

Additive Manufacturing Journey GE HealthCare, Zipf - Austria

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GE HealthCare

This is GE HealthCare

April 2025



GE HealthCare

A leading global healthcare solutions provider



\$20.6B

2025 Annual Revenue



~5M

Installed base



1B

Patients served annually



\$5.1B

Innovation investment since 2022 ⁽¹⁾



18.6K

Customer-facing colleagues



115

AI-enabled device authorizations in U.S., top of recent FDA list⁽²⁾

Notes: Figures are accurate as of December 31, 2025, unless otherwise noted

¹Includes Research and development expense plus engineering costs for design follow-through on new product introductions and key product lifecycle maintenance subsequent to the initial product launch reported within cost of revenues

²U.S. Food and Drug Administration. Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices. December 05, 2025

Available at: <https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices>

Additive manufacturing

So what?

Additive manufacturing - So what? Who cares?

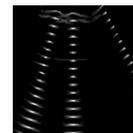
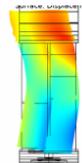


T0	T1	T2	TE	T3
Identify needs and opportunities Establish program management Technology solution trade-off matrix Resources and costs Go/NoGo criteria for T1, T2	Technical approaches & risks Patent search & IP strategy Customer VOC Down select of technical approaches Establish CTQ Estimate cost & Timing for T2	Technology feasibility demonstrated CTQs measured Update IP status Clarify what technology transitioned to NPI Estimate cost & Timing for T3	TE Go/No Go criteria met HAT & UPT Update IP status Use case defined for TE CMT per risk management	Technology demonstration complete All technical & clinical risks retired CTQ targets met Transition plan established Technology transition complete
T0 review	T1 review	T2 review	TE review	T3 review

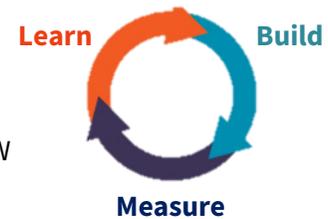
TRL: Technology Readiness Level			MRL: Manufacturing Readiness Level		
Phase	TRL	State of Development	Phase	MRL	State of Development
Real World	9	Actual Technology Proven Through successful Use in an Operational Environment	Production Implementation	9	Full Production Process Qualified for Full Range of Parts and Full Metrics achieved
	8	Actual Technology Completed and qualified Thorough Tests and Demonstrations		8	Full Production Process Qualified for Full Range of Parts
	7	System Prototype Demonstration in an Operational Environment		7	Capability and Rate Confirmed
Simulated World	6	System / Subsystem Model or Prototype Demonstrated in a Simulated Environment	Pre-Production	6	Process Optimised for Production Rate on Production Equipment
	5	Component Validation in a Simulated Environment		5	Basic Capability Demonstrated
	4	Component Validation in a Laboratory Environment		4	Production Validated in Lab Environment
Research Lab	3	Analytical and Experimental Critical Function and/or Characteristic Proof-of-Concept	Technology Assessment and Proving	3	Experimental Proof of concept Completed
	2	Technology Concept and/or Application Formulated		2	Application and Validity of concept Validated or Demonstrated
	1	Basic Principles Observed and Reported		1	Concept Proposed with Scientific Validation

R&D Agility
Faster Vitality & growth mindset

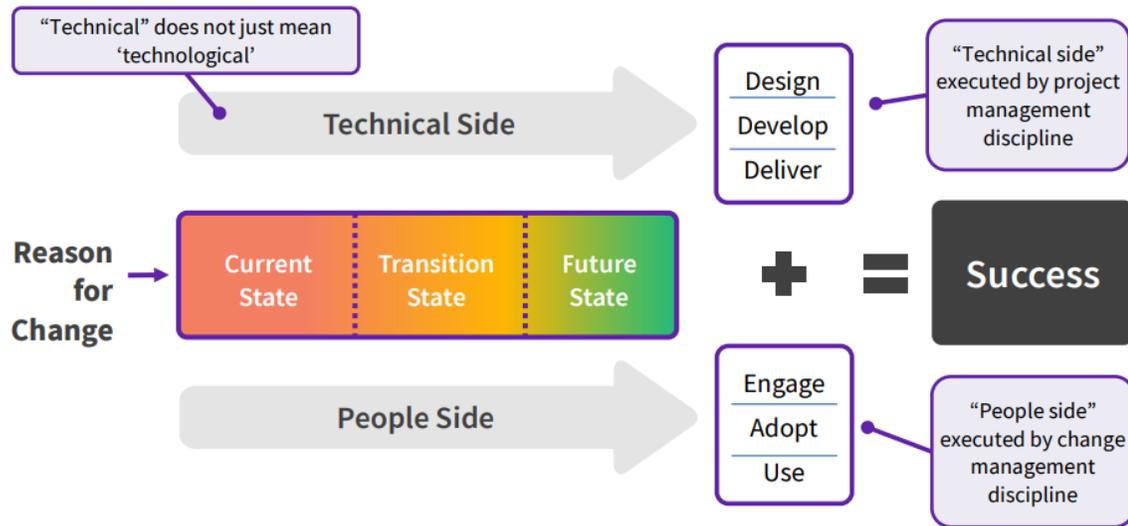
Digital Twins to guide design & integration



