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## Introduction

The Thermage FLX system is an energy delivery medical device with over 2,300 units in service outside of the United States (OUS).

The handpiece (HP) must be within design limits to avoid injury to patients during treatment.

HP repairs require calibration to be performed in at Solta Medical HQ in the US.

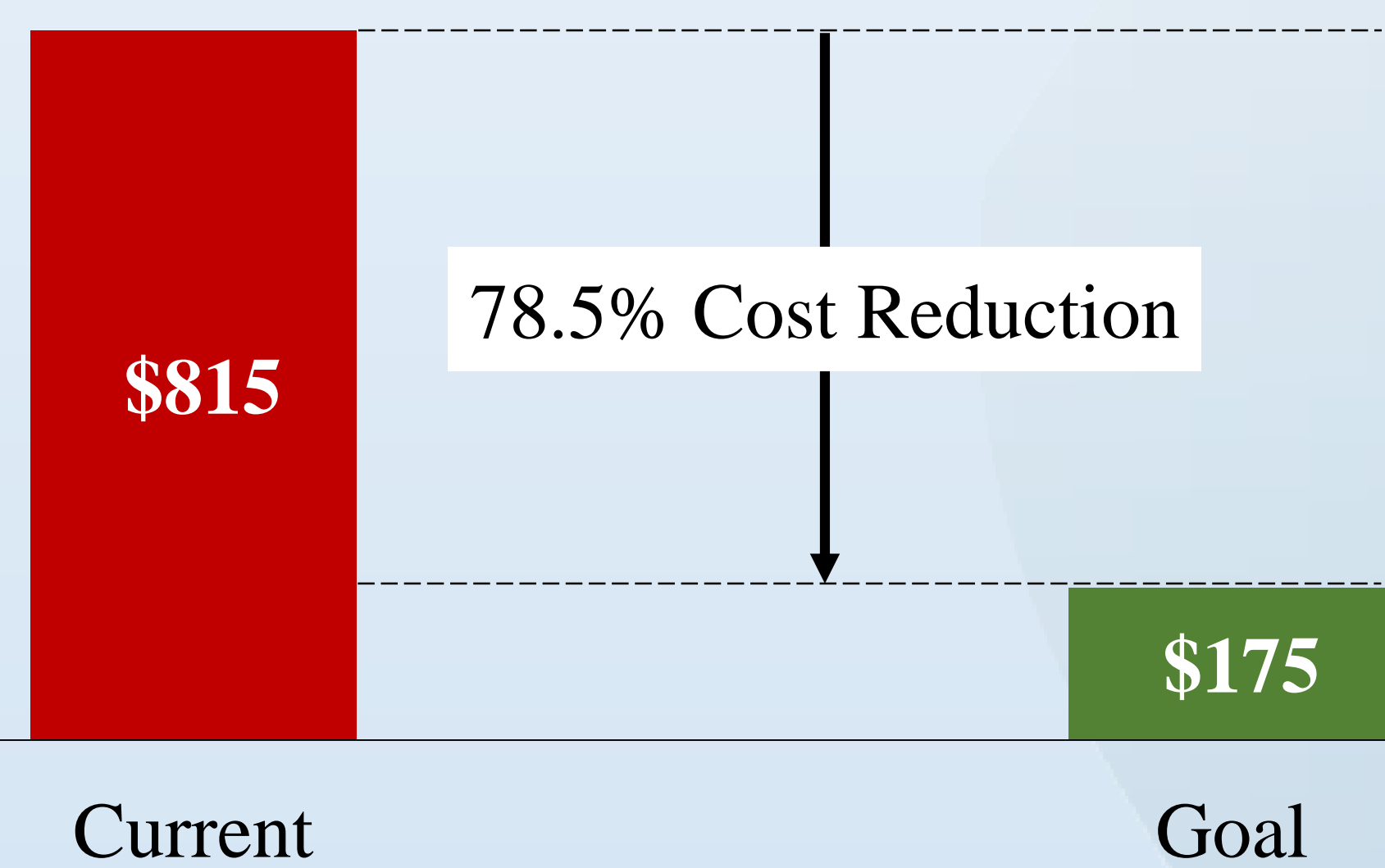
## Business Problem & Objective

Intellectual property at risk of counterfeit OUS.

