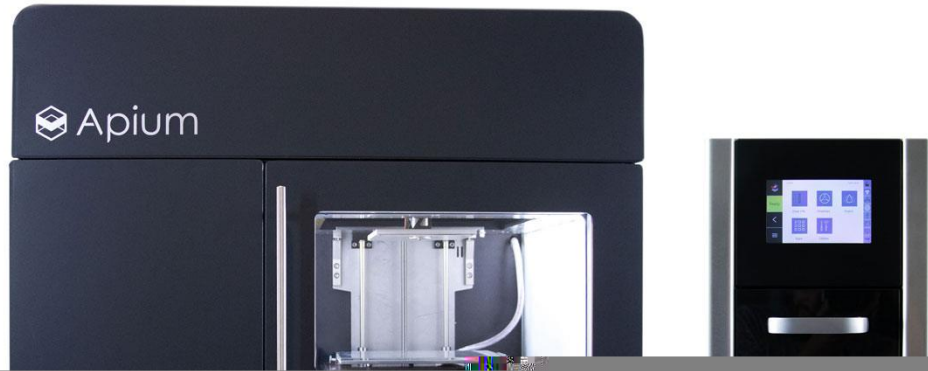




Apium
Additive Technologies GmbH

Apium M220 Medical Device Manufacturing Machine

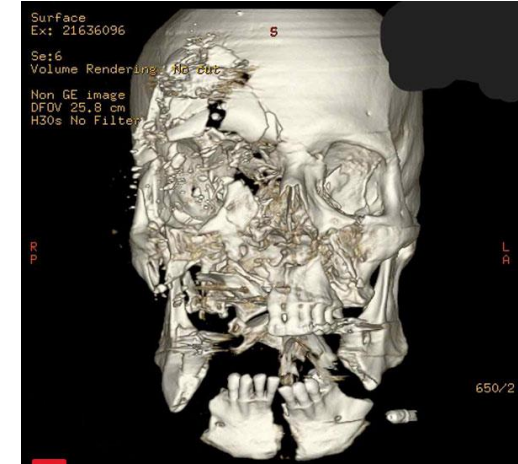
Applications



Medical Vision and Workflow

ISO 13485

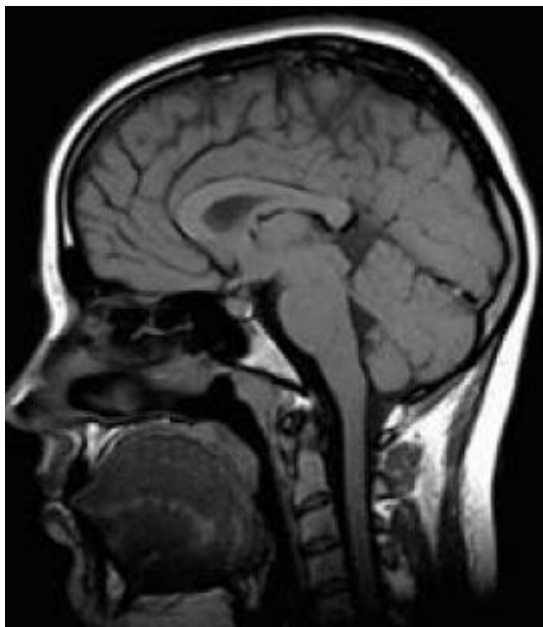
Software



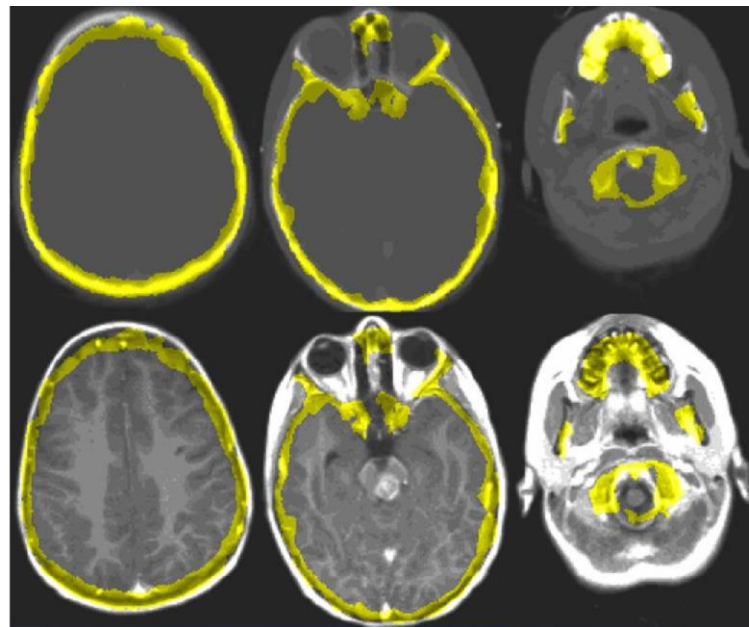
ISO 10993



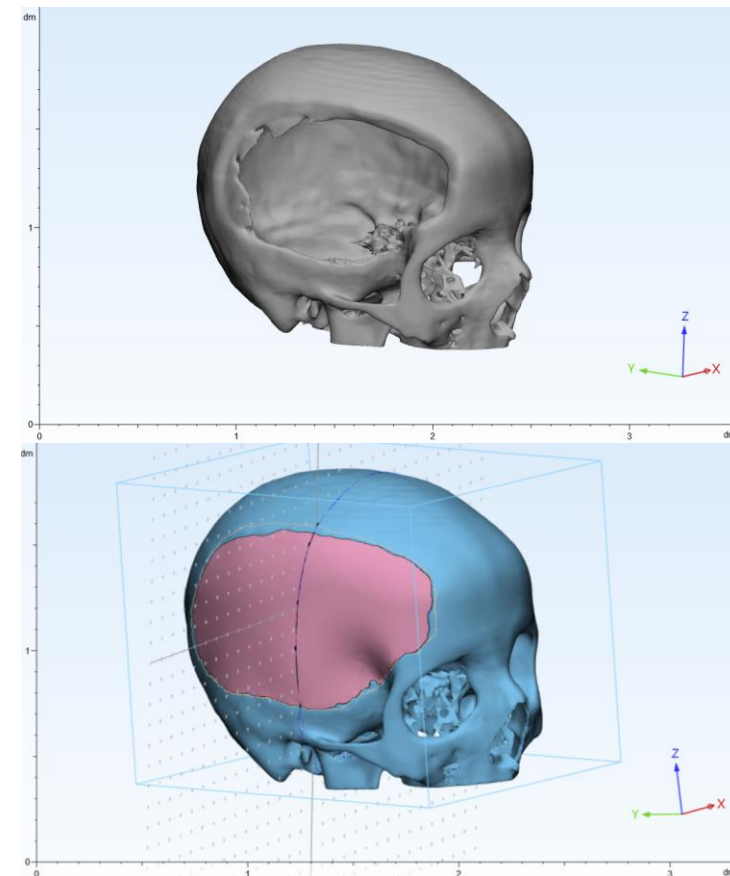
Workflow



MRI / CT

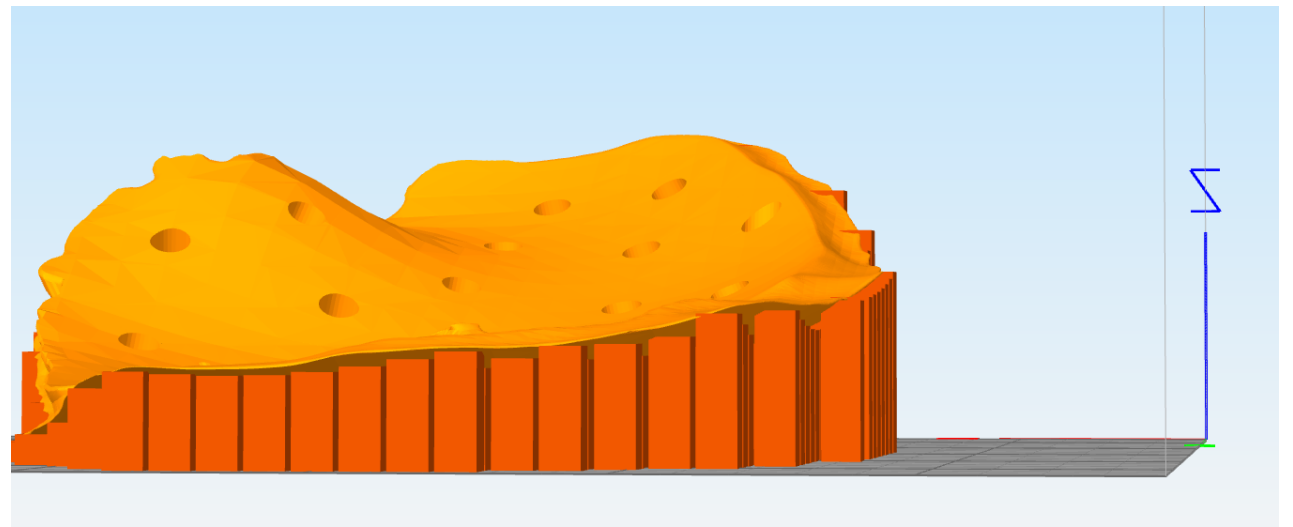
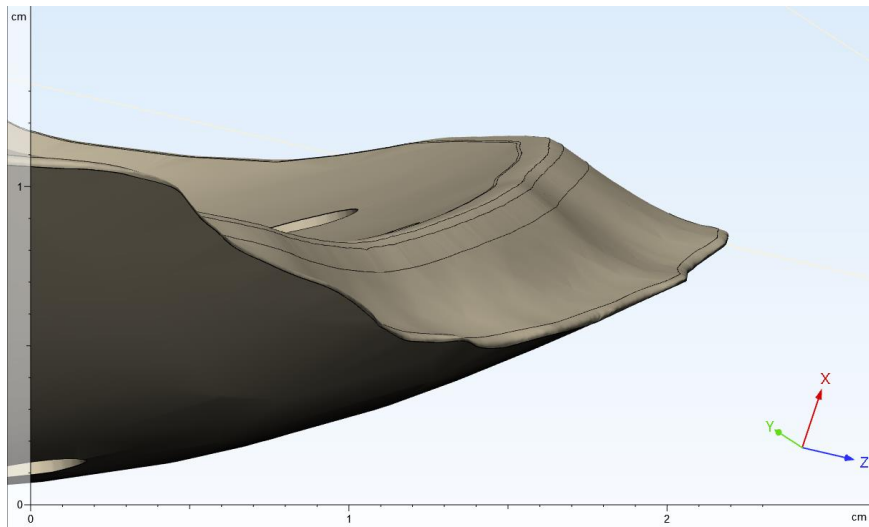