BML Loop
(Eric Ries, The Lean Startup – SW inspired)



Additive manufacturing – a (change) journey with multiple dimensions

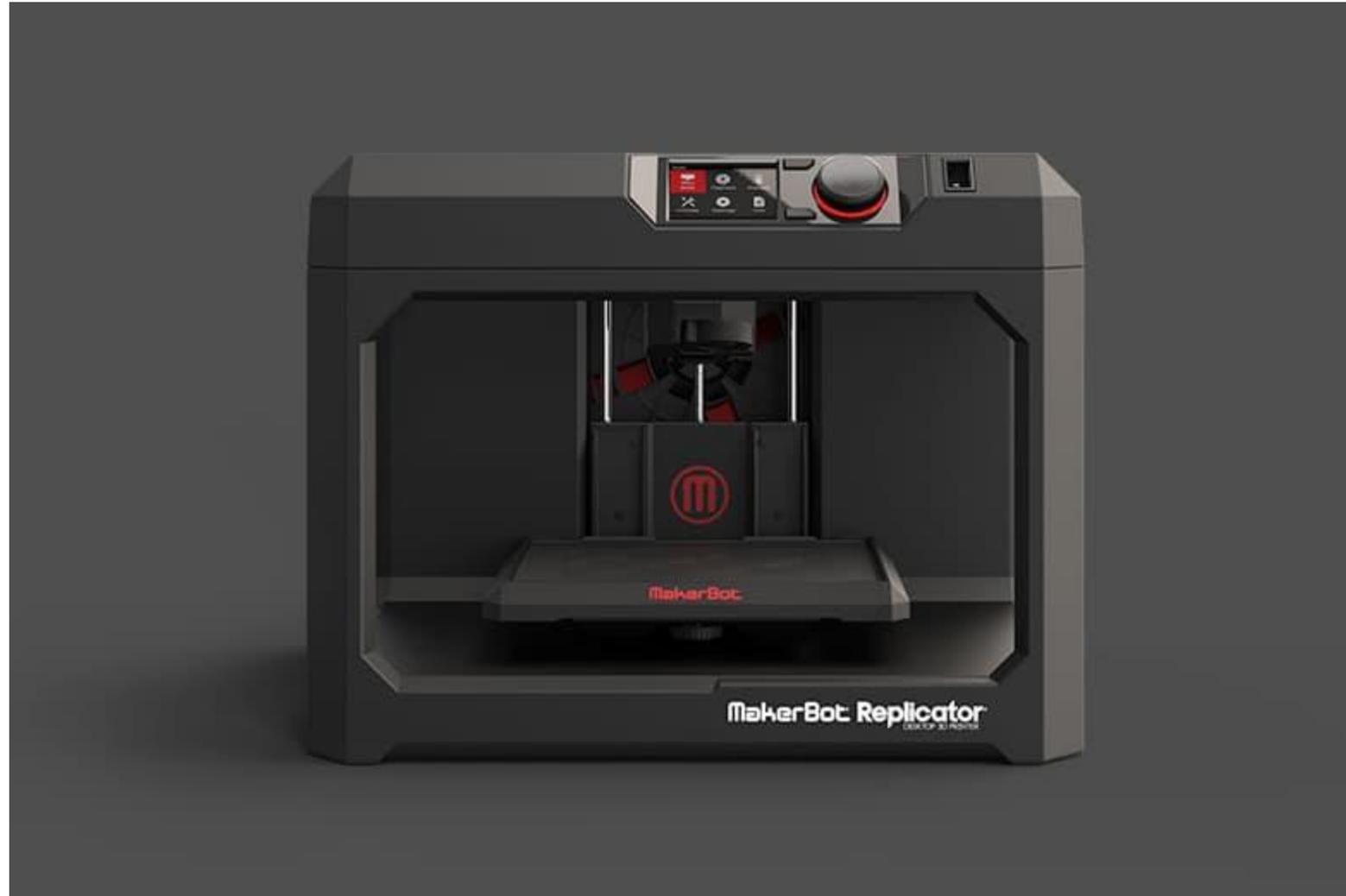


The Psychology of Change



Change - It's a team sport

How it started in 2016



How it`s going...



