Thermage FLX Handpiece OUS Service Procedure

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Abstract *— High international shipping cost and repair turnaround times negatively affect Solta Medical's revenues. The cause of these costs and turnaround times stem from the inability to calibrate repaired handpieces internationally since they require intellectual property at risk of counterfeit. An alternate test procedure was developed that allowed global service affiliates to perform repairs of the handpiece and test to see if they remained within calibration before putting them back into service. The test procedure was validated and proved feasible.*

Key Terms *— Field tests; international shipping; international repairs; repair lead-time; process validation; control limits.*

INTRODUCTION

Solta Medical, a division of Bausch Health, develops treatment technologies to provide aesthetic care options to consumers and physicians alike. The Solta Medical portfolio includes the Thermage® system as one of its more popular devices. The Thermage FLX (or FLX) is an RF medical aesthetic device which uses radio frequencies (RF) to deliver focused energy to stimulate collaged production which provides several benefits for the appearance of the skin [1]. There are over 2,700 FLX systems installed globally with 85% outside of the United States (OUS), making that market extremely important to the business.

The device is composed of the following major components: (1) the generator, (2) the handpiece (HP), and (3) the treatment heads (tips). The tips are attached to the HP and are used to deliver targeted treatments across different areas of the face and body. Additionally, the HP delivers bursts of cryogen to the tips to prevent burning the patient's skin.

The tips are consumables and serve as the main revenue stream for this product. If a console or HP is unable to deliver treatments, users would not procure additional tips, resulting in reduced revenue.

BUSINESS PROBLEM AND OBJECTIVE

Repairs to FLX HPs require return to Solta's service department headquarters (HQ) in the US state of Washington. This requirement stems from the need to recalibrate the HP to factory specifications following repair. Factory calibration is performed by using intellectual property which cannot be released outside of Solta HQ due to a high risk of Solta technology being counterfeited.

As a result, the product support division incurs high international shipping costs to transport these devices from and to customers across the world. The average cost to ship from OUS to HQ and back has been calculated to be approximately $518. Additionally, the average lead time to ship our product from OUS to HQ and back to the customer was found to be 30 days. Therefore, revenues are impacted not only because of high shipping cost, but also because of long customer downtime.

The objective of this project was to reduce average repair shipping costs from $518 (OUS shipping) to $175 (regional shipping), and overall repair turnaround time from 30 to 7 days.

METHODOLOGY

To achieve the objective, a new service test procedure was developed which allowed regional field service technicians to repair FLX HPs and perform functional checks to verify if the HP remains in its calibrated state instead of performing a factory recalibration.

The scope of the project was limited to verifying if the HPs were within specification following

repair. Efforts to reduce the number of commonly recurring failures was outside the scope of this project.

Project Activities

To complete this project, the following activities were performed:

- Calculated OUS average cost of shipping from historical service cases.
- Calculated OUS average repair turnaround time from historical service cases.
- Developed alternate test procedure.
- Performed test procedure dry run.
- Released test procedure and specifications into document control database.
- Validated the test procedure.
- Implemented the test procedure.

Project Resources

Human resources required to complete this project comprised of a subject matter expert (SME), a service technician, a change control board consisting of the following: a quality engineer, a buyer, test engineer, and systems engineer.

Material resources to complete this project consisted of an FLX system, an FLX HP, treatment tips, cryogen cans, tripod support base, and a clamp holder.

Project Risks

The risks associated with the implementation of this project was only related to the force sensor check test. If a HP is outside the lower force limit, there is a risk of delivering RF energy prematurely. On the other hand, if a HP is found to be outside the upper force limit, there is a risk of the user applying excessive force onto the patient resulting in injury.

Test Procedure and Specifications

The service procedure consisted of verifying the following HP functions:

- Force sensor is within operational limits
- Cryogen valve delivers cryogen
- Button functionality
- Vibration motor functionality

The button and vibration motor tests were adapted directly from the manufacturing procedures since they are manually performed by an operator without the need of any special tools or equipment. On the other hand, the force sensor and cryogen valve tests were modified so that they did not require a computer with proprietary software to connect to the system that could read or write data to the system.

Force Sensor Test Procedure

For the force sensor test, a Min and Max product spec exists. The force sensor test required the use of a triple beam balance to apply a controlled load onto the nose of the HP as shown in Figure 1. Based on the design of the FLX device, the system should not deliver a treatment if a minimum force is not applied. Conversely, if a force greater than the maximum limit is applied, the system will issue an error. To account for any variance introduced by the balance, the linearity (deviation) of the balance was increased by a factor greater than 6. This reduces the risk of an undesirable result, due to the balance's linearity, to nearly zero per the principles of a normal distribution [2].