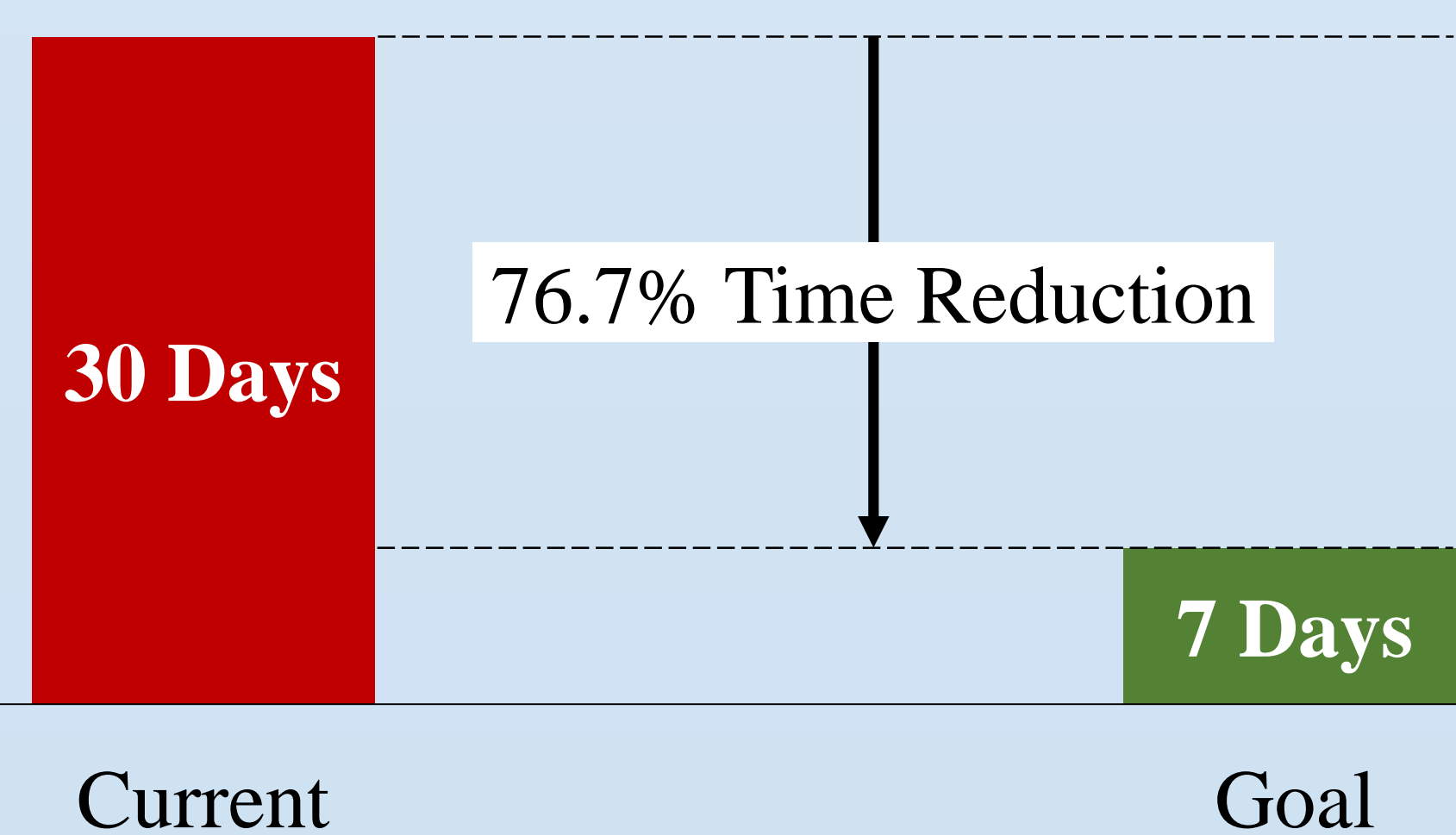
High shipping cost for OUS repairs.

Long turnaround time for OUS repairs.

OUS Average Shipping Cost per Repair



OUS Average Turnaround Time per Repair



## Methodology

Calculated OUS average cost of shipping from historical service cases.

Calculated OUS average repair turnaround time from historical service cases.

Developed alternate test procedure.

