix B of the Test protocol lists the hazard-related use scenarios for validation, and indicates the minimum number of device samples, number and type of users required for evaluation of each hazard-related use scenario within scope of the system design validation, as well as rationale for sample size selection. The Appendix C of the Test protocol lists the Design validation datasheet for Small GUI. Design Validation Datasheet for Large GUI can be found in the Appendix D tab of the Test Protocol.
- System design validation will evaluate the DUNs under simulated user conditions in a surgical cart-type (with Arthroscopic or Laparoscopic devices) settings.
- The purpose of this test is to simulate the clinical process as closely as possible in the system design validation setup. Each evaluation consisted of the different system configurations. Consideration was given to the user profile necessary to properly evaluate the given user need.

These procedures were followed in an equivalent surgical setting that sufficiently emulates an environment appropriate for the evaluation of the user need. Surgical (rubber) gloves and a surgical mask were worn when completing procedural tasks to simulate actual use conditions of the user profiles.

- System Design Validation was required to test against an approved design validation test protocol, production equivalent IFU and production equivalent equipment (both primary and secondary, where applicable).

4.2.1 Logistics

The procedural flow chart below depicts the logistics of executing design validation per the protocol.

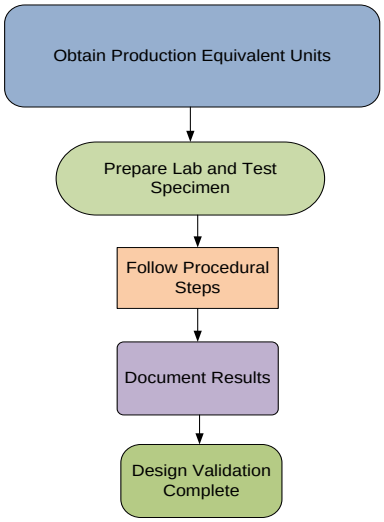

Fig.3: Testing Flow chart
(Source: http://agile.endo.strykercorp.com/Agile/PLMServlet)

Figure 3 depicts the testing flowchart.The first step show the production equivalent units being obtained from the production unit which are then prepared for testing by setting up in the laboratory and are then tested by following a validation protocol that contains the procedural steps. The documentation of the results being the last step following which the Design validation is completed.

4.2.2 Hazard-Related Use Scenarios Requiring Validation and Associated Sample Size

Sample size of one or more was required.Before initiaiting the validation, Reasonably foreseeable hazard-related use scenarios from the SDC and its accessories risk table were reviewed. All hazard-related use scenarios with a severity of harm of S3 and above that could

be caused by use error will be included in the system design validation based on guidance from, except for hazard-related use scenarios which has the potential to result in harm to a test participant. For hazard-related use scenarios which has the potential to result in harm to a test participant (e.g. plugging cables into wet connectors), it is determined that the risk assessment is adequate and actual testing of the hazard-related use scenarios with a severity of harm of S3 may not be necessary to evaluate during system design validation.

4.3 Arthroscopic Cart – Design Validation

4.3.1 Set up of SDC and another devices

- During System design validation testing, multiple equipment configurations were explored, and these configurations are depicted in (but not limited to) the figures below. Positioning, setup and Cart configurations of the equipment may differ from the scenarios outlined.
- The setup for Cart included a knee, shoulder and a belly model as necessary for surgical simulation.
- SDC in arthroscopy cart scenario and arthroscopy surgical setup is described in Fig.4 (a.) and (b.) respectively.

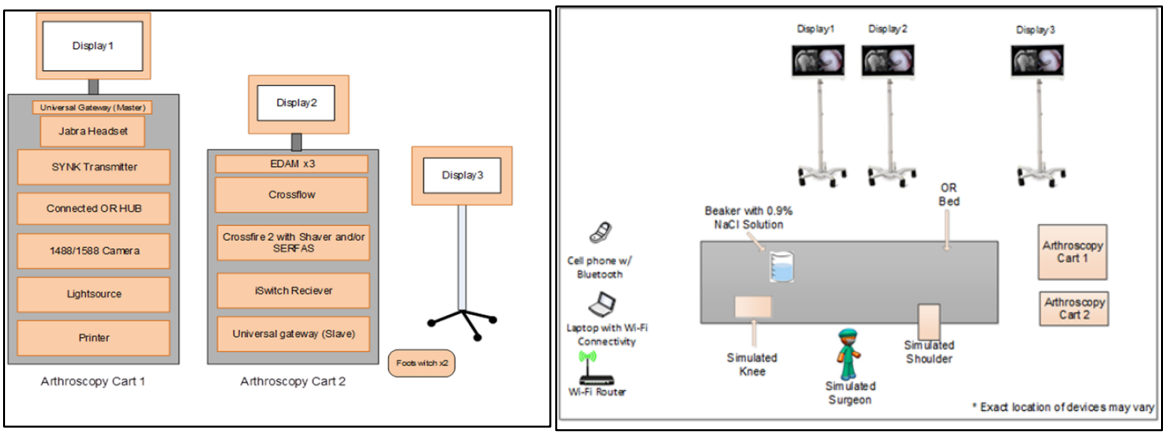

Fig.4(a) SDC in Arthroscopy Cart scenario shows two carts with all the primary devices used for surgeries and **fig (b)** shows the Arthroscopy surgical setup within an operating room

(Source: http://agile.endo.strykercorp.com/Agile/PLMServlet)

4.2.2 Connection of the required devices and installation of Packages:

The SDC was then connected to a power supply and the required devices were then connected to the SDC. To this, the required packages were then installed for both the software versions. The following table describes the test samples that were installed onto the SDC for Arthroscopy cart scenario.

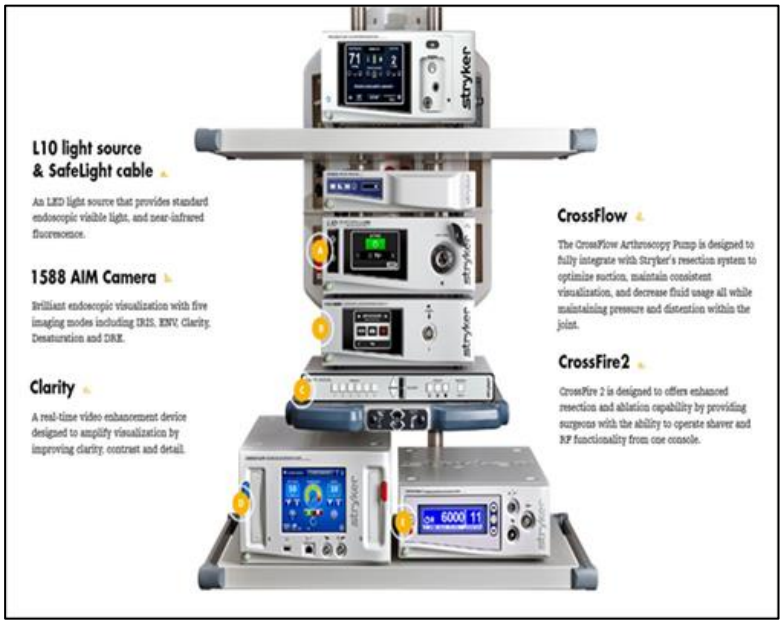

Fig.5: Arthroscopic Design validation Cart

Source: (http://1588aim.com/)

Figure 5 shows the Primary devices that are required for the Arthroscopic design validation.

a.) L10 AIM Light source & safelight cable that comes with Advanced Imaging Modality Technology is a light-generating unit designed to illuminate surgical sites in the following applications: visible light (White Light mode), near-infrared fluorescence (ENV mode), and near-infrared transillumination (IRIS mode).

b.) 1588 AIM camera comes with Infrared Compatibility and is an endoscopic camera system that is used to produce still and video images in the surgical field during surgical endoscopic procedures. It has 5 Advanced imaging Modalities.

c.) Clarity Console is used in the OR to minimize the presence of smoke within the camera.

d.) Crossflow is a fluid management system that integrates with compatible resection consoles within an OR.

e.) Crossfire powers a motorized shaver handpiece for the mechanical cutting and debridement of bone and soft tissue Generates bipolar radio frequency (RF) energy for the electrosurgical cutting and coagulation of tissue.

#	Description	Quantity
1	Pkg, SDC Base System	1
2	SDC Device Control Package	1
3	SDC Voice Package	1
4	SDC 4k Recording Package	1
9	Mypatient SDC Ipad App	1
10	Stryker Surgeon Profile Manager	1

(a)

#	Description	Quantity
1	Pkg, SDC Base System	1
2	SDC Device Control Package	1
3	SDC Voice Package	1
4	SDC 4k Recording Package	1
6	SDC Dicom Package	1
7	SDC EMR Connectivity Package	1
9	SDC Powershare License	1
10	Mypatient SDC Ipad App	1
11	Stryker Surgeon Profile Manager	1

(b)

Table 1: Table 1 (a) shows the Test samples for Arthroscopy set up for Cart limited release (v1.2.0) and Table (b) shows the test samples for Cart Full release (v1.2.1)

4.4 Laparoscopy Cart – Design Validation

4.4.1 Set up of SDC and other devices:

The configuration of the SDC and other devices used in laparoscopic surgeries are depicted in the Figure 6. SDC in laparoscopy cart scenario and laparoscopy surgical set up has been descibed in Fig.6 (a) and (b) respectively.

