

+ ActivCellpen[®]

Advancing **Safe, Mobile Plasma Therapy** Together

A modern **plasma technology** in a compact, **battery-powered** and **wireless** handheld device — designed for easy, flexible **clinical integration**.

COMPACT | WIRELESS | CLINIC-READY



TECHNICAL DEVELOPMENT FOR A CLASS IIa MEDICAL DEVICE

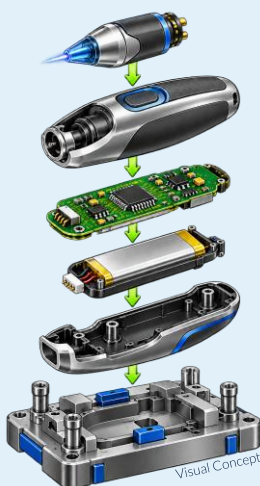
ICU tech further developed the existing **electronics** and aligned the **embedded software** with medical-device requirements. The key challenge was to **safely** integrate a battery-powered **high-voltage** system generating up to **25 kV** within a **compact** architecture.

The project covered hardware and firmware **development**, technical verification, **risk management**, testing, documentation and industrialization — approximately **2'500 project hours** end to end.



ICU TECH CONTRIBUTION

- ELECTRONICS + HARDWARE**
Existing platform adapted for a compact, battery-powered high-voltage system.
- EMBEDDED C FIRMWARE**
Developed to IEC 62304; software safety class A.
- TECHNICAL VERIFICATION**
Complete verification of hardware and firmware.
- DOCUMENTATION + APPROVAL**
Technical documentation and regulatory approval support.



- EMC + ELECTRICAL SAFETY**
Tests in accordance with IEC 60601-1-2 and IEC 60601-1.
- RISK MANAGEMENT**
Risk-management process aligned with ISO 14971.
- INDUSTRIALISATION**
Production handover and preparation for repeatable manufacturing.



PROJECT DATA AT A GLANCE

~2'500

PROJECT HOURS
END-TO-END

CLASS IIa

MEDICAL DEVICE
MDR CONFORMITY
ASSESSMENT

25 kV

HIGH VOLTAGE
BATTERY-POWERED

CLASS A

SOFTWARE LIFE CYCLE
PROCESS
MEDICAL DEVICES IEC 62304

FROM DEEP ENGINEERING TO A MANUFACTURABLE MEDTECH SOLUTION

ICU tech combines electronics, **embedded software**, verification, regulatory alignment and industrialization into one **reliable delivery path**.



Click or scan
to find out more

ActivCell
Group