ROI / Business Case

Quick wins

PBF - HP MJF 540

early adoption



Part "5929181" -used in serial production

**approved:
AM parts for
serial production**



quick design iterations - probe holder mock-ups for a console



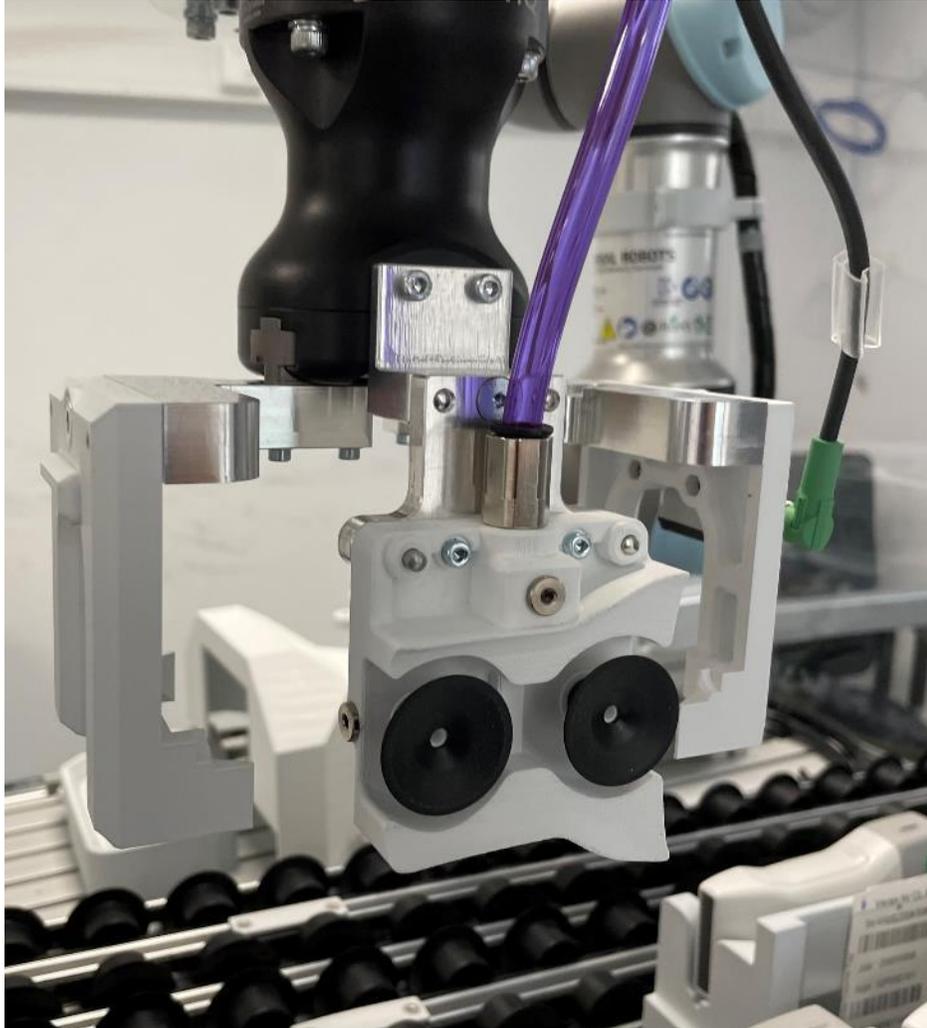
Tooling & Jigs: e.g. plasma tool for surface prep