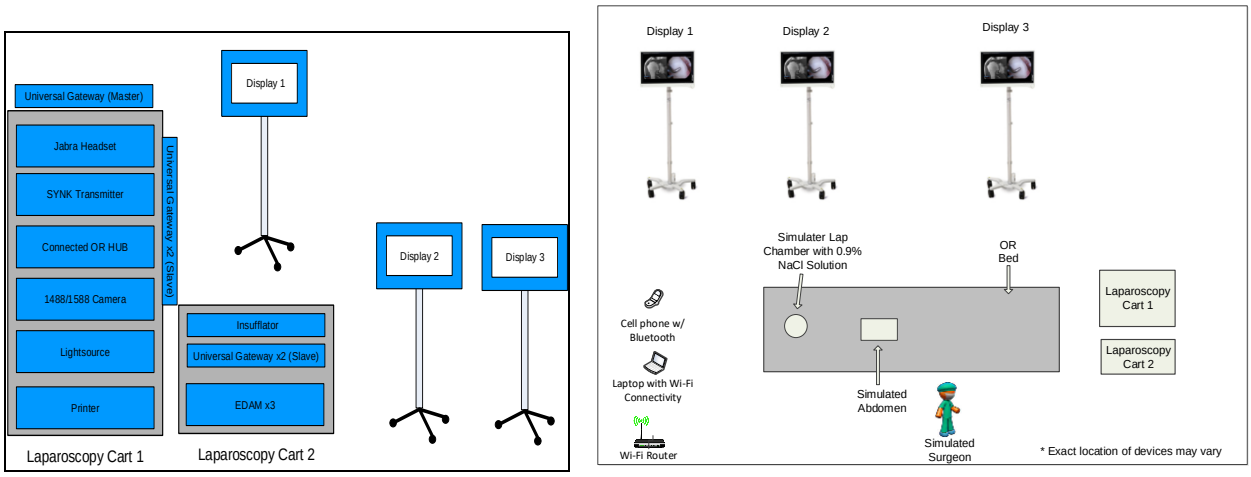

Fig.6: SDC in laparoscopy cart scenario **(a)** and laparoscopy surgical setup **(b).** The figure **(a)** shows two laparoscopy carts where the SDC is placed along with all the primary devices and figure **(b)** shows the laparoscopy surgical set up in an operating room.

(Source: http://agile.endo.strykercorp.com/Agile/PLMServlet)

4.4.2 Connection of the required devices and installation of Packages

The SDC was connected to a power supply alongwith all the other required devices . The required packages were then installed onto the SDC. All the required devices are described in the figure 8 and required test samples alongwith the packages are described in figure 9.Production equivalent devices and packages were used for the system design validation.

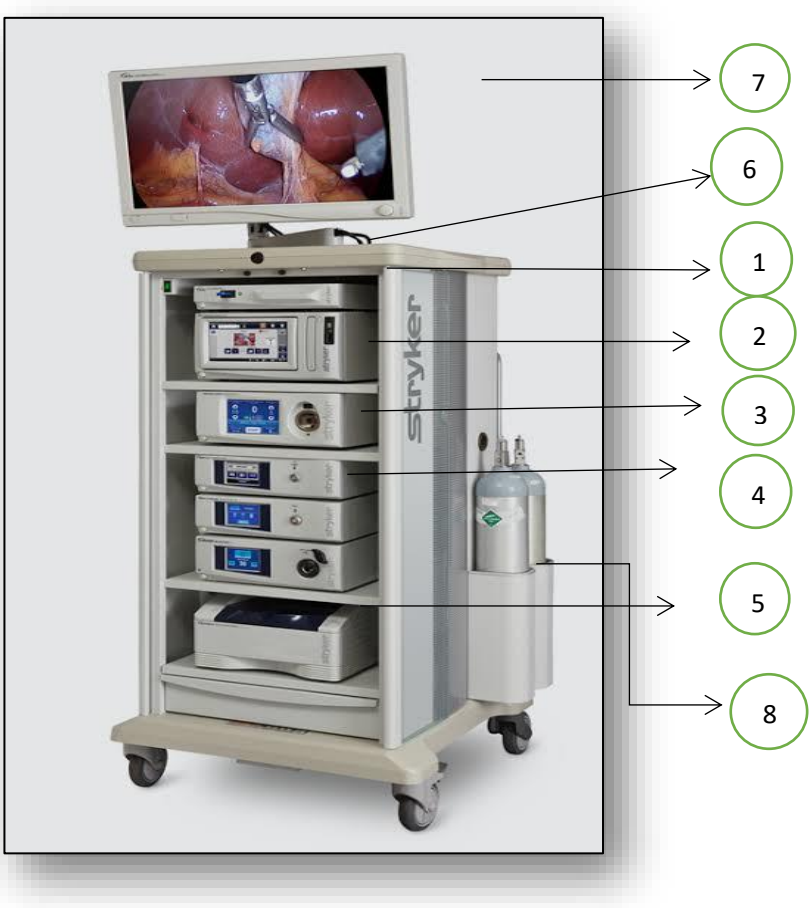

Figure 7: Laparascopy Design validation Cart

The figure shows the Primary devices that are required for the Arthroscopic design validation.

1.) Stryker Digital Capture is the previous generation of SDC that is a documentation system which is used in th OR for a number of reasons.
2.) Insuffalation device is a device that is used only in the laparoscopic surgeries to pump fluid under pressure to aid in surgery. Surgical insufflation safely transports CO2 to the patient's body.
3.) Endoscopic Cameras (1488 Camera and 1588 camera) specialize in low light videography at reduced noise levels. They also operate on lower power levels than ordinary cameras to reduce patient risk. 1588 camera comes with AIM technology and has five advanced imaging modalities: ENV, IRIS, Clarity, DRE, and DESAT.
4.) The Stryker L10 LED Light Source with Advanced Imaging Modality Technology is a light-generating unit designed to illuminate surgical sites in visible light (White Light mode), near-infrared fluorescence (ENV mode), and near-infrared transillumination (IRIS mode).

5.) SDP1000 printer provides high quality and high resolution printing of Stryker Digital Capture Device image data. It is a dye sublimation thermal transfer printer.

6.) SYNK wireless transmitter is used to receive a high-definition video signal over a radio-frequency link and is used to wirelessly transmit video signal to the display.

7.) The 26" VisionPro SYNK Wireless Display has a LED backlighting and wireless technology and is brighter, thinner, and lighter than previous generations.

8.) Insufflation Cylinders contain the CO_2 that is used up in the Insufflators during the surgeries.

Test Samples for Laparoscopic cart v1.2.0		
#	**Description**	**Quantity**
1	Pkg, SDC Base System	1
2	SDC Device Control Package	1
3	SDC Voice Package	1
4	SDC 4k Recording Package	1
9	MyPatient Hub SDC iPad App	1
10	Stryker Surgeon Profile Manager	1

(a)

Test Samples for Laparoscopic cart v1.2.0		
#	**Description**	**Quantity**
1	Pkg, SDC Base System	1
2	SDC Device Control Package	1
3	SDC Voice Package	1
4	SDC 4k Recording Package	1
6	SDC Dicom Package	1
7	SDC EMR Connectivity Package	1
9	SDC Powershare License	1
10	Mypatien Hub SDC Ipad App	1
11	SSPM	1

(b)

Table 2: The table **2(a)** shows the Test samples for Laparoscopy design validation v1.2.0 and table **(b)** shows the Test samples for Laprascopy Design validation for v1.2.1.

4.5 Procedure for Validation

1.) Appendix C that contains the Design validation datasheets and the procedural steps for Cart release was followed for Arthroscopic and Laparoscopic System Design Validation for both the softwares.

2.) Data was documented in the Test Result Datasheets located in Appendix C of the Test protocol.

3.) Each DUN was evaluated in a complete surgical OR workflow only even if it was not explicitly mentioned against the test steps.

4.) For simulated/actual power loss/crash related scenarios, additional factors such as failsafe, preservation of user data on system reboot, boot time following a crash, windows error logs/ screens etc. were evaluated as well.

5.) Certain validations steps were negative testing and/or push the limit test steps that were performed only when the functionality related to those steps were thoroughly evaluated i.e. when the steps of the same DUN which are used to evaluate the DUN were performed**.**

4.6 DUNs Requiring Validation and Associated Sample Size:-

The DUNs assessed are taken from the SDC & its accessories following DIOVV's.