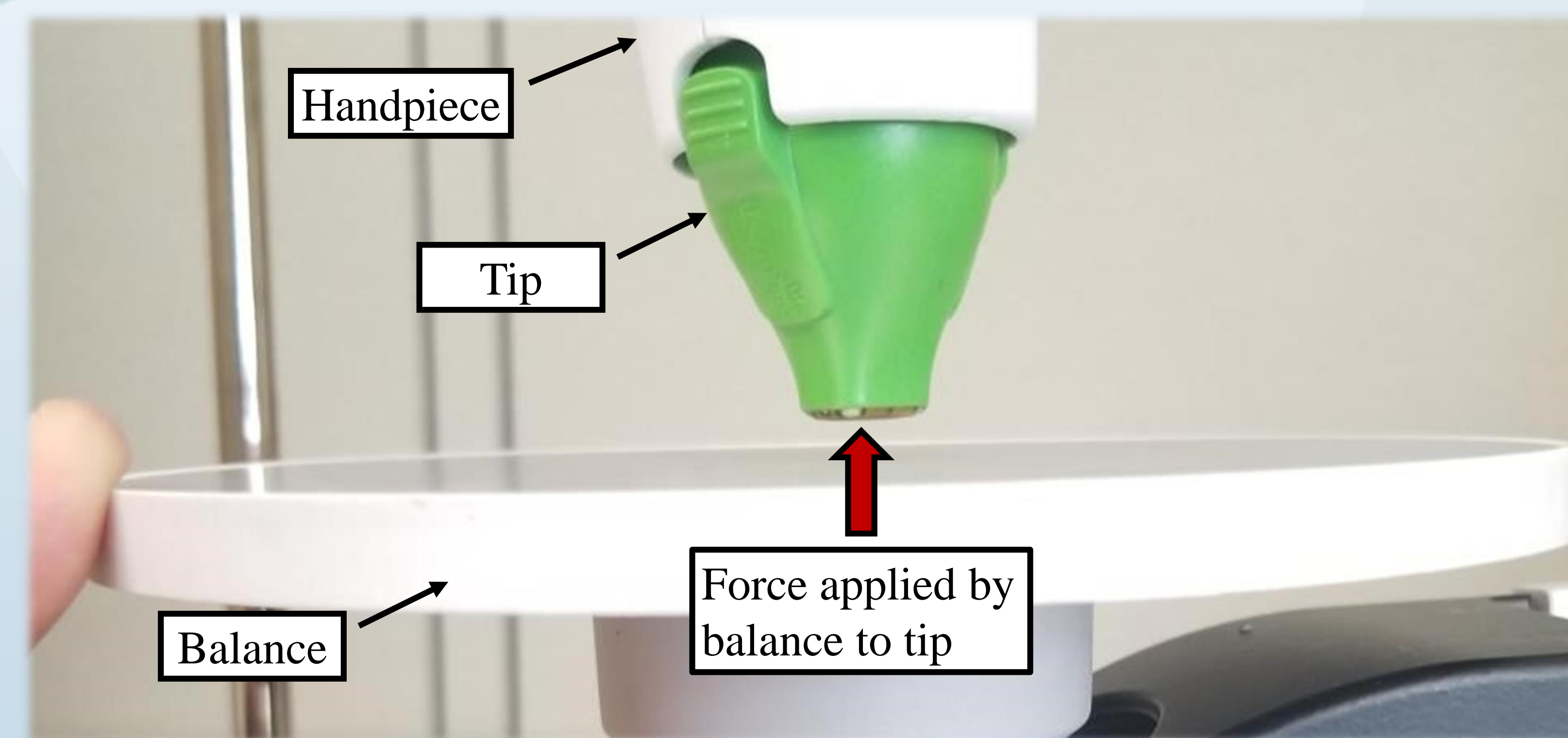
Released test procedure and specifications into document control database.

Validated the test procedure.

Implemented the test procedure.

## Alternate Test Procedures

### Force sensor calibration check



### Cryogen valve functional check

THERMISTOR_1	THERMISTOR_2	THERMISTOR_3	THERMISTOR_4	THERMISTOR_1	THERMISTOR_2	THERMISTOR_3	THERMISTOR_4
20.80	20.80	20.90	21.10	12.30	12.30	12.40	14.00
		20.90	21.20			21.00	21.20
		21.00	21.20			21.10	21.20
		21.10	21.30			21.10	21.20
		21.10	21.30			21.10	21.20
		21.20	21.40			21.10	21.30
21.30	23.50	21.50	21.70	21.20	21.10	21.20	21.30
21.40	24.70	21.60	22.80	21.20	21.10	21.20	21.30
21.60	25.40	21.70	22.60	21.20	21.10	21.20	21.30
22.10	23.80	21.80	24.00	21.30	21.10	21.20	21.30
22.10	24.90	22.00	23.30	21.30	21.20	21.20	21.40
22.00	23.50	22.00	22.90	21.30	21.20	21.30	21.40
22.10	23.10	22.10	22.70	21.30	21.20	21.30	21.40
22.10	22.90	22.10	22.70	9.10	12.70	15.90	6.10
22.10	22.80	22.10	22.60	18.30	19.20	20.10	18.30
22.20	22.70	22.10	22.60	11.00	17.40	15.70	2.50
22.20	22.60	22.10	22.60	12.10	17.90	17.80	7.00
22.20	22.60	22.10	22.50	8.30	15.70	17.20	5.40

Defective Valve Thermal Profile No Cooling

Functional Valve Thermal Profile Active Cooling

## Results and Discussion

DUT	Expected Result	Test Result	Overall Result
1	Fail	Fail	Pass
2	Fail	Fail	Pass
3	Fail	Fail	Pass
4	Fail	Fail	Pass
5	Fail	Fail	Pass
6	Fail	Fail	Pass
7	Pass	Pass	Pass
8	Pass	Pass	Pass
9	Fail	Fail	Pass
10	Fail	Fail	Pass

Validation results showed the test procedure distinguishes between defective and functional HPs.

## Conclusion

Test procedure proven feasible through validation.

Reduced OUS FLX HPs returns expected.

## Recommendations

Collect or calculate the following metrics:

- 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