FDM - Stratasy's Fortus 450mc

adoption for bigger and tough parts



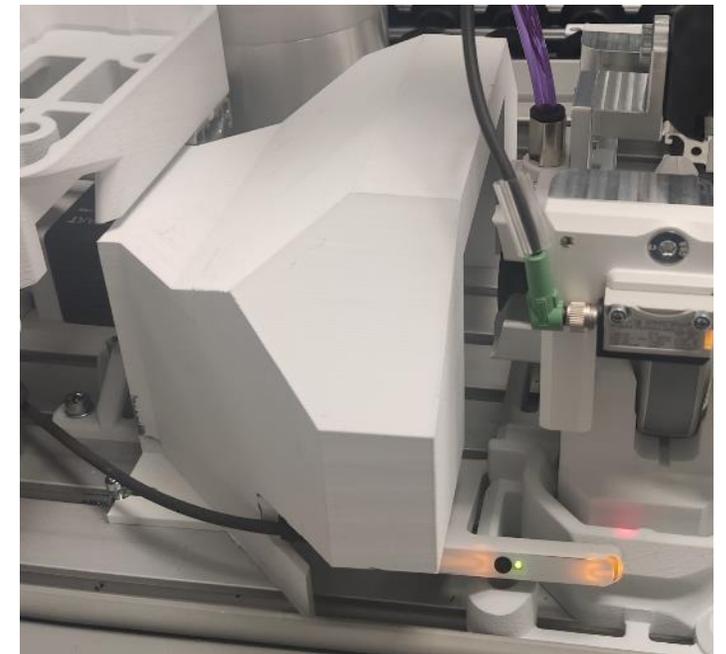
Poka-Yoke guides for inserting probes into test station



Robotic end-effector - vacuum gripper (PBF)