For Cart Limited release Design validation the DUN's mentioned in the following FS were considered:

- FS10432 (DIOVV For MyPatient SDC SDC IPad Application)
- FS10585 (DIOVV For Stryker Surgeon Profile Manager)
- FS10737(DIOVV For SDC Base System)
- FS10739 (DIOVV For SDC Voice Package)
- FS10740(DIOVV For SDC Device Control Package)

For Cart Full release Design validation the DUN's in the above mentioned FS alongwith the following FS were considered:

- FS10741- SDC EMR Connectivity Package
- FS10743- SDC Dicom Package
- FS10747- SDC Powershare Package
- FS10855- SDC 4k Recording Package

4.7 Acceptance Criteria

At several points during the execution of this design validation, continous evaluation of the SDC system was done for:

4.7.1 Usability/ Ergonomics

- LCD panel brightness and LCD panel viewing angles
- Visibility of the GUI icons. Are the GUI icons and text readable? Icons too big, too small?
- Intuitiveness of the Graphical User Interface (GUI) workflow.
- Stack ability and weight of the console
- Ability to make connections to the SDC console on the front panel and rear panel.
- Amount of information conveyed by on device labels/logos/decals/silkscreen. Does the placement on the device hinder any other information conveyed?
- Robustness of aforementioned printed material. Does it wear out with use?
- Power button tactile feel and power button response
- Does the user always need to use an IFU to operate the system? Are the instructions in the IFU clear to the user?
- Does the IFU provide adequate information on Failsafe?

4.7.2 System Performance

- SDC system shall have acceptable response times (For ex: SDC boot up times, Touchscreen response time, time to print, time to archive data to external media)
- SDC shall update device status updates without user perceptible delays.
- The system shall recover gracefully from any unexpected errors.
- On SDC systems activated with Voice and Device packages, the system shall have quick response times to voice control commands and device control commands from the SDC Touchscreen or the Remote Control.

4.7.3 Date and Time

- Ensure that the Date and Time appears correctly with the correct format on the (ex: MM/DD/YYYY) on the SDC system (Patient ID Field, MWL etc). Additionally, date and time shall appear correctly in the following locations:
    a) Archived cases including hard drive, CD/DVD, DICOM, USB, FTP4
    b) Printouts

c) PDFs
d) Surgical Timeout Checklists

4.7.4 Image/Video /Audio Quality

- Ensure that image/video quality (For ex: image colors) is acceptable through all testing scenarios
- Aspect ratio for all live video, captured images and recorded video must remain the same as original.
- OSD (including text overlays, PIP, PBP, flip screens and review of captured images) must work properly.
- Video through SDC must not shift.
- Video through SDC must display without distortion/interference.
- Images captured and videos recorded shall not have interference or distortion.
- Audio output from SDC (Ex: voice announcements) shall not be distorted.
- Recorded audio shall playback without any distortion or noise.
- The user must be able to review any images capture/videos recorded (that are saved to external media) on another computer.

4.7.5 Voice and Device Control (for activated packages)

- Voice Timeout function adequate to navigate through menus and return to main menu? Too little or too much?
- OSD menu text size too small or too large
- Headset Ergonomics: Easy to wear, light weight etc
- Time to charge Voice headset
  - Voice recognition/recognition accuracy
  - Remote control button functionality
  - IR Remote control range (distance)
  - Wireless coexistence of IR Remote and Jabra headset with other RF devices
  - Menu navigation, annotations and device control using IR Remote, Voice and 1588 CCU camera head

4.7.6 EMR, DiCOM and Powershare (for activated packages)

- Ease of enabling
- Relative performance on the same network

4.7.7 4K Recording (for activated packages)

- Perceptible video latency
- Quality of recording i.e. video bitrate.

4.7.8 Video Editing and Telestration (for activated packages)

- Quality of streaming
- Lag in streaming
- Performance of RTP vs UDP.

4.7.9 Routing (for activated packages)

- Ease of creating route/sinks
- Video latency, clarity and route performance.
- Ensure that route failsafes work under all intended circumstances.

4.8 Documentation of Results:

It was the final step involved in the Design validation of SDC. The results obtained were then documented in two different Test Reports, one for the Cart Limited Release and the other for the Cart Full Release. These reports were then routed on the Agile tool, assigned to a number of reviewers and implemented after they were reviewed. These test reports marks the end of the Design Validation and only those results that are documented in the reports are considered valid. Any deviations from the report was not considered.

Chapter 5
RESULTS AND DISCUSSION

7.1 System design validation data analysis

The data collected for system design validation will be attribute (pass/fail) which signifies whether the product is safe and effective and shall be released in the market or not. The purpose of the pass/fail criteria as attribute data was to determine whether the product has met the DUN to a clinically acceptable level. System Design Validation determination of a pass or fail was based upon the ability to successfully complete a surgical task/step without an unexpected result or behavior. Acceptance of results was assessed based on any observations, issues, or findings during design validation testing. Additional criteria for pass/fail determination was dependent on meeting the acceptance criteria.

The requirements of the users for different modules of the product SDC which they desire in the product and are termed as Defined User Needs/Intended use and are described in Annexure A. These modules are:

1.) Packaging, Labeling, Identifiation and IFU
2.) SDC Base
3.) EMR
4.) DICOM
5.) Streaming
6.) Powershare
7.) 4K recoding
8.) My Patient Hub iPad App
9.) Stryker Surgeon Profile Manager
10.) Device Control
11.) Voice Control

These User Needs are assosiated with a number which is termed as DUN Number. Some of the DUN's were passed for both the software versions or either of them while some of them failed for both the software versions. These results were still considered valid and the product was successfully released in the market as the failed DUN's did not impact the user or the environment as the risk of severity was very low and were categorised as enhancement.

5.2 User data analysis for tasks from external display:

The data was obtained from the users of SDC during SDC Nurse Focus Group Presentation. The following data was observed during various SDC workflows by the users/surgeons. The data depicts the importance of tasks from external display and importance of tasks from the console of the SDC in general surgeries.

The importance of tasks from the external display are depicted in **Figure 8**. The ratings show the surgeon preferences for the SDC features that are accessible from the external display. According to the data provided, it is seen that the surgeons use the external display majorly for entering the patient information and scheduling cases. It is also majorly used for viewing the image gallery, annotating the images, exporting the cases to different networks, routing videos onto different sources. The External display is used for almost all important SDC functions such as capturing images and videos. It is least used for the messaging features.

The importance of tasks from the console are depicted in **Figure 9**. The data depicts the importance of tasks from the SDC console in mostly Orthopedics and the general surgeries**.** The ratings depict the surgeon preferences for a particular feature. According to the data provided, it is seen that the users prefer to use the SDC console for capturing the images and recording videos, saving the cases to a network (say, EMR, DICOM, FTP, Powershare), entering the patient details, changing the printer settings and for routing videos onto different sources. These are the features of the SDC that the users find nice to have in the SDC whereas the messaging feature and the checklist feature is found to be of no value to the user.