Segmentation



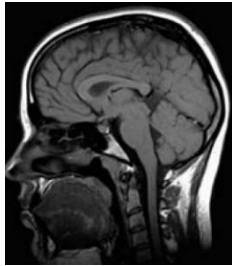
Reconstruction

Workflow

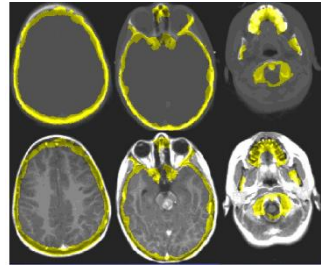


Slicing / G-code generation

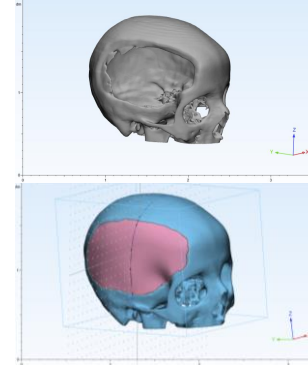
Workflow



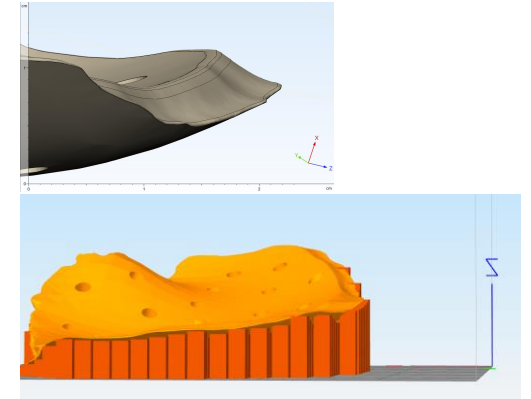
MRI / CT



Segmentation



Reconstruction



Tool path generation

Data processing

Dicomm file
handling

Segmenation

CAD Modelling

CAM / G-Code
Generation

➔ **Additive Manufacturing**

ISO 10993

- ISO 10993-1: Biological evaluation of medical devices Part 1: Evaluation and testing
- ISO 10993-2: Biological evaluation of medical devices Part 2: Animal welfare requirements
- ISO 10993-3: Biological evaluation of medical devices Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- ISO 10993-4: Biological evaluation of medical devices Part 4: Selection of tests for interactions with blood
- ISO 10993-5: Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
- ISO 10993-6: Biological evaluation of medical devices Part 6: Tests for local effects after implantation
- ISO 10993-7: Biological evaluation of medical devices Part 7: Ethylene oxide sterilization residuals
- ISO 10993-8: Biological evaluation of medical devices. Part 8: Selection and qualification of reference materials for biological tests
- ISO 10993-9: Biological evaluation of medical devices Part 9: Framework for identification and quantification of potential degradation products
- ISO 10993-10: Biological evaluation of medical devices Part 10: Tests for irritation and delayed-type hypersensitivity
- ISO 10993-11: Biological evaluation of medical devices Part 11: Tests for systemic toxicity
- ISO 10993-12: Biological evaluation of medical devices Part 12: Sample preparation and reference materials (available in English only)
- ISO 10993-13: Biological evaluation of medical devices Part 13: Identification and quantification of degradation products from polymeric medical devices
- ISO 10993-14: Biological evaluation of medical devices Part 14: Identification and quantification of degradation products from ceramics
- ISO 10993-15: Biological evaluation of medical devices Part 15: Identification and quantification of degradation products from metals and alloys
- ISO 10993-16: Biological evaluation of medical devices Part 16: Toxicokinetic study design for degradation products and leachables
- ISO 10993-17: Biological evaluation of medical devices Part 17: Establishment of allowable limits for leachable substances
- ISO 10993-18: Biological evaluation of medical devices Part 18: Chemical characterization of materials
- ISO/TS 10993-19: Biological evaluation of medical devices Part 19: Physico-chemical, morphological, and topographical characterization of materials
- ISO/TS 10993-20: Biological evaluation of medical devices Part 20: Principles and methods for immunotoxicology testing of medical devices

ISO 10993

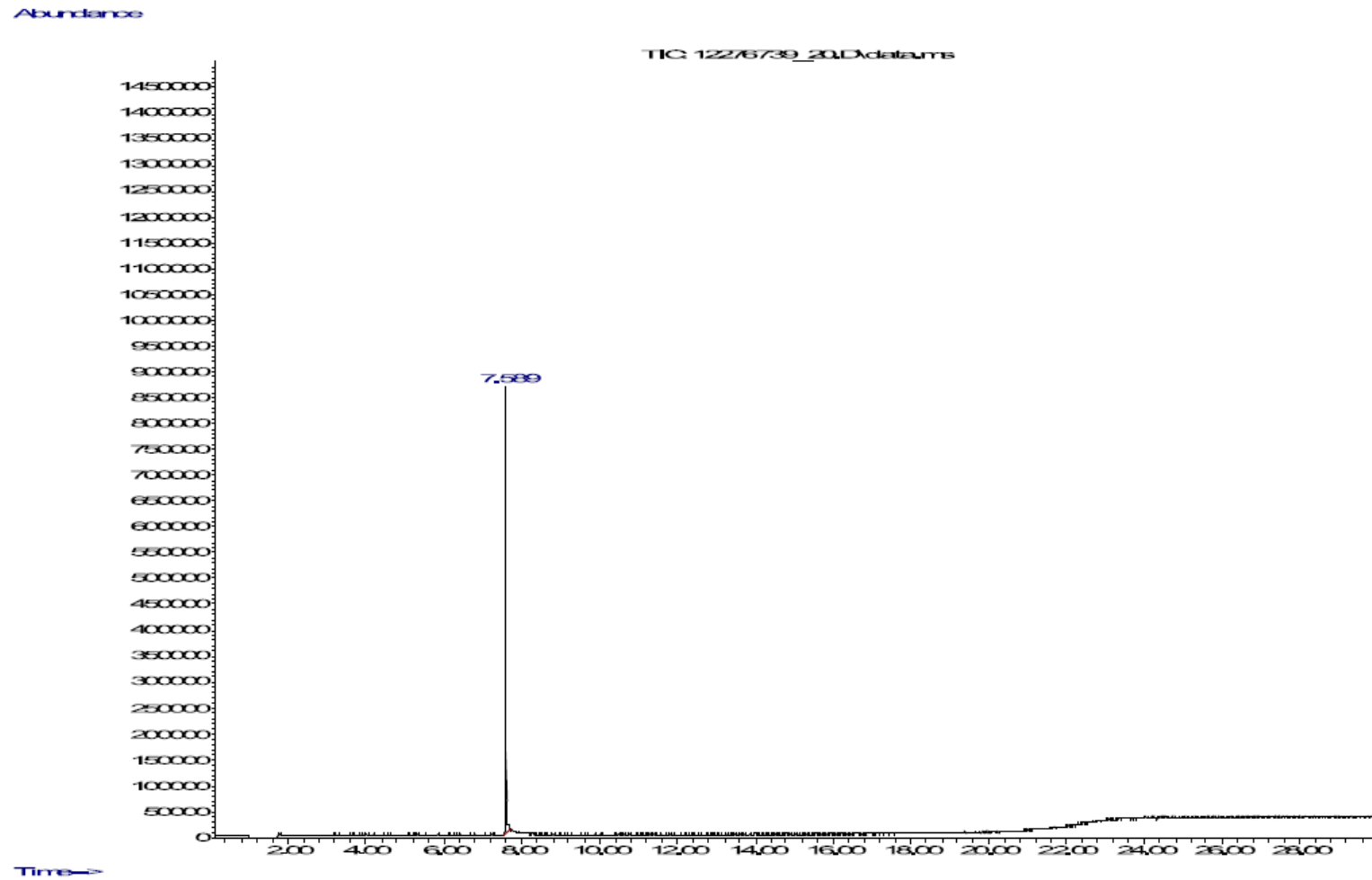


Figure 1: System standardization ($C_{14}H_{30}$ in n-hexane)