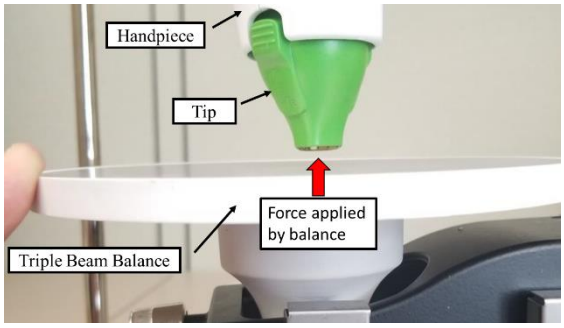

Figure 1
Force sensor test setup

Force Sensor Test Specification

To prevent the undesirable event of putting a HP outside of product specification back into service, stricter limits where necessary. The upper and lower limits are 61.1g and 318g, respectively. The amount by which these limits where tightened was based on the added uncertainty introduced by the balance's

linearity. The balance linearity requirement was specified as a maximum of ±0.1g. This linearity value was increased by a factor of 9 for the lower limit and 10 for the upper limit. These factors make the error introduced by the balance statistically negligible since it is well beyond a six-sigma factor. The factor of 9 and 10 were chosen to simplify the test setup for operators by using rounded test loads which would be easy to input into a manual balance. The test loads were calculated using (1) and (2):

$$TL_{LL} = LL + 9\sigma \quad (1)$$

$$TL_{UL} = UL - 10\sigma \quad (2)$$

where,

TL_{LL} = Lower limit test load,

TL_{UL} = Upper limit test load,

LL = Product lower spec limit = 61.1g

UL = Product upper spec limit = 318g

σ = Linearity of balance = ±0.1g

For the TL_{LL}, the linearity factor was added, whereas for the TL_{UL}, it was subtracted. This produces the strictest acceptance condition for this test.

Cryogen Valve Test Procedure

For the cryogen valve test, a quantitative method to confirm cryogen delivery was required. Each treatment tip includes a set of thermistors which reads the temperature on the tip's surface which contacts the patient's skin. Once the tip thermistors detect a temperature greater or equal to 18ºC, it activates the cryogen valve to spray bursts of liquid cryogen inside the tip which then cools the patient contact surface.

The cryogen valve test procedure required for the technician to set the device into training mode to prevent inadvertently delivering any energy and then proceeded to touch the nose of the tip to apply body heat onto it. The technician was instructed to hear for the distinct noise produced by the valve bursting cryogen into the tip. To qualitatively show cooling produced by cryogen, a system log file needed to be exported to observe the thermistor temperatures. If at least one of the thermistors showed a value of 18ºC or below, a pass was issued.

Cryogen Valve Test Specification

Cryogen 1234ze has an atmospheric saturation temperature of -15ºC [3], therefore, a properly functioning valve will cool at least one of the tip thermistors below room temperature (20ºC). For this test procedure, a thermistor reading below 18ºC was considered a pass since the thermistor temperature was elevated beyond room temperature by applying a warm body onto the surface of the tip. Figure 2 shows a sample log file with passing thermistor values.

AB	AC	AD	AE
THERMISTOR_1	THERMISTOR_2	THERMISTOR_3	THERMISTOR_4
21.70	21.50	21.00	17.80
20.80	20.80	20.10	12.80
21.50	21.30	20.70	17.30
20.50	20.50	19.60	7.80
18.50	18.60	15.30	-5.70
19.70	20.10	17.90	1.70
20.30	20.40	18.90	11.80
20.50	20.60	19.40	14.60
19.00	19.30	17.50	5.60
18.90	19.30	17.20	-1.60
19.80	19.90	18.10	10.60

Figure 2
Sample log file with passing thermistor values

VALIDATION ACTIVITIES

Validation Protocol

Following the release of the test procedure and specifications into the document control system, the procedure was validated by performing two sets of tests. The first test involved a screening to see if the test procedure can identify known failed HPs. Ten (10) HPs under various states were used. The states of the HPs or devices under test (DUT), along with their expected test result, are described in Table 1. A successful validation required for the test operator's observations to match the states of each DUT. The states of each DUT were unknown to the operator.

The second set of tests required for the operator to perform a limited scope of repairs to the HPs that has a force sensor within calibration but failed cryogen valves. Following the repairs, the DUTs were subjected to the test procedure and the results were noted. The same DUTs were then subjected to the manufacturing procedure to confirm the results of the second test.

Table 1
Test procedure screening DUT states

DUT	Force Sensor	Cryogen Valve	Expected
1	Calibrated	Non-functional	Fail
2	Calibrated	Non-functional	Fail
3	Out of cal (low)	Non-functional	Fail
4	Out of cal (high)	Functional	Fail
5	Calibrated	Non-functional	Fail
6	Out of cal (low)	Functional	Fail
7	Calibrated	Functional	Pass
8	Calibrated	Non-functional	Pass
9	Calibrated	Non-functional	Fail
10	Out of cal (high)	Non-functional	Fail

Validation Results

For the first set of tests, all the observations of the operator matched the states defined in Table 1. For the second set of tests, all the observations from the operator matched the results of the manufacturing tests. The validation protocol was deemed successful; therefore, the test procedure was proven to identify FLX HPs that are outside of calibration.

RECOMMENDATIONS

To determine whether the test procedure has achieved the project objectives, the following data should be collected or calculated from service cases:

- Total FLX OUS HP repairs
- Total FLX OUS HPs returned to Solta HQ for repair
- Total repairs cost of non-returned FLX OUS HPs
- Total repair cost of returned FLX OUS HPs
- Average repair turnaround time of non-returned FLX OUS HPs
- Average repair turnaround time of returned FLX OUS HPs

CONCLUSION

All deliverables were successfully met. The test procedure proved to distinguish between good and bad HPs. This should cause a significant reduction in the number of OUS HPs returning to Solta HQ for repairs. Therefore, a significant reduction in shipping cost and turnaround time should be observed since the devices will be traveling regionally instead of internationally.

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