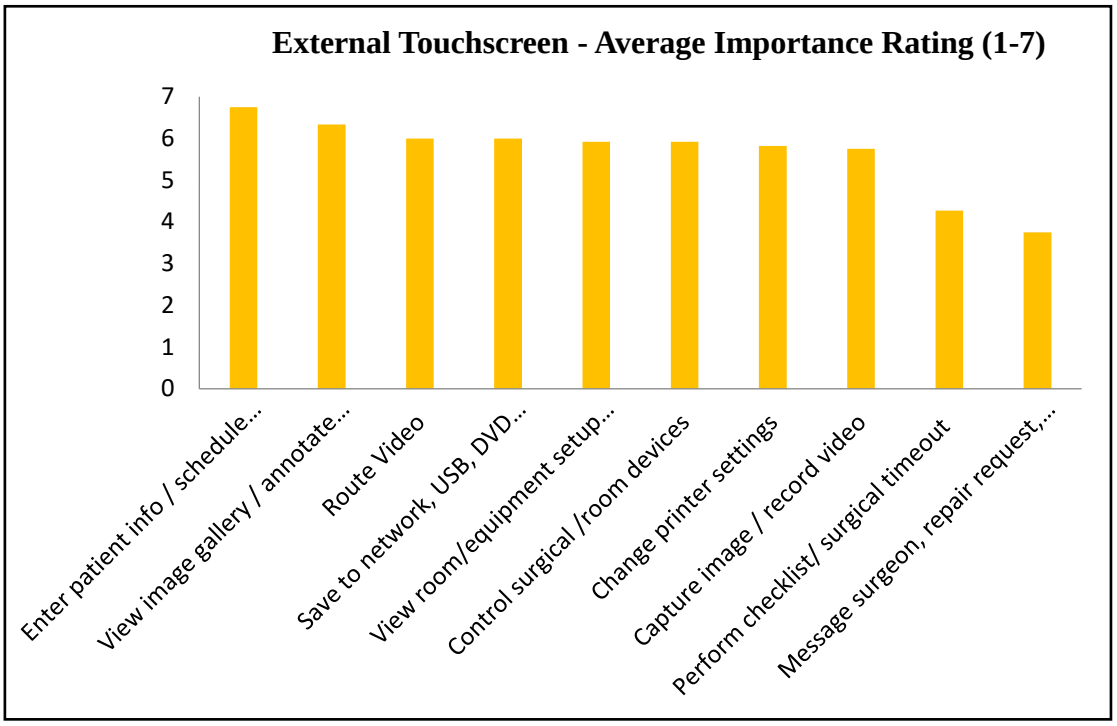

Fig.8: Importance of tasks from External Display

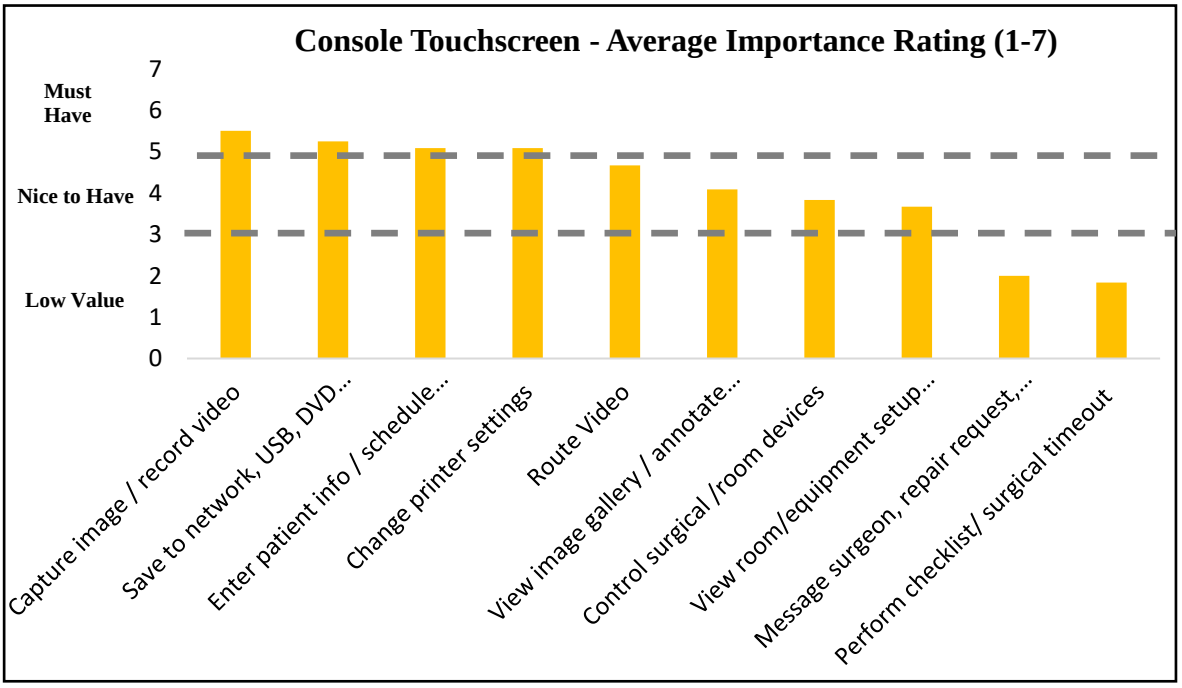

Fig.9: Important of tasks from SDC Console

5.3 User data analysis for Features of SDC:

The data depicts the importance of features of SDC. The favorite feature/part of the SDC are depicted in **Figure 10**. According to the data provided by The SDC Nurse Focus Group Presentation, it was concluded that the most favorite feature of the surgeons happens to be the Surgeon Preference/ Presets feature, which has increased the efficiency of the surgeons within an Operating room. This is followed by the Top Linear navigation that is present within a case. This feature has enabled easy to and fro from the case to other settings of the SDC during a surgical workflow. Out of all the servers, EMR proves to be the favorite of the users whereas the messaging feature of the SDC comes out to be the least favorite feature of some users.

The most utilized part of the SDC are depicted in **Figure 11**. Surgeon Preferences/Presets was the overwhelming feature favored by users to be most useful and utilized during a surgical workflow. Some of the users also prefer using the Messaging feature. Exporting feature is also utilized by the users as it turns to out to be easy to store onto a USB, Disc drive or to an iPad. The least used feature turns out to be the Timeout Checklist feature that is used by the nurses in an operating room shows the most useful part of the SDC. The most useful part of SDC are depicted in **Figure 12**. According to the data provided by The SDC Nurse Focus Group Presentation, it was concluded that the Surgeon Preference/ presets feature happens to be the most successful feature followed by Barcode scanning feature using which the patient details can be retrieved just by scanning the code. This feature remains successful as it saves time during a surgical workflow . The preload patients/ scheduled cases feature and messaging feature happens to be the least successful features and are not used by the surgeons in the operating room.

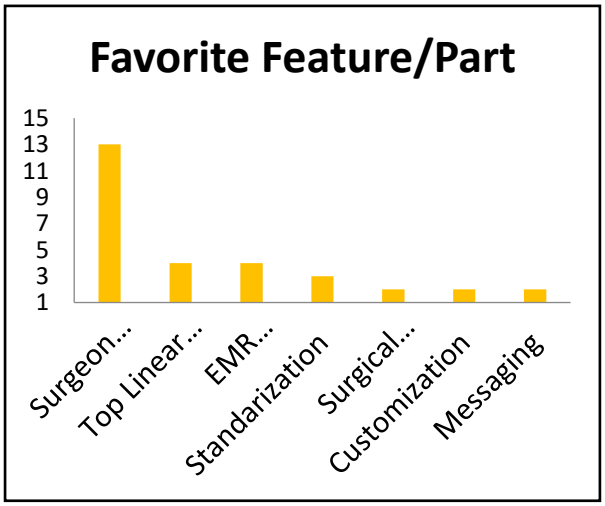

Fig.10: Favorite feature/Part of the user

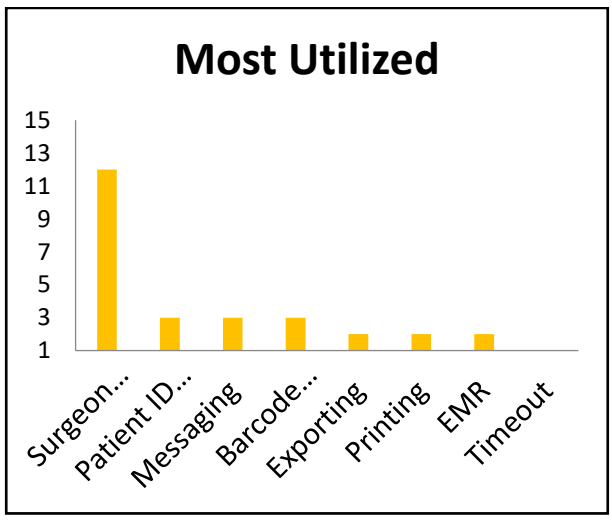

Fig.11:Most utilized part

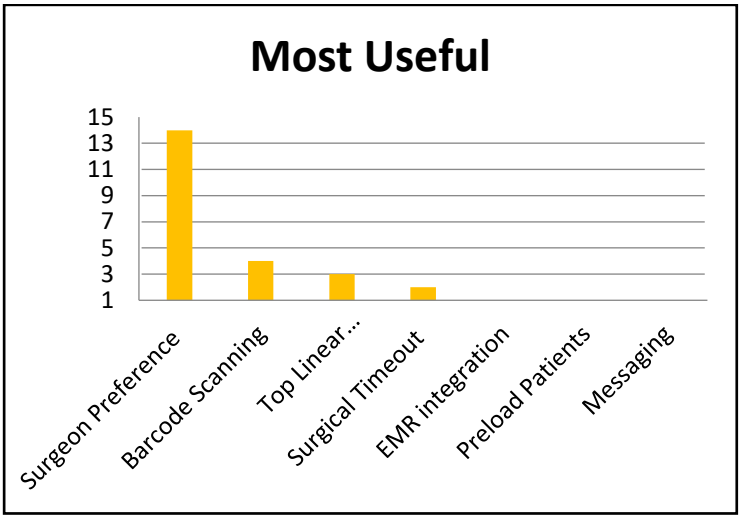

Fig.12: Most useful part of SDC

5.4 User data analysis of Saving and Software Defects:

The data shows the percentage of Saving and Software Defects that arose during an SDC workflow. The data in **Figure 13** was provided by the 2018 SDC Tech support calls and shows the modules of the SDC that arose difficulties to the users during the surgical workflow. The major difficulties were faced by the users during saving i.e- saving onto the USB, iPad, Disc drive and various servers. In about 55 cases, software issues such as blue screen were observed. Image flickering on the OSD monitors was seen in almost 42 cases whereas in 21 cases part failure was observed.