ISO 10993

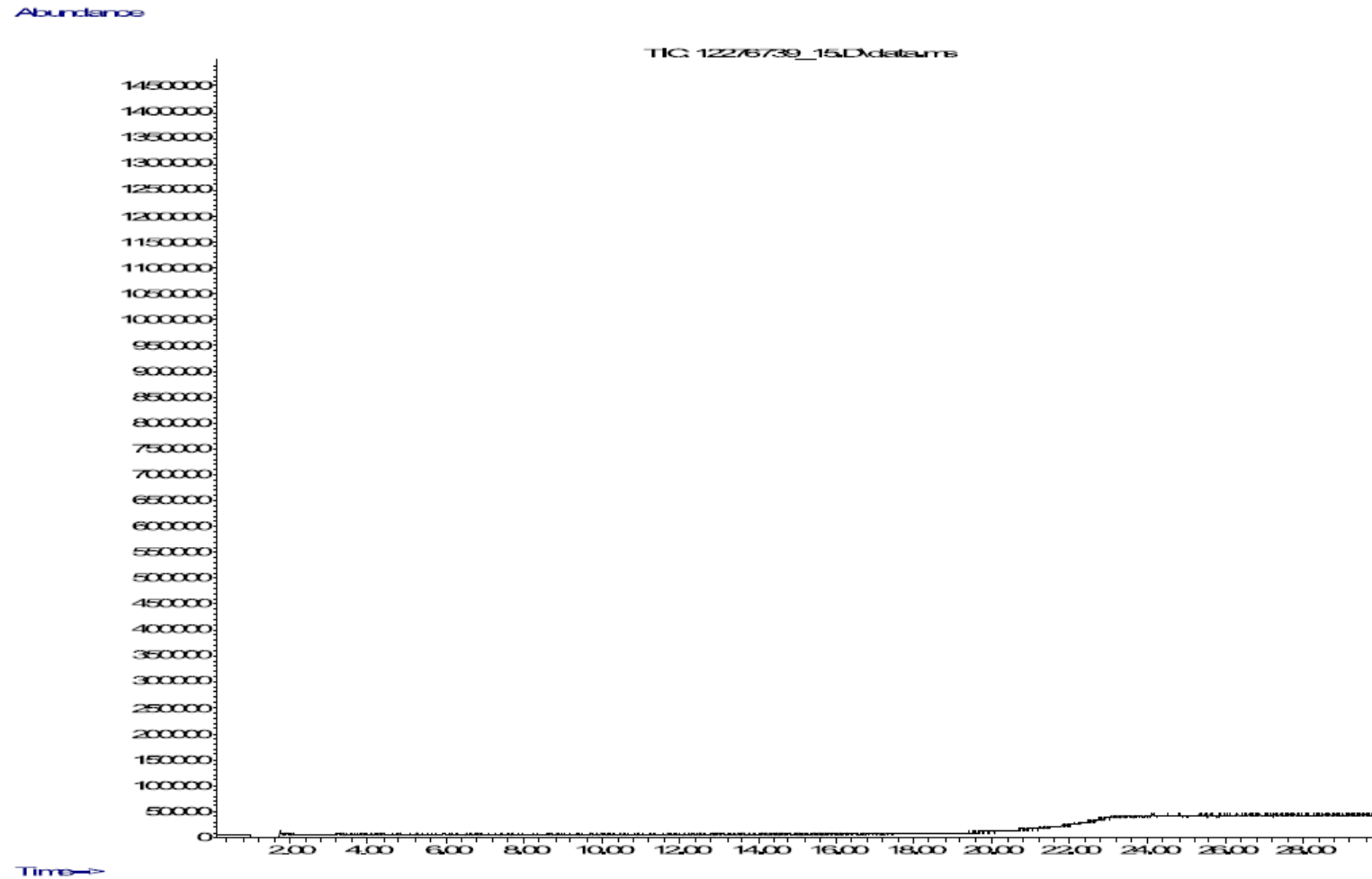


Figure 2: 0.9 % NaCl solution (negative control)