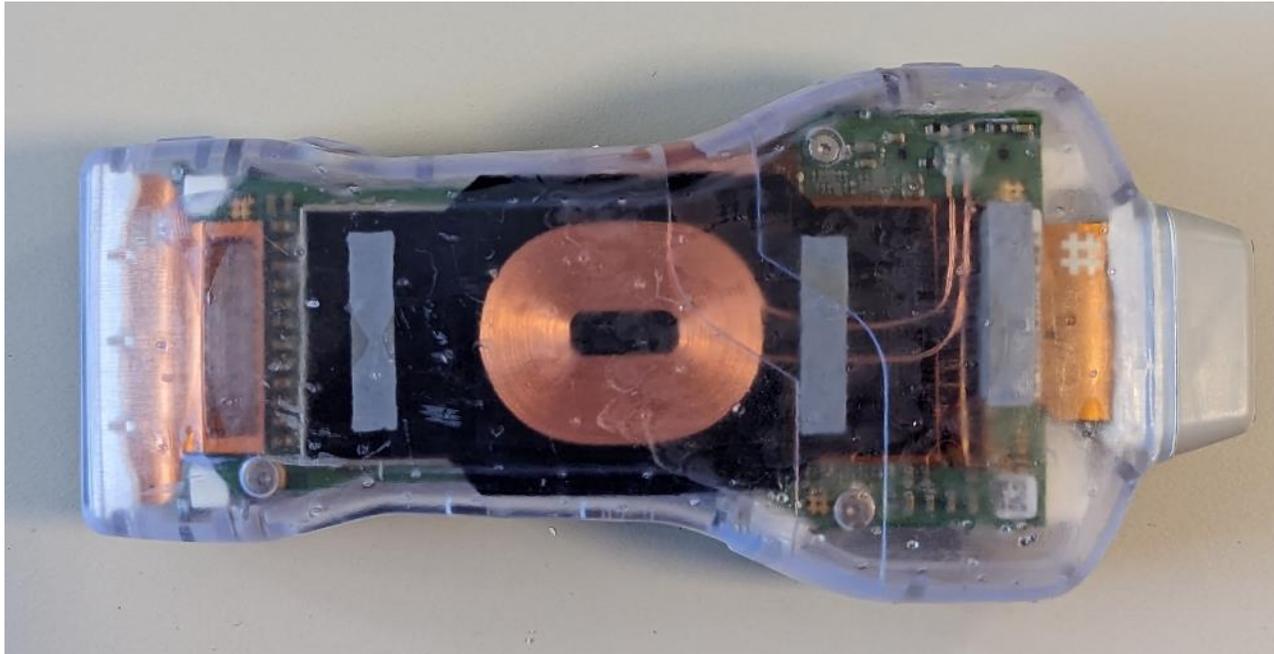
vacuum gripper (PBF) with probe



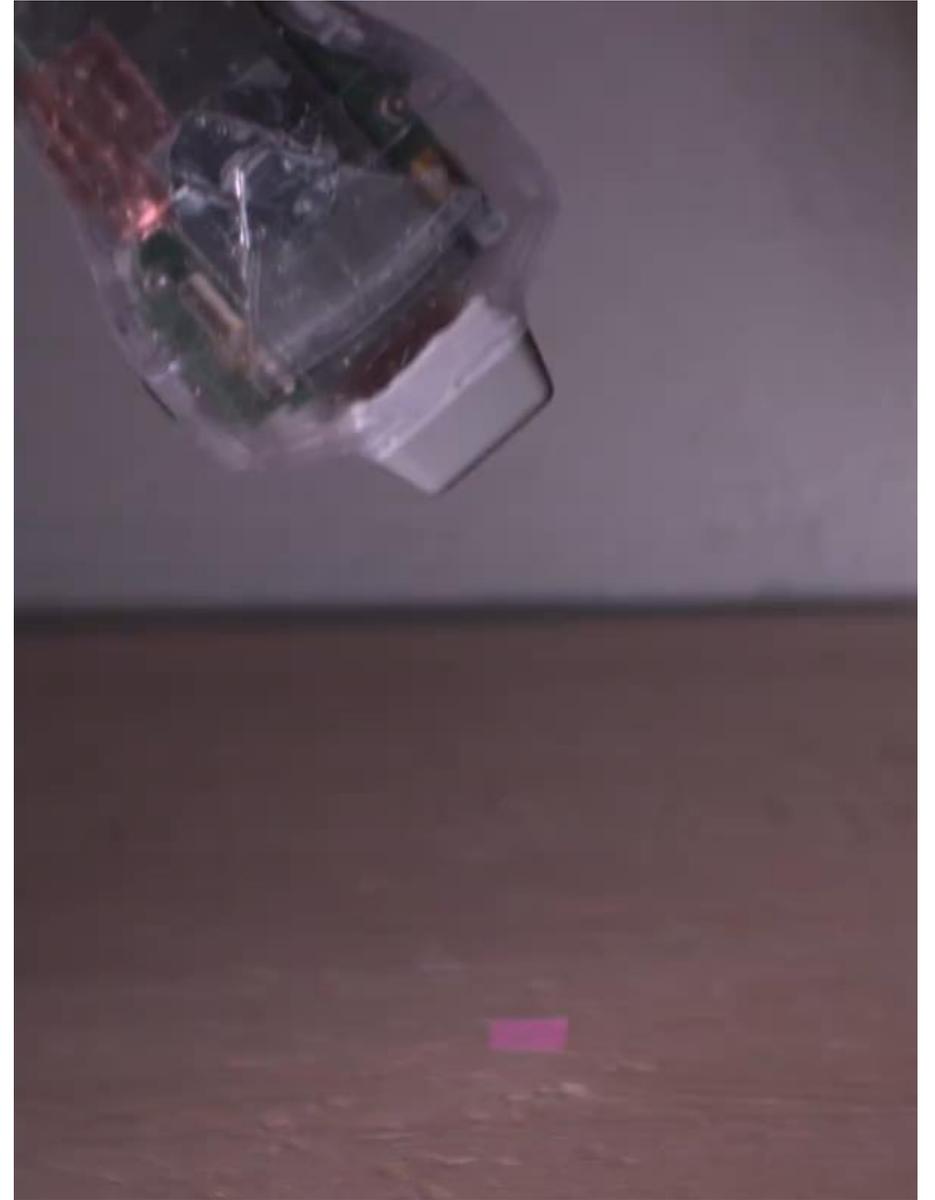
camera housing

Resin - Formlabs 3B+

adoption for design and engineering studies



Vscan Air SL drop analysis with transparent housing



Case Study BARDA

AM as an enabler

User and Business Needs

Core Problem

Provide safe electrical insulation within extremely tight space, without compromising structural robustness, biocompatibility, cost, or timeline.