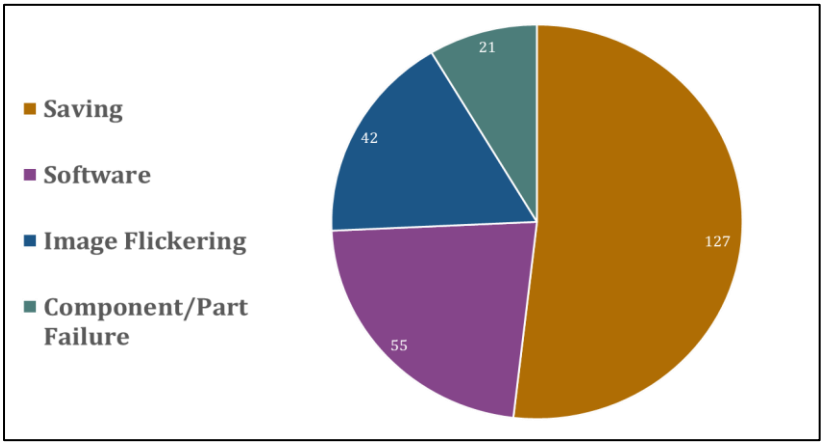

Fig.13: Savings and Software defects

5.5 User data analysis on Saving defects and Software defects:

The following data was provided by the 2018 Q1 SDC Tech support calls and shows the percentage of software and savings defects during an SDC workflow**.** The Saving defects are depicted in **Figure 14** and shows that in case of USB and DVD, primary failure was observed in cases larger than 4gb. In the case of iPad, primary failure was seen in case of software compatibility with SDC and ios. It can be concluded from the data that the save successful rate was maximum in case of USB and iPad whereas in case of FTP and EMR, not much difference was seen in the case successful and case failed rate. The Software defects are described in **Figure 15**. The data shows the three major defects arising due to the software**.** From this, it can be concluded that blue screen on the SDC accounts for the major software defect which can happen upon boot up or during mid case. The auto print accounts for almost 15% of the defects which happens during mid case whereas the remote calibration accounts for 10% of the total software defects.

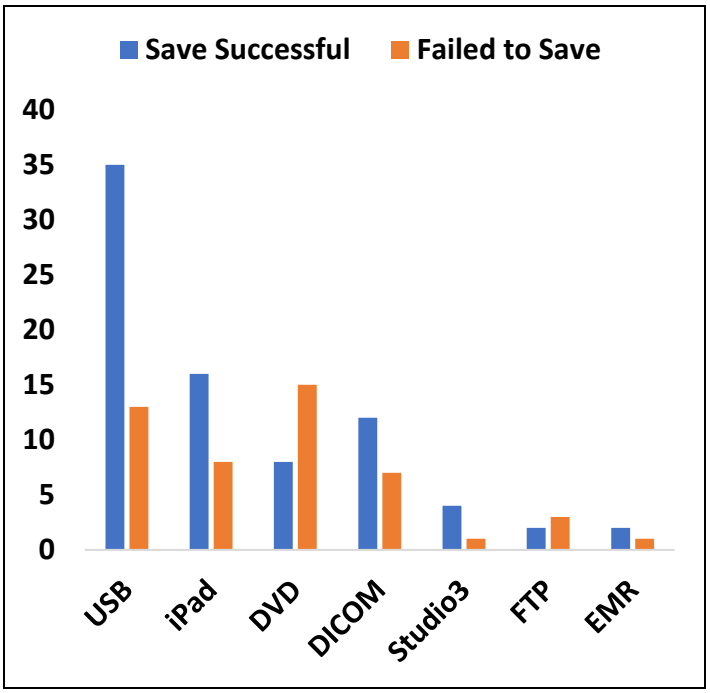

Fig. 14 : Savings defects

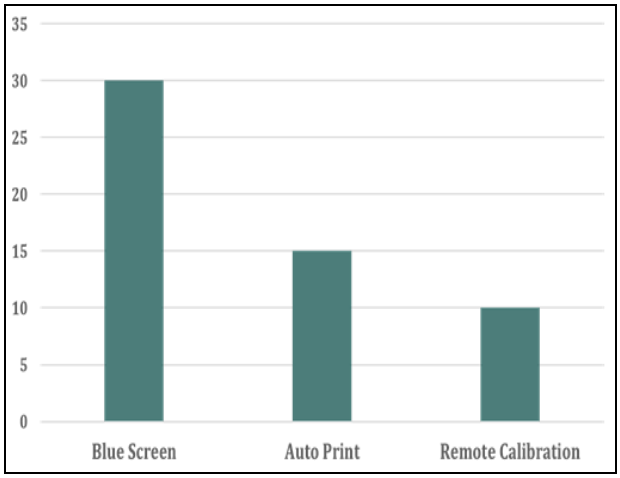

Fig. 15: Software Defects

Chapter 6

CONCLUSIONS

Quality testing is a procedure that is undertaken to ensure optimum product performance and more importantly to ensure complete and absolute patient safety. Since most of these devices contain extensions that enter the sterile field and even the human body quality testing is absolutely essential. Process validation is a process that ensures that a product consistently produces a result meeting its predetermined specifications.

The goal of System Design Validation of Stryker Digital Capture was to reduce the risks associated with SDC in the operating room in order to ensure that the SDC has met all the defined user needs and was effective and safe for the use. The validation was carried out in multiple evaluations on two different SDC production equivalent units, one unit for Arthroscopic Design Validation and other for Laparoscopic Design Validation for both the softwares. Most of the DUN's were passed but some of them failed for the product. The failed DUN's were mainly Enhancement to the product and had no potential to impact the patient's life as the severity of harm was very low. 16 DUN's had failed for v1.2.0 whereas for v1.2.1 , 8 DUN's had failed . Total of 24 DUN's had failed but the product was successfully released in the market as the product was safe for the use.

With products that actively help in saving people's lives in over 72 countries throughout the globe, the quality division of Stryker Corporation works around the clock, all year long to ensure the safety and comfort of its customers.

Chapter 7

REFERENCES

1.) de Sierra, C. V. G., Estevez-Cid, F., & Cuenca-Castillo, J. J. (2018). High-Definition Video Recording: Taking Sport Technology to the Operating Room. *The Thoracic and cardiovascular surgeon*, *66*(08), 667-669.

2.) Ejaz, A., Sachs, T., He, J., Spolverato, G., Hirose, K., Ahuja, N., ... & Pawlik, T. M. (2014). A comparison of open and minimally invasive surgery for hepatic and pancreatic resections using the Nationwide Inpatient Sample. *Surgery*, *156*(3), 538-547.

3.) Ibach, B., Benzko, J., Schlichting, S., Zimolong, A., & Radermacher, K. (2012). Integrating medical devices in the operating room using service-oriented architectures. *Biomedizinische Technik/Biomedical Engineering*, *57*(4), 221-228.

4.) López-Mir, F., Martınez-Martınez, F., Fuertes, J. J., Lago-Angel, M., Rupérez-Moreno, M., Naranjo, V., & Monserrat, C. (2011). LAPAROSCOPIC SURGERY. *Int J CARS*, *6*(1), S98-S102.

5.) Schurr, M. O., Arezzo, A., & Buess, G. F. (1999). Robotics and systems technology for advanced endoscopic procedures: experiences in general surgery. *European Journal of Cardio-Thoracic Surgery*, *16*(Supplement_2), S97-S105.

6.) Scollato, A., Perrini, P., Benedetto, N., & Di Lorenzo, N. (2007). A professional and cost effective digital video editing and image storage system for the operating room. *Journal of neurosurgical sciences*, *51*(2), 103.

ANNEXURE – A

Table 3: System Design validation Datasheets for v1.2.0 and v1.2.1		
DUN #	**Intended Use/User Need**	**Results (Pass/Fail/Not Tested)**
Module1: Packaging, Labeling, Identification and IFU		
559816 (FS10739)	The voice package shall include a means to activate voice control module on the SDC4K.	Passed for v1.2.0 and v1.2.1
559870 (FS10739)	(Package Labeling) The device packaging must be marked with the information necessary to identify and protect the device during transport and storage.	Passed for v1.2.0 and v1.2.1
559872 (FS10739)	(Instructions for Use) The device must be accompanied by the information necessary to identify it and use it safely in accordance with its intended use.	Passed for v1.2.0 and v1.2.1
559874 (FS10739)	(Warranty) The device must be accompanied by the information that explains the product warranty and terms of service.	Passed for v1.2.0 and v1.2.1
559880 (FS10739)	(On-Device Labeling) The device must be marked with the information necessary to identify it and use it safely in accordance with its intended use.	Passed for v1.2.0 and v1.2.1
559796 (FS10740)	(Package Labeling) The device packaging must be marked with the information necessary to identify and protect the device during transport and storage.	Passed for v1.2.0 and v1.2.1