ISO 10993

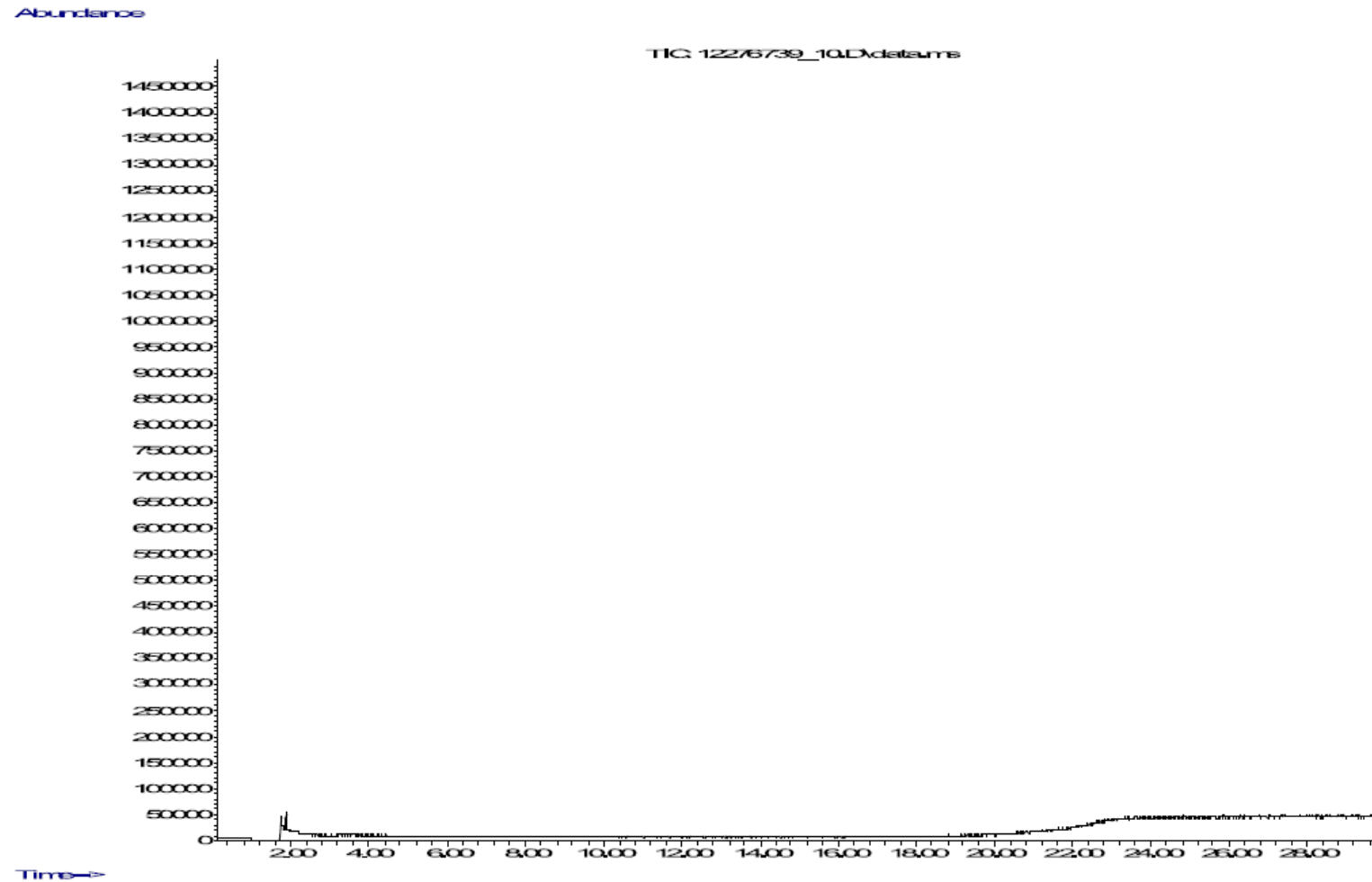