Design Challenge Triangle – balancing of:

- Electrical safety (2.6kV)
- Mechanical robustness + tight tolerances
- Cost + iteration speed + manufacturability

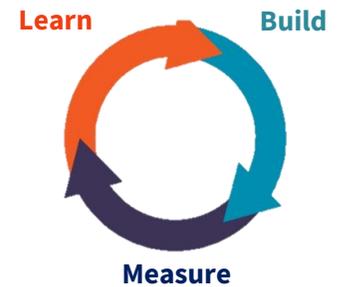
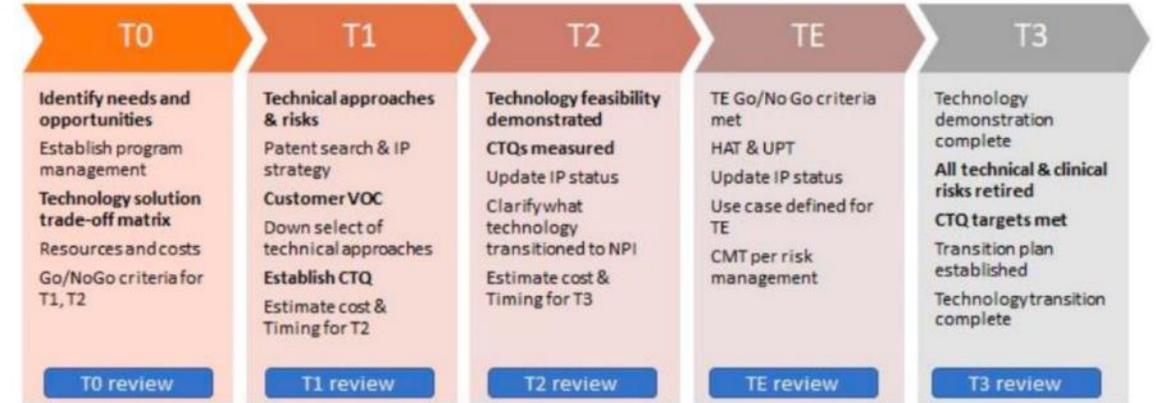
User Needs (Outcome-Oriented, Non-Solution Specific)

Patient & Safety Needs

- The patient must be protected from electrical hazards.
- The device must remain safe under mechanical shock (e.g., drops).
- The device must maintain biocompatibility in patient-contact areas.

Functional Needs

- The part must maintain precise internal component alignment.
- The part must integrate insulation without compromising structural integrity.



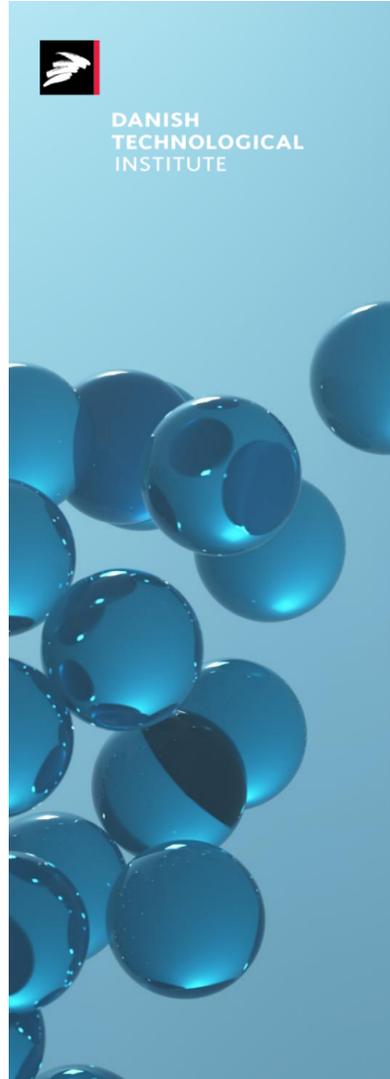
Engineering / Development Needs

- The design & technology must allow fast iteration during prototyping.
- The solution must transition efficiently into series production.
- The design should simplify overall system architecture where possible.

Business Needs

- The solution must be cost-effective for series production.
- The development approach must minimize financial risk during prototyping.
- The project must stay within timeline constraints.

Technology screening, where did we start from?