Table 3: System Design validation Datasheets for v1.2.0 and v1.2.1		
DUN #	**Intended Use/User Need**	**Results (Pass/Fail/Not Tested)**
559798 (FS10740)	(Instructions for Use) The device must be accompanied by the information necessary to identify it and use it safely in accordance with its intended use.	Passed for v1.2.0 and v1.2.1
559800 (FS10740)	(Warranty) The device must be accompanied by the information that explains the product warranty and terms of service.	Passed for v1.2.0 and v1.2.1
559806 (FS10740)	(On-Device Labeling) The device must be marked with the information necessary to identify it and use it safely in accordance with its intended use.	Passed for v1.2.0 and v1.2.1
794945 (FS10740)	SDC4 shall be cleanable and can be disinfected	Passed for v1.2.0 and v1.2.1
515105 (FS10737)	As a technician, I want to be able to service the software so that the SDC4K is running in an stable state.	Passed for v1.2.0 and v1.2.1
559840 (FS10739)	Appropriate servicing and repair must be available.	Passed for v1.2.0 and v1.2.1
559858 (FS10739)	The Microphone/Headset system shall be cleanable.	Passed for v1.2.0 and v1.2.1
559772 (FS10740)	Appropriate servicing and repair must be available.	Passed for v1.2.0 and v1.2.1
559788 (FS10740)	The device control package shall be cleanable.	Passed for v1.2.0 and v1.2.1

Table 3: System Design validation Datasheets for v1.2.0 and v1.2.1		
DUN #	**Intended Use/User Need**	**Results (Pass/Fail/Not Tested)**
515100 (FS10737)	The system shall be labeled such that the user must be able to identify the device and use it safely in accordance with its intended use.	Passed for v1.2.0 and v1.2.1
Module 2: SDC Base		
1011659 (FS10737)	The system shall be compatible with other Stryker equipment in the OR	Passed for v1.2.0 and v1.2.1
515109 (FS10737)	The system shall provide a user interface.	This DUN failed for both the software versions i.e the system failed to provide a User interface
712122 (FS10737)	As a user, I want my system to be portable.	Failed for v1.2.0 and passed for v1.2.1
515043 (FS10737)	The system shall provide a mechanism to turn system ON/OFF.	Passed for v1.2.0 and v1.2.1
515108 (FS10737)	The system shall provide an easily accessible USB port.	This DUN failed for both the software versions i.e- the USB port did not function as intended
515095 (FS10737)	The system Shall have acceptable initialization and response times.	Failed for v1.2.0 and passed for v1.2.1
515055 (FS10737)	The system shall accept video input from common operating room sources and provide video output to common operating room displays.	Passed for v1.2.0 and Failed for v1.2.1
515052 (FS10737)	The system shall be able to connect to customer networks.	Failed for both the software versions i.e.- SDC was unable to connect to customer networks

Table 3: System Design validation Datasheets for v1.2.0 and v1.2.1		
DUN #	**Intended Use/User Need**	**Results (Pass/Fail/Not Tested)**
916817 (FS10737)	As a Service Technician I want to update the SDC with a SW image (OS + Application) so that my customer gets the updated SW capabilities	Passed for v1.2.0 and v1.2.1
515275 (FS10737)	The system shall provide a (self-help) interface.	Passed for v1.2.0 and v1.2.1
515060 (FS10737)	The system shall allow population of patient and case information.	Passed for v1.2.0 and v1.2.1
515064 (FS10737)	The system shall support surgical timeout and operating room checklist functionality.	Passed for v1.2.0 and v1.2.1
515093 (FS10737)	The system shall recover from unexpected power loss (or other events).	Passed for v1.2.0 and v1.2.1
515072 (FS10737)	The system shall record videos from internal and connected external sources.	Failed for both the software versions i.e. SDC was unable to record videos from internal sources
515044 (FS10737)	The system shall capture still images from internal and connected external sources.	Passed for v1.2.0 and v1.2.1
515083 (FS10737)	The system shall provide audio feedback.	Failed for v1.2.0 and passed for v1.2.1
611119 (FS10737)	The system shall display the number of videos recorded	Failed for v1.2.0 but passed for v1.2.1
515021 (FS10737)	The system shall provide a way to control recording from the sterile field.	Passed for v1.2.0 and v1.2.1

Table 3: System Design validation Datasheets for v1.2.0 and v1.2.1		
DUN #	**Intended Use/User Need**	**Results (Pass/Fail/Not Tested)**
515050 (FS10737)	The system shall provide a way to control image capture from the sterile field.	Passed for v1.2.0 and Failed for v1.2.1
515036 (FS10737)	The system shall display the number of images captured.	Passed for v1.2.0 and v1.2.1
515143 (FS10737)	The system shall provide video passthrough during unexpected power loss (or other events).	Passed for v1.2.0 and failed for v1.2.1
515023 (FS10737)	The system shall allow review of the recorded videos.	Passed for v1.2.0 and v1.2.1
515038 (FS10737)	The system shall allow review of the captured images.	Passed for v1.2.0 and v1.2.1
515062 (FS10737)	The system shall export case data to external storage.	Passed for v1.2.0 and Failed for v1.2.1
515103 (FS10737)	As a user, I want to use a system with an ergonomic user interface	Failed for both the softwares i.e. SDC failed to provide an ergonomic user interface
515071 (FS10737)	The system shall support printing of case data.	Passed for v1.2.0 and v1.2.1
611117 (FS10737)	As a Super Operator, I want to be able to assign roles to the operators so that the operators can access the device with least (minimal) privileges.	Passed for v1.2.0 and v1.2.1

Table 3: System Design validation Datasheets for v1.2.0 and v1.2.1		
DUN #	**Intended Use/User Need**	**Results (Pass/Fail/Not Tested)**
733637 (FS10737)	As a technician, I want to be able to secure the network connections to and from the system so that system is less vulnerable to network threats.	Passed for v1.2.0 and v1.2.1
733641 (FS10737)	As a technician, I want to be able to run the SDC4K with the least number of privileges or configuration required.	Passed for v1.2.0 and v1.2.1
515120 (FS10737)	As a Super Operator, I want to configure the date and time on the device so that the timestamps in the information generated on the system is accurate.	Passed for v1.2.0 and v1.2.1
515067 (FS10737)	As a Super Operator, I want to be able to setup unique operator accounts so that the operators can access the device in a secure way.	Passed for v1.2.0 and Failed for v1.2.1
725294 (FS10737)	As a operator, I want to be able to access the SDC4K using my account credentials so that I can access the device in a secure way.	Passed for v1.2.0 and v1.2.1
733633 (FS10737)	As a technician, I want to be able to protect BIOS so that the changes to hardware level configurations can be prohibited.	Passed for v1.2.0 and v1.2.1
611123 (FS10737)	As a technician, I want to allow execution of whitelisted applications only so that any attempts of installation or execution of unknown applications can be prevented.	Passed for v1.2.0 and v1.2.1
619089 (FS10737)	As a technician, I want to store sensitive information in an encrypted format so that the confidentiality of the data can be maintained.	Passed for v1.2.0 and v1.2.1

Table 3: System Design validation Datasheets for v1.2.0 and v1.2.1		
DUN #	**Intended Use/User Need**	**Results (Pass/Fail/Not Tested)**
733625 (FS10737)	As a technician, I want to transport sensitive information in an encrypted format so that the confidentiality of the data can be maintained.	Passed for v1.2.0 and v1.2.1
515098 (FS10737)	As a technician, I want to be able to obtain diagnostic information from the SDC4K so that I can monitor and troubleshoot the issues in the device.	Passed for v1.2.0 and v1.2.1
725089 (FS10737)	As a Super Operator, I want to be able to access the audit trail so that I can monitor the device for a typical usage.	Passed for v1.2.0 and v1.2.1
515133 (FS10737)	As a technician, I shall be able to receive device data and usage statistics on a central server so that data can be analyzed for various metrics and reports generation.	Failed for v1.2.0 and passed for v1.2.1
Module 3: EMR		
559906 (FS10741)	The system shall includes means to activate SDC4K EMR Connectivity Package in SDC4K.	Passed for v1.2.0 and v1.2.1
559908 (FS10741)	The SDC4K EMR Connectivity Package shall provide an interface for configuring Hospital EMR system.	Passed for v1.2.0 and v1.2.1
559910 (FS10741)	The SDC4K EMR Connectivity Package shall enable sending Case Data from SDC4K directly to hospital EMR systems for storage.	Passed for v1.2.0 and v1.2.1
559912 (FS10741)	The EMR Connectivity Package shall provide a means to verify patient data imported into the SDC4K against the hospital EMR system	Passed for v1.2.0 and Failed for v1.2.1