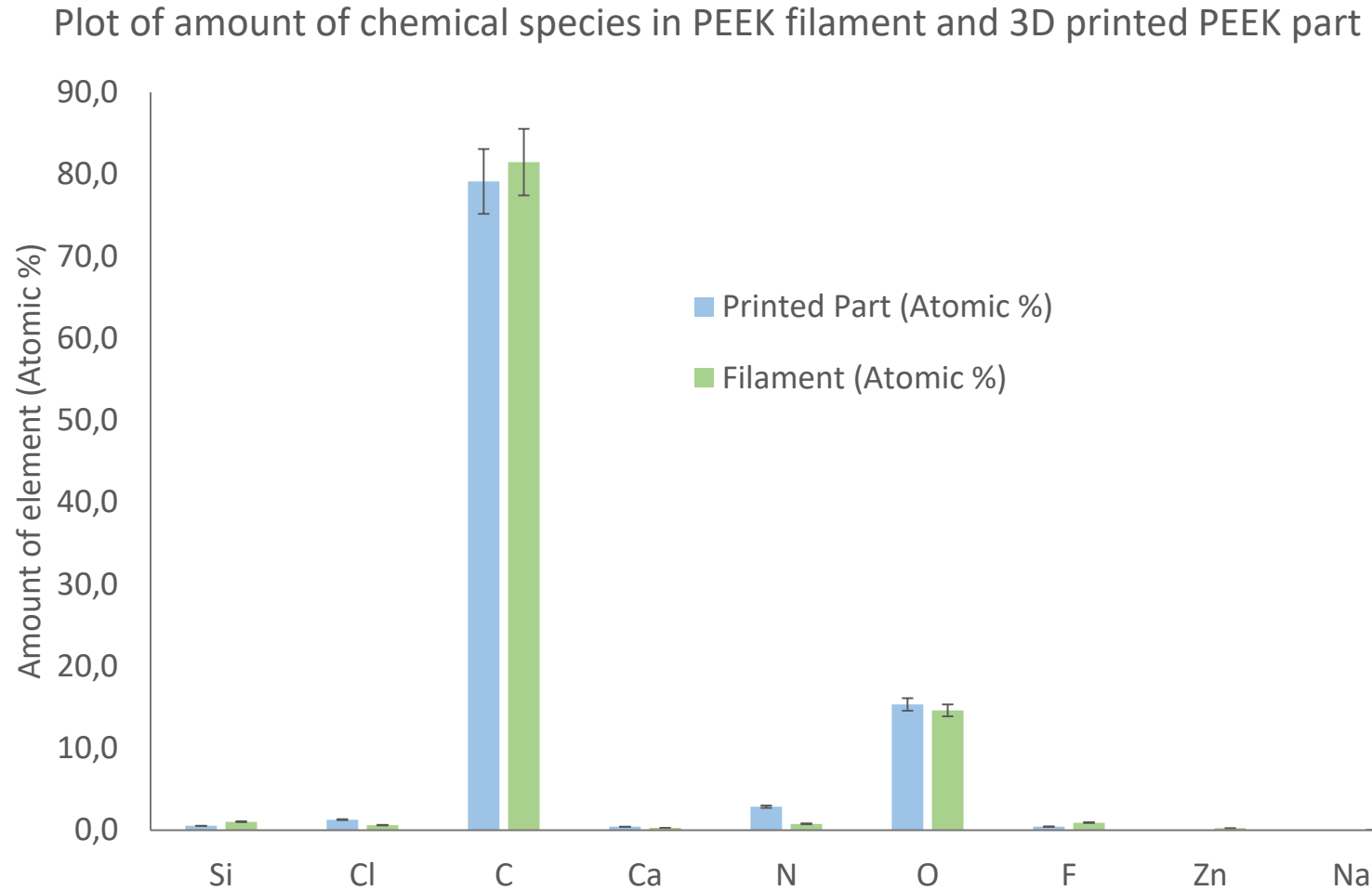
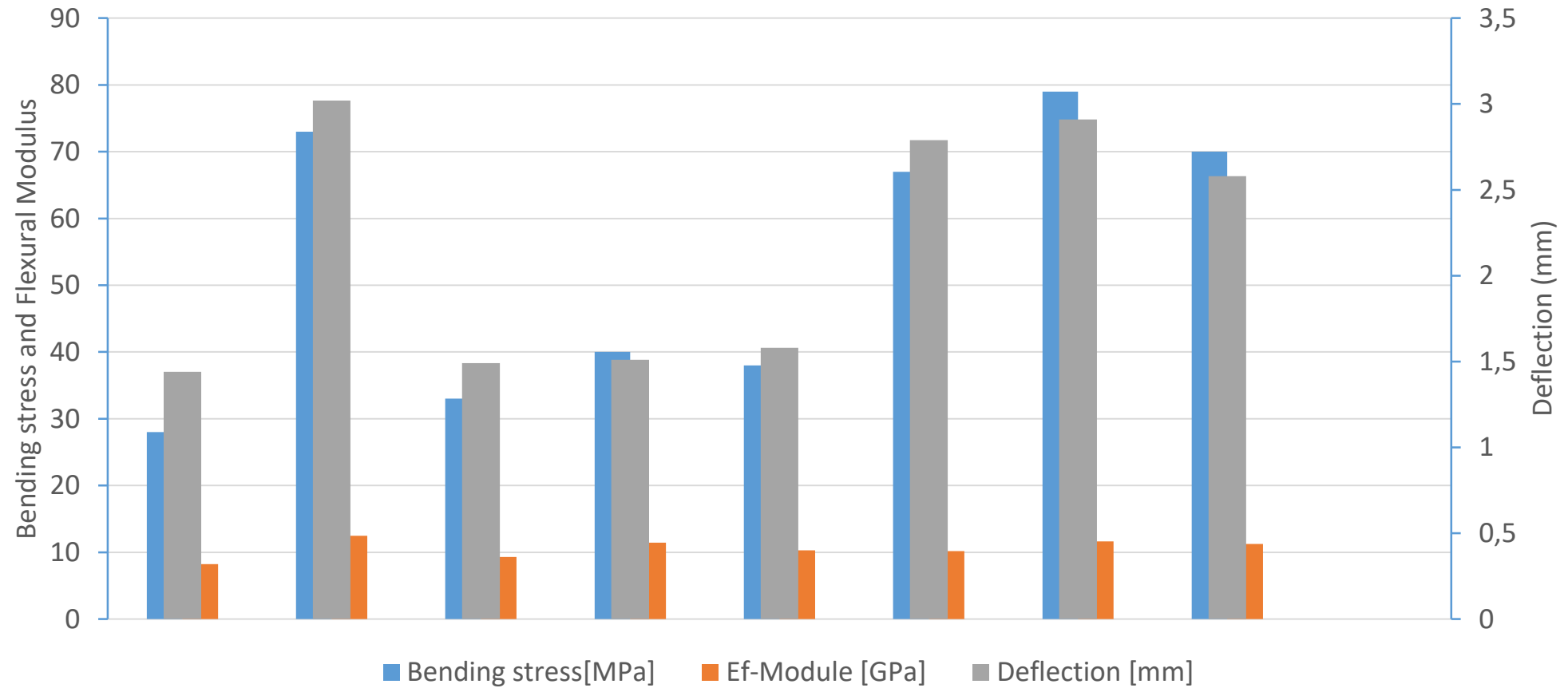