Rating the technological solution

Risk evaluation

		Risk score (1-25) for each technology-risk combination (Multiplication of Probability 1-5 and Severity 2-5)												
Severity		S5	S5	S5	S5	S4	S4	S3	S3	S3	S2	S2	S2	
Consequence in terms of...		Adhesion to materials	High voltage resistance	ESD resistance	Material durability	Thermal performance	Out and reliability	Casting uniformity	Process challenges/complexity	Application challenges	Environmental and logistical impact	Mechanical stress resistance	Damage visibility	Info/Comments
Technologies		Explanation of consequence												
Reason for selection		Explanation of consequence												
Silicone overmolding		P2	P1	P3	P1	P1	P2	P1	P2	P1	P1	P1	P1	
RTV silicone spray/dip coating		P3	P1	P3	P1	P1	P1	P3	P1	P2	P1	P1	P1	Requires a thicker layer, but is a well-known technique.
Vacuumforming (PE)		P3	P1	P2	P1	P1	P1	P2	P2	P1	P1	P2	P1	High form = shell if no primer is used in the entire piece. No PE could it still creep.
Vacuumforming (PETG)		P3	P1	P2	P2	P1	P1	P2	P1	P1	P1	P2	P1	High form = shell if no primer is used in the entire piece. No PETG could it still creep. PETG should be very good at complex forms
Electrostatic powder coating with epoxy		P1	P1	P1	P1	P1	P3	P2	P2	P2	P2	P1	P1	
Part CNC machining of epoxy cured layer		P1	P1	P1	P1	P1	P2	P2	P1	P2	P1	P2	P1	
Polymer brusher		P1	P1	P3	P1	P1	P5	P3	P4	P2	P5	P2	P3	
Lubricant (epoxy)		P1	P1	P1	P1	P1	P1	P4	P4	P3	P1	P1	P1	

Atomic Requirements / Design Criteria

Electrical Requirements

- ER1 – The insulation system shall withstand ≥ 2.6 kV DC without dielectric breakdown.
- ER2 – No conductive metal surface in patient-contact area shall be electrically exposed.

Mechanical Requirements

- MR1 – Maximum insulation thickness shall not exceed 0.6 mm in defined areas.
- MR2 – Critical alignment tolerances shall be ± 0.1 mm.
- MR3 – The assembly shall pass 1.22m drop robustness requirements (MIL drop test standard).
- MR4 – Structural integrity shall not be degraded by integration of insulation layer.

Integration / Design Requirements

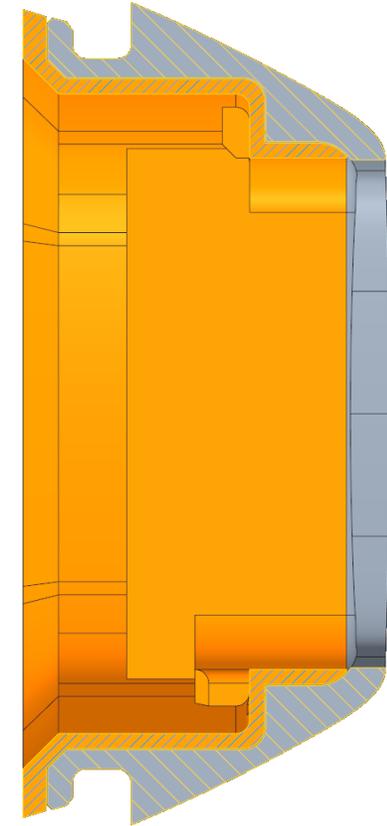
- DR1 – The solution shall fit within limited internal surface space.
- DR2 – The insulation approach shall not require full external coating of the metal part.
- DR3 – The design shall enable simplification of metal component geometry where possible.
- DR4 – The solution shall support functional fusion (replace complex metal attachment features).

Biocompatibility Requirements

- BR1 – No external insulation coating shall compromise biocompatibility compliance.
- BR2 – Patient-contact materials shall comply with applicable medical standards (ISO 10993).

Manufacturing & Development Constraints

- Prototype iteration cycle shall not exceed 1 working day turnaround.
- Prototype manufacturing shall be feasible entirely in-house.
- The solution shall allow migration to injection molding after design freeze.



Additive manufacturing as design enabler

Allowed quick iterations, currently at version 15+

Cost < 25 USD vs coating between 60 to 80 USD

Retires technical risks of coatings and simplifies outer part (integration of alignment features)

Combination of additive manufacturing and CNC post-processing

Pure in-house production with full control

Process contained to 2 machines and 1 employee

- Additive manufacturing for master geometry with complex features – pushing the technology (DLP Genera G3)
- CNC machining for tight tolerance area (DATRON Neo)
 - also used to remove supports and reduce manual postprocessing needs
- 1-Day design iteration loop, yielding 20+ parts
 - Redesign (1h) → Tray and machine setup (1h) → Print & cure (4h) → CNC (2h)
 - Full ownership of the “Build – Measure – Learn” loop



Wrap up

It's a journey (technical + people / mindset)

Vertical integration (+ reduces complexity, +++ speed (BML))

Needs to fit your needs – end to end solutions over latest technology



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