Table 3: System Design validation Datasheets for v1.2.0 and v1.2.1		
DUN #	**Intended Use/User Need**	**Results (Pass/Fail/Not Tested)**
559916 (FS10741)	(Package Labeling) The device packaging must be marked with the information necessary to identify and protect the device during transport and storage.	Passed for v1.2.0 and v1.2.1
559918 (FS10741)	(Instructions for Use) The device must be accompanied by the information necessary to identify it and use it safely in accordance with its intended use.	Passed for v1.2.0 and v1.2.1
559922 (FS10741)	(On-Device Labeling) The device must be marked with the information necessary to identify it and use it safely in accordance with its intended use.	Passed for v1.2.0 and v1.2.1
Module 4: DICOM		
559884 (FS10743)	The system shall support communication with a PACS server using the DICOM standard.	Passed for v1.2.0 and v1.2.1
559886 (FS10743)	The system shall provide a DICOM image album interface.	Passed for v1.2.0 and v1.2.1
559888 (FS10743)	The system shall provide a DICOM video album interface.	Passed for v1.2.0 and v1.2.1
559890 (FS10743)	The system shall provide an interface for configuring DICOM.	Passed for v1.2.0 and v1.2.1
559892 (FS10743)	The DICOM package shall include a means to activate DICOM module on the SDC Unit.	Passed for v1.2.0 and v1.2.1
559896 (FS10743)	The device packaging must be marked with the information necessary to identify and protect the device during transport and storage.	Passed for v1.2.0 and v1.2.1

Table 3: System Design validation Datasheets for v1.2.0 and v1.2.1		
DUN #	**Intended Use/User Need**	**Results (Pass/Fail/Not Tested)**
559898 (FS10743)	The device must be accompanied by the information necessary to identify it and use it safely in accordance with its intended use.	Passed for v1.2.0 and v1.2.1
559902 (FS10737)	The device must be marked with the information necessary to identify it and use it safely in accordance with its intended use.	Passed for v1.2.0 and v1.2.1
Module 4: Streaming		
876897 (FS10737)	The system shall be able to stream video from any of its inputs out onto the network	Passed for v1.2.0 and v1.2.1
515078 (FS10737)	The system shall be able to stream video from internal and connected external video sources.	Passed for v1.2.0 and v1.2.1
Module 5: Powershare		
559940 (FS10747)	The system shall includes means to activate Powershare Package in SDC4K	Passed for v1.2.0 and v1.2.1
559942 (FS10747)	The powershare package shall have an interface to configure Powershare account settings.	Passed for v1.2.0 and v1.2.1
559944 (FS10747)	The Powershare Package shall enables an interface with Powershare to store cases in Powershare account.	Passed for v1.2.0 and v1.2.1
559946 (FS10747)	The Powershare Package shall provide means to share case information with Surgeon or Patient.	Passed for v1.2.0 and v1.2.1
559950 (FS10747)	(Instructions for Use) The device must be accompanied by the information necessary to identify it and use it safely in accordance with its intended use.	Passed for v1.2.0 and v1.2.1

Table 3: System Design validation Datasheets for v1.2.0 and v1.2.1		
DUN #	**Intended Use/User Need**	**Results (Pass/Fail/Not Tested)**
Module 6: 4K Recording		
843889 (FS10855)	As a Surgeon/Nurse I want to record a 4K video in highest quality.	Failed for v1.2.0 and passed for v1.2.1
843895 (FS10855)	As a Surgeon /Nurse I want to be able to export a previously recorded 4K Video.	Passed for v1.2.0 and v1.2.1
843903 (FS10855)	As a Surgeon/Nurse I want to be able to play back a previously recorded 4K Video on the SDC4K	Passed for v1.2.0 and v1.2.1
843901 (FS10855)	As a Surgeon/Nurse I want to be able to play back a previously recorded and exported 4K Video on common media players.	Passed for v1.2.0 and v1.2.1
843893 (FS10855)	As a Sales Rep I want to sell SW Packages individually, so that I can enable/disable SW Packages according to my customers needs.	Passed for v1.2.0 and v1.2.1
Module 7: My Patient Hub iPad Application		
100219 (FS10432)	The user shall be able to access and install the application	Passed for v1.2.0 and v1.2.1
100221 (FS10432)	The user shall able to view/edit images, videos and case metadata for cases saved to the iPad	Failed for v1.2.0 and passed for v1.2.1
100223 (FS10432)	The user shall be able to store images and/or videos directly from the SDC onto the iPad via a tethered connection	Failed for v1.2.0 and passed for v1.2.1
100225 (FS10432)	The user shall be able to share case data via email	Failed for v1.2.0 and passed for v1.2.1
100227 (FS10432)	The user shall be able to search for saved cases+	Passed for v1.2.0 and v1.2.1

Table 3: System Design validation Datasheets for v1.2.0 and v1.2.1		
DUN #	**Intended Use/User Need**	**Results (Pass/Fail/Not Tested)**
100229 (FS10432)	The software application shall facilitate privacy, security, integrity and availability of protected patient health information	Passed for v1.2.0 and v1.2.1
100231 (FS10432)	The application must include the information necessary to identify it and use it safely in accordance with its intended use.	Passed for v1.2.0 and v1.2.1
115834 (FS10432)	The application shall support multiple languages	Passed for v1.2.0 and v1.2.1
138699 (FS10432)	The user shall be able to import and export media between their MyPatient SDC cases and other media in the device	Failed for v1.2.0 and passed for v1.2.1
169393 (FS10432)	The application shall allow the user to view, download and share the videos and images stored in Studio3	Failed for v1.2.0 and passed for v1.2.1
417856 (FS10432)	The application shall allow to view, download, upload, edit and share (link and/or via email) the images and document stored on PowerShare.	Failed for v1.2.0 and passed for v1.2.1
417858 (FS10432)	Application shall be able to download surgeon profile from Cloud	Passed for v1.2.0 and Failed for v1.2.1
473191 (FS10432)	The user shall be able to import, create, share and print PDF Reports.	Passed for v1.2.0 and v1.2.1
733942 (FS10432)	The application shall have default PDF templates, and shall have the ability to backup custom PDF templates to cloud	Passed for v1.2.0 and v1.2.1
Module 8: Stryker Surgeon Profile Manager		
515129 (FS10737)	The system shall allow for cloud storage and retrieval of user profiles.	Passed for v1.2.0 and v1.2.1

Table 3: System Design validation Datasheets for v1.2.0 and v1.2.1		
DUN #	**Intended Use/User Need**	**Results (Pass/Fail/Not Tested)**
515134 (FS10737)	The system shall provide the ability to associate a console with an account.	Passed for v1.2.0 and v1.2.1
177526 (FS10585)	The user shall be able to access application over the internet.	Passed for v1.2.0 and v1.2.1
177528 (FS10585)	The user shall be able to access application using Stryker's domain credentials	Passed for v1.2.0 and v1.2.1
177530 (FS10585)	The user shall be able to create, edit, save and delete SDC global settings to be applied on customers SDC machines for the customers mapped against his account	Passed for v1.2.0 and v1.2.1
177532 (FS10585)	The user shall be able to create, edit, save and delete Surgeon Profiles to be applied on customers SDC machines.	Passed for v1.2.0 and v1.2.1
177534 (FS10585)	The user shall be able to search surgeon Profiles.	Passed for v1.2.0 and v1.2.1
918232 (FS10585)	The user shall be able to export Surgeon Profiles.	Passed for v1.2.0 and v1.2.1
177536 (FS10585)	The user shall be able to associate surgeon profiles with the customers.	Passed for v1.2.0 and v1.2.1
324793 (FS10585)	The user shall be able associate customer and surgeons of a Sale Rep to another Sale Rep.	Passed for v1.2.0 and v1.2.1

Table 3: System Design validation Datasheets for v1.2.0 and v1.2.1		
DUN #	**Intended Use/User Need**	**Results (Pass/Fail/Not Tested)**
177540 (FS10585)	The user shall be able to customize OpNotes template to be used in SDC machine.	Passed for v1.2.0 and v1.2.1
177542 (FS10585)	The user shall be able to create, edit, arrange and delete device presets to be applied on SDC machines.	Passed for v1.2.0 and v1.2.1
177544 (FS10585)	The user shall be able to create, edit, arrange and delete Annotations to be used in SDC machines.	Failed for v1.2.0 and passed for v1.2.1
192974 (FS10585)	The user shall securely access Surgeon Profiles and SDC global settings from SDC machine over the internet (Cloud).	Passed for v1.2.0 and v1.2.1
192976 (FS10585)	The system shall securely store Surgeon Profiles and SDC global settings from SDC machine over the internet (Cloud).	Passed for v1.2.0 and v1.2.1
192978 (FS10585)	The system shall securely store PowerShare attributes from SDC machine over the internet (Cloud).	Passed for v1.2.0 and v1.2.1
192982 (FS10585)	The system shall store payload data from SDC device to be used for remote monitoring and diagnostics.	Passed for v1.2.0 and v1.2.1
192984 (FS10585)	The system shall have mechanism to read order, sales rep, customers and devices from extract files generated by ERP system and store them in cloud database.	Passed for v1.2.0 and v1.2.1
192986 (FS10585)	The system shall create Entitlement for the customer.	Passed for v1.2.0 and v1.2.1