Figure 3: Isopropyl alcohol (negative control)

Surface Analysis – XPS Data



PEEK Screening – 3 Point Bending Test



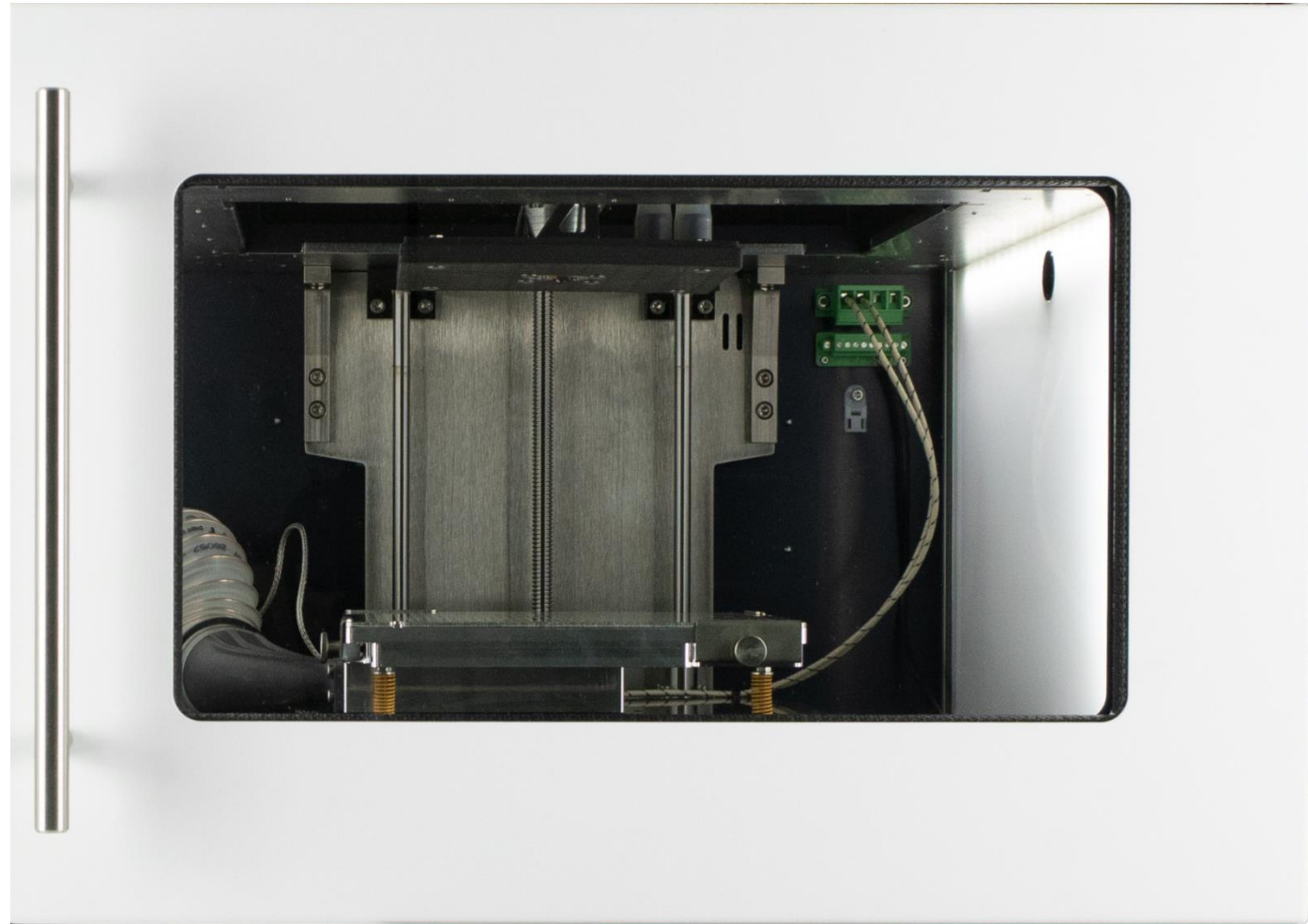
Biocompatibility tests available for i4 G

