



➤ Health in place

- - Telemedicine, IoT, 5G

➤ Connected devices

- - IoT with data analytics and AI

➤ Demand surge of medical devices & PPE

- - Quality and Regulatory

➤ Great Bay Area

- - > 70 millions population
- - Policies to support imported medical devi

➤ The increasing uncertainties

- Trade Disputes are making daily headlines
- New Rules are emerging to evaluate technology flows
- Geopolitical tensions are becoming more heated

➤ Supplier relationship

- - Changing relationship to collaborator

➤ Logistic surcharge and turnaround time

- - Addition cost and lock down

- Design to manufacturability
 - early stage involvement
- Modularization
 - division of labor and mitigate risks
- Decentralization
 - sourcing alternatives and substitute
- s
- Integration
 - - total solutions

Case Study – Helpwear Inc

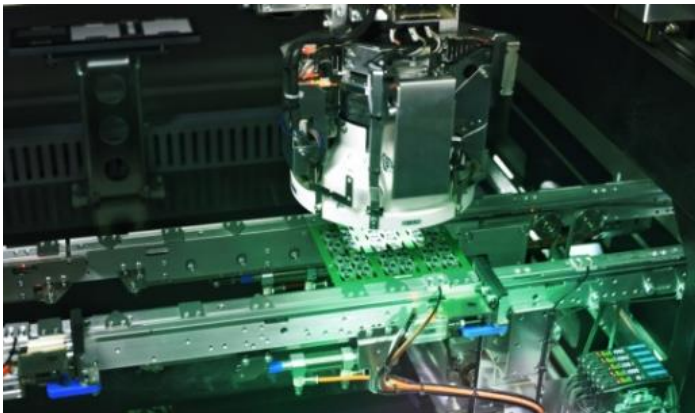
Introduction

- Technology Start-Up Company in Toronto, Canada
- Providing Disruptive solution for ECG Monitoring
- Class II Medical Device Class



Wise Ally Support

- *Provide Design For Manufacturability (DFM) Proposal*
- *Alternative Sourcing for Cost Reduction & lead time Improvements*
- *Set-Up Production Line, Jig, Tester for Assembly and Testing*
- *Regulatory Batch Build for Testing Submission / Clinical Trials*



Collaboration Model



Product Design

- *Industrial Design*
- *Hardware Design*
- *Firmware*
- *Algorithm*



Product Marketing

- *Regional Filing*
- *Clinical Trials*
- *End User Engagement*



Product Manufacturing

- *Product Assembly*
 - *PCBA*
 - *Sub-Assemblies*
 - *Sensor Straps*
- *Product Testing*

Supplier Chain Management

- *Local Vendor Sourcing*
- *Audit & Qualification*
- *Material Management*
 - *Electronics Parts*
 - *Mechanical Parts*
 - *Packaging Material*

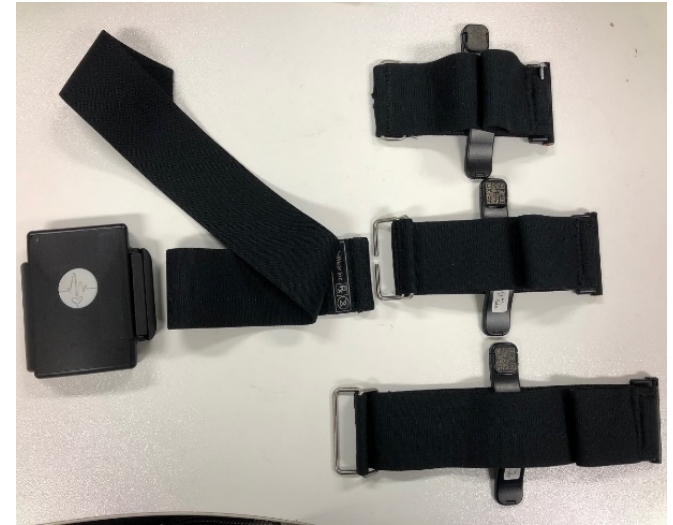
Main Device

- Challenges
 - ☐ *Availability of Critical Electronic Components in market*
 - ☐ *Short Manufacturing Set-up Time*
 - ☐ *Traceability Requirement*
- Wise Ally Achievement
 - ☐ *Leverage Global Supply Chain Network to secure Raw material Delivery*
 - ☐ *Leverage Process Engineering & Project Management to Design & Set-up Manufacturing line for Clinical Units Delivery*
 - ☐ *Set-Up Unique Device Identification for Product from Component to Finished Goods Level*



Sensor Strap & Disposable Strap

- Challenges
 - ☐ *Material Biocompatibility Requirement*
 - ☐ *Cytotoxicity, Skin Irritation*
 - ☐ *Customized Manufacturing Method*
 - ☐ *Reliable Supply*
- Wise Ally Achievement
 - ☐ *Supplier Sourcing & Qualification in China*
 - ☐ *Leverage Local Type Approval Lab for Quick material assessment for Biocompatibility*
 - ☐ *Set-Up Unique Device Identification for Sensor Strap*



Testimonial from Helpwear



“WISE ALLY has been a vital partner in HelpWear’s manufacturing process. Their team has demonstrated outstanding capabilities for both design and manufacturing(...) Their support has been professional and provides meaningful contribution under tight timelines during global health pandemic crisis.”

Frank Nguyen

Chief Technical Officer, HelpWear