Table 3: System Design validation Datasheets for v1.2.0 and v1.2.1		
DUN #	**Intended Use/User Need**	**Results (Pass/Fail/Not Tested)**
426582 (FS10585)	The user shall be able to access Surgeon Profiles from MySDC3 and MyPatient SDC (iPad App) over the internet (Cloud).	Passed for v1.2.0 and v1.2.1
426586 (FS10585)	The system shall send PDF password of a Case PDF created in MySDC3 and MyPatient SDC (iPad App) to user via email	Passed for v1.2.0 and v1.2.1
532089 (FS10585)	The user shall be able to send messages to Stryker Representative , Hospital staff and Patient family	Passed for v1.2.0 and v1.2.1
532091 (FS10585)	The system shall be able to retrieve contacts and OR schedules from Procare Application database	Passed for v1.2.0 and v1.2.1
205868 (FS10585)	(Instructions for Use) The device must be accompanied by the information necessary to identify it and use it safely in accordance with its intended use.	Passed for v1.2.0 and v1.2.1
713679 (FS10585)	The Surgeon shall be able to upload, download, share and sync PDF Email Templates from MySDC3 and MyPatient SDC iPad App.	Passed for v1.2.0 and v1.2.1
713810 (FS10585)	The system shall send PowerShare Image Share Token of a shared images using MySDC3 and MyPatient SDC (iPad App) to user via email.	Passed for v1.2.0 and v1.2.1
713834 (FS10585)	The Sales Rep shall be able to designate his/her Associate Sales Reps to access application and perform all the operations on his/her behalf.	Passed for v1.2.0 and v1.2.1
713903 (FS10585)	The Sales Rep shall be able to search existing Sales Reps, Customers , Surgeons, Devices and PowerShare Image Share Requests in application database.	Passed for v1.2.0 and v1.2.1

Table 3: System Design validation Datasheets for v1.2.0 and v1.2.1		
DUN #	**Intended Use/User Need**	**Results (Pass/Fail/Not Tested)**
918246 (FS10585)	The Sales Rep shall be able to manage and synchronize operators with SDC.	Passed for v1.2.0 and v1.2.1
Module 9: Device Control		
559764 (FS10740)	The Device Control Package shall allow users to capture/edit device presets within chosen specialties and/or procedures and apply them to connected devices if desired.	Failed for v1.2.1 and passed for v1.2.0
559754 (FS10740)	The SDC4K shall support an optional device control package that allows control of compatible connected devices.	Passed for v1.2.0 and v1.2.1
559756 (FS10740)	The Device Control Package shall include a means to activate the device control module on the SDC4K.	Failed for v1.2.0 and passed for v1.2.1
559758 (FS10740)	The Device Control Package shall provide a Mechanism to allows on-screen menu navigation/selection and control of Stryker and third-party devices via IR Remote control.	Failed for v1.2.0 and passed for v1.2.1
559760 (FS10740)	The Device Control Package shall provide a mechanism for annotating captured images using IR Remote Control.	Passed for v1.2.0 and v1.2.1
559762 (FS10740)	The Device Control package shall coexist with other IR and wireless devices commonly found within an OR.	Passed for v1.2.0 and v1.2.1
559792 (FS10740)	The IR Remote Control shall be user friendly and shall be handheld.	Passed for v1.2.0 and v1.2.1
515040 (FS10740)	The system shall allow annotation of captured images.	Passed for v1.2.0 and v1.2.1

Table 3: System Design validation Datasheets for v1.2.0 and v1.2.1		
DUN #	**Intended Use/User Need**	**Results (Pass/Fail/Not Tested)**
Module 10: Voice Package		
559814 (FS10739)	The voice package shall include a headset/microphone system that allows the user to issue voice commands to the SDC4K via microphone as well as hear audio via the headset.	Passed for v1.2.0 and v1.2.1
515028 (FS10739)	As a user, I want record audio from internal and connected external sources.	Passed for v1.2.0 and v1.2.1
619597 (FS10739)	As a user, I require that I am able to use a system that coexists with the intended wireless use environment in the OR.	Passed for v1.2.0 and v1.2.1
515025 (FS10739)	The system shall provide status for external connected devices	Failed for v1.2.0 and passed for v1.2.1
672018 (FS10739)	The system should not be excessively noisy during operation	Passed for v1.2.0 and v1.2.1
559820 (FS10739)	The voice package shall provide a mechanism for annotating captured images using voice recognition	Passed for v1.2.0 and v1.2.1
559822 (FS10739)	The Voice package shall coexist with other wireless devices commonly found within an OR.	Passed for v1.2.0 and v1.2.1
515070 (FS10739)	The system shall accept audio input from and provide audio output to common operating room audio equipment.	Passed for v1.2.0 and v1.2.1
559826 (FS10739)	The speech recognition shall perform accurately.	Passed for v1.2.0 and v1.2.1
559828 (FS10739)	The system shall have quick response times to voice commands.	Passed for v1.2.0 and v1.2.1

Table 3: System Design validation Datasheets for v1.2.0 and v1.2.1		
DUN #	**Intended Use/User Need**	**Results (Pass/Fail/Not Tested)**
559866 (FS10739)	The microphone/headset shall be user friendly.	Passed for v1.2.0 and v1.2.1
IFU-1	Ensure that the information for safety provided in the IFU is adequate	Passed for v1.2.0 and v1.2.1
IFU-2	Ensure that the information for safety provided in the IFU is adequate	Passed for v1.2.0 and v1.2.1
IFU-3	Ensure that the information for safety provided in the IFU is adequate	Passed for v1.2.0 and v1.2.1
IFU-5	Ensure that the information for safety provided in the IFU is adequate	Passed for v1.2.0 and v1.2.1
IFU-6	Ensure that the information for safety provided in the IFU is adequate	Passed for v1.2.0 and v1.2.1
IFU-7	Ensure that the information for safety provided in the IFU is adequate	Passed for v1.2.0 and v1.2.1
IFU-8	Ensure that the information for safety provided in the IFU is adequate	Passed for v1.2.0 and v1.2.1

Table 3: Datasheets for System Design Validation of SDC for v1.2.0 and v1.2.1. The table describes the DUN's that has been passed/failed for both the softwares and describes the basis of product release in the market. All the failed DUN's did not imapact the patient life.

Thesis

ORIGINALITY REPORT

11%	8%	5%	%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	www.healthdirect.gov.au Internet Source	1%
2	resiliencepost.com Internet Source	1%
3	en.wikipedia.org Internet Source	1%
4	"Laproscopic surgery", International Journal of Computer Assisted Radiology and Surgery, 2011 Publication	1%
5	lib.bioinfo.pl Internet Source	1%
6	Ejaz, Aslam, Teviah Sachs, Jin He, Gaya Spolverato, Kenzo Hirose, Nita Ahuja, Christopher L. Wolfgang, Martin A. Makary, Matthew Weiss, and Timothy M. Pawlik. "A comparison of open and minimally invasive surgery for hepatic and pancreatic resections using the nationwide inpatient sample",	1%

	Surgery, 2014. Publication	
7	www.ncbi.nlm.nih.gov Internet Source	1%
8	ethesis.nitrkl.ac.in Internet Source	1%
9	bmcsurg.biomedcentral.com Internet Source	1%
10	C. de Sierra, F. Estevez-Cid, J. Cuenca-Castillo. "High-Definition Video Recording: Taking Sport Technology to the Operating Room", The Thoracic and Cardiovascular Surgeon, 2018 Publication	<1%
11	etd.gatech.edu Internet Source	<1%
12	Lee, Daniel Jin Keat. "Endoscopic surgery - exploring the modalities", World Journal of Gastrointestinal Surgery, 2015. Publication	<1%
13	advinurology.com Internet Source	<1%
14	globalinforesearch.biz Internet Source	<1%
15	pace.ac.in Internet Source	<1%

16	documents.mx Internet Source	<1%
17	rhapsody.health Internet Source	<1%
18	mtech.iiita.ac.in Internet Source	<1%
19	www.studymode.com Internet Source	<1%
20	ntrs.nasa.gov Internet Source	<1%
21	Bastian Ibach, Julia Benzko, Stefan Schlichting, Andreas Zimolong, Klaus Radermacher. "Integrating medical devices in the operating room using service-oriented architectures", Biomedizinische Technik/Biomedical Engineering, 2012 Publication	<1%
22	Chien-An Liu, Kuo-Hung Huang, Ming-Huang Chen, Su-Shun Lo, Anna Fen-Yau Li, Chew-Wun Wu, Yi-Ming Shyr, Wen-Liang Fang. "Comparison of the surgical outcomes of minimally invasive and open surgery for octogenarian and older compared to younger gastric cancer patients: a retrospective cohort study", BMC Surgery, 2017 Publication	<1%

23	www.nist.gov Internet Source	<1%
24	"Regulatory issues for exoskeletons", Institution of Engineering and Technology (IET), 2018 Publication	<1%
25	www.suddenlysmart.com Internet Source	<1%
26	Zhao, C.. "Pattern-based design evolution using graph transformation", Journal of Visual Languages and Computing, 200708 Publication	<1%
27	finance.jeffersonpost.com Internet Source	<1%

Exclude quotes	On	Exclude matches	< 8 words
Exclude bibliography	On		