Standard	Description
ISO 10993-3	Genotoxicity: Ames Test
ISO 10993-3	Genotoxicity: Chromosome aberration test
ISO 10993-3	Genotoxicity: Mouse Lymphoma test
ISO 10993-5	Cytotoxicity
ISO 10993-6	Test for local effects after Implantation in bone (90 days)
ISO 10993-10	Sensitization: Maximization test according to Magnusson and Kligman
ISO 10993-10	Irritation: Intracutaneous Reactivity
ISO 10993-11	Subchronic Systemic Toxicity
ISO 10993-12	GC/MS Fingerprint
USP Class VI	Acute Systemic Toxicity Intracutaneous Reactivity Muscle Implantation

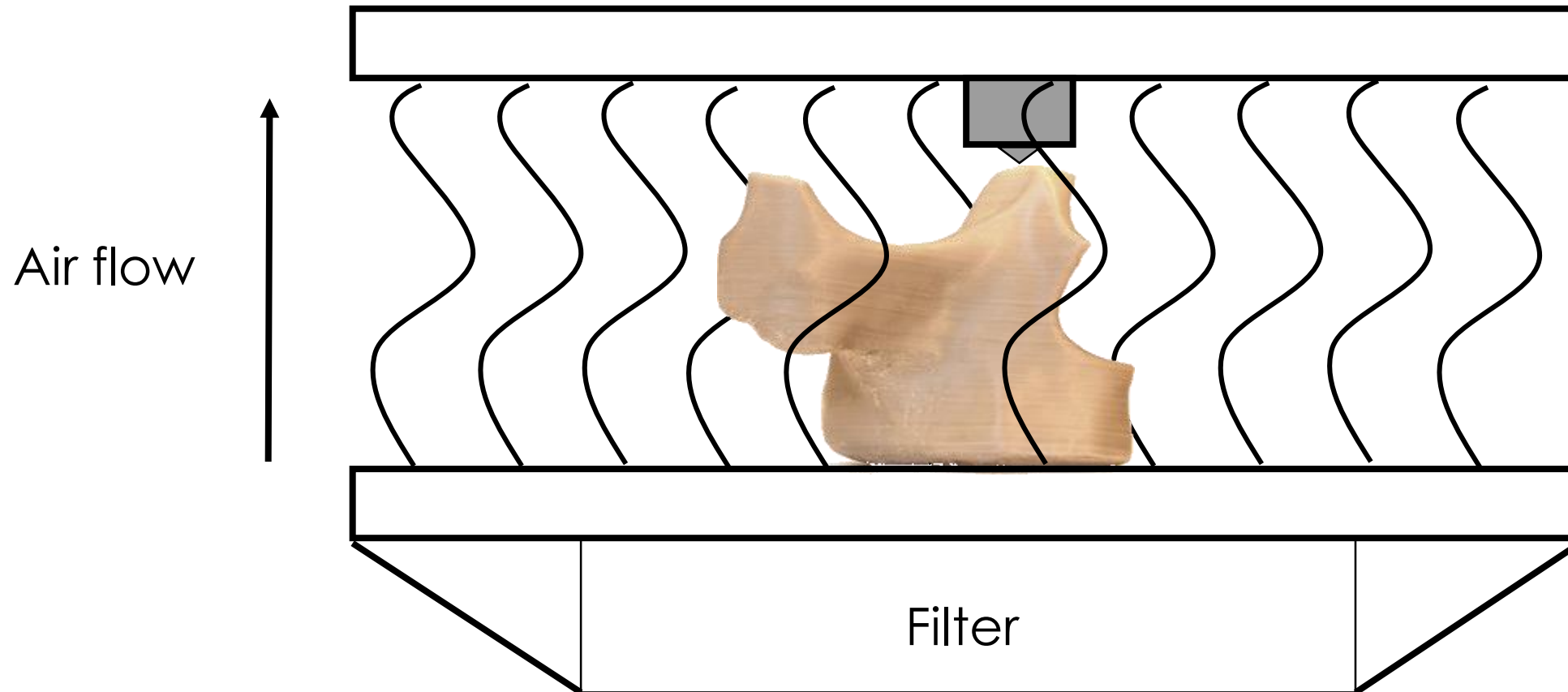
Workflow



Workflow



Workflow



Workflow



Print Job Details

M220_B1_PEEK_3x_p18_007_9x_peek_huelse

Start Time:	2019/02/21 15:32
End Time:	2019/02/21 18:51
Status:	Success
Filament Length:	7.682 m
Filament Volume:	135.542 cm ³
Filament Type:	Apium PEEK 450 Natural 1.75mm 200g
Spool Number:	A111111
Started By:	admin

Download Report

Close

Print Job ID: 000069

Print Job Filename: M220_B1_Peek_3x_p18_007_9x_peek_huelse.g-code

Print Started By: admin

Print Started: 2019-02-21 15:32:38

Print Finished: 2019-02-21 18:51:31

Print Duration: 03:18:52

Filament Length: 7.682 m

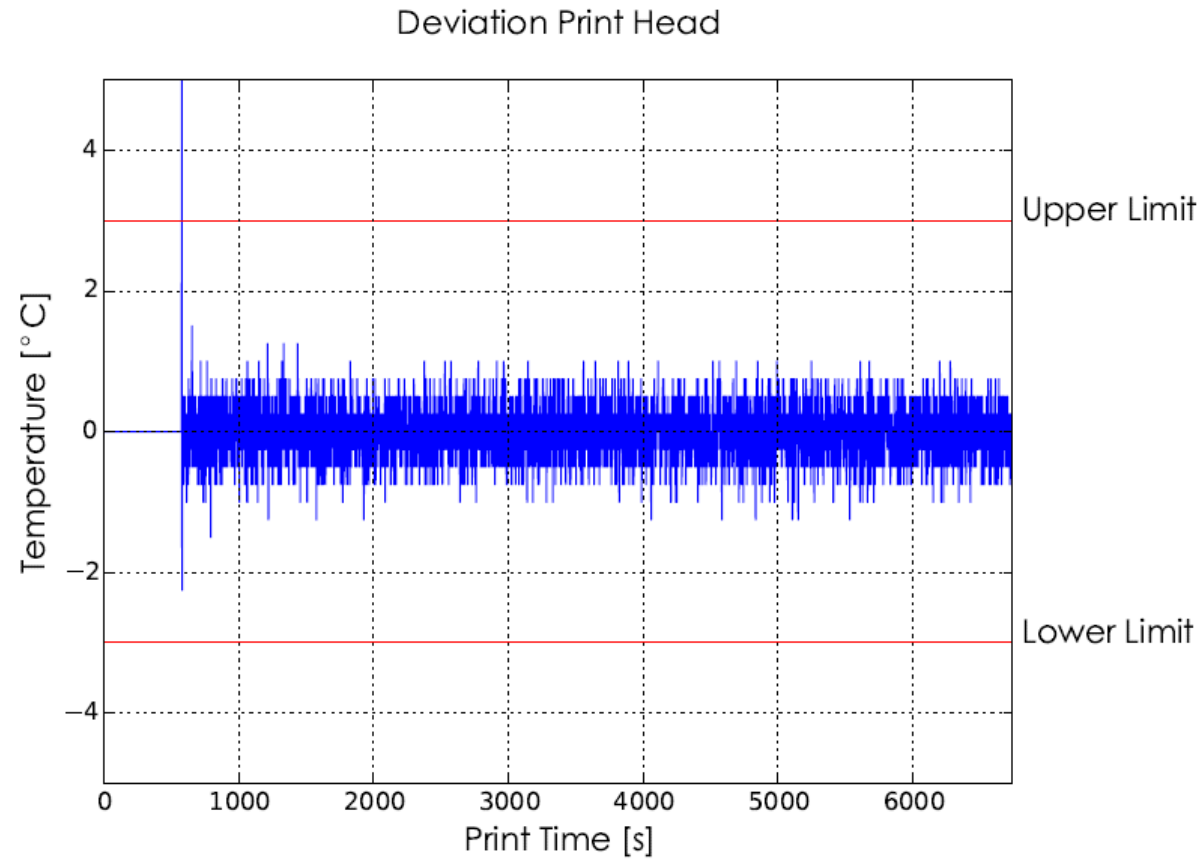
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Filament Type: Apium PEEK 450 Natural 1.75mm 200g

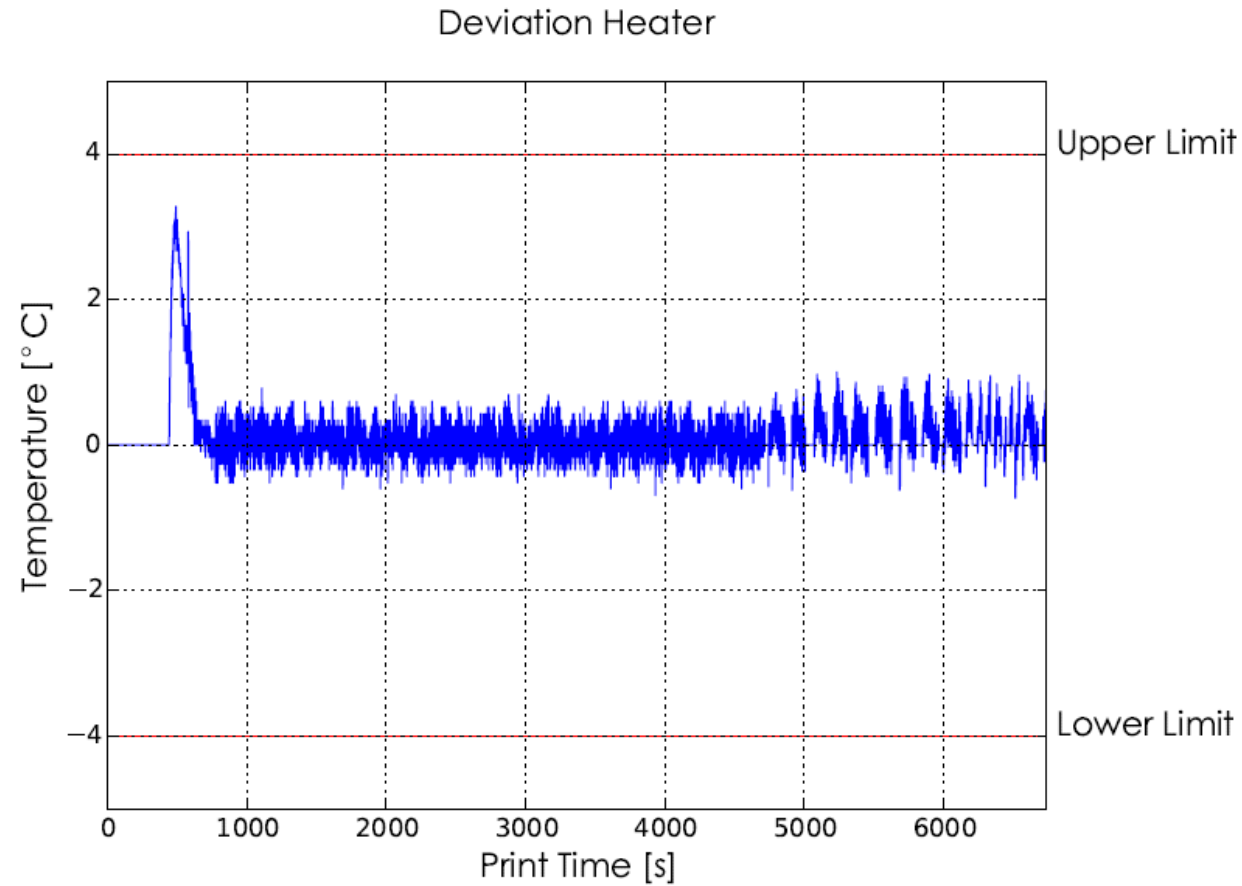
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Printer SN: M220G01R010002

Print Job Completed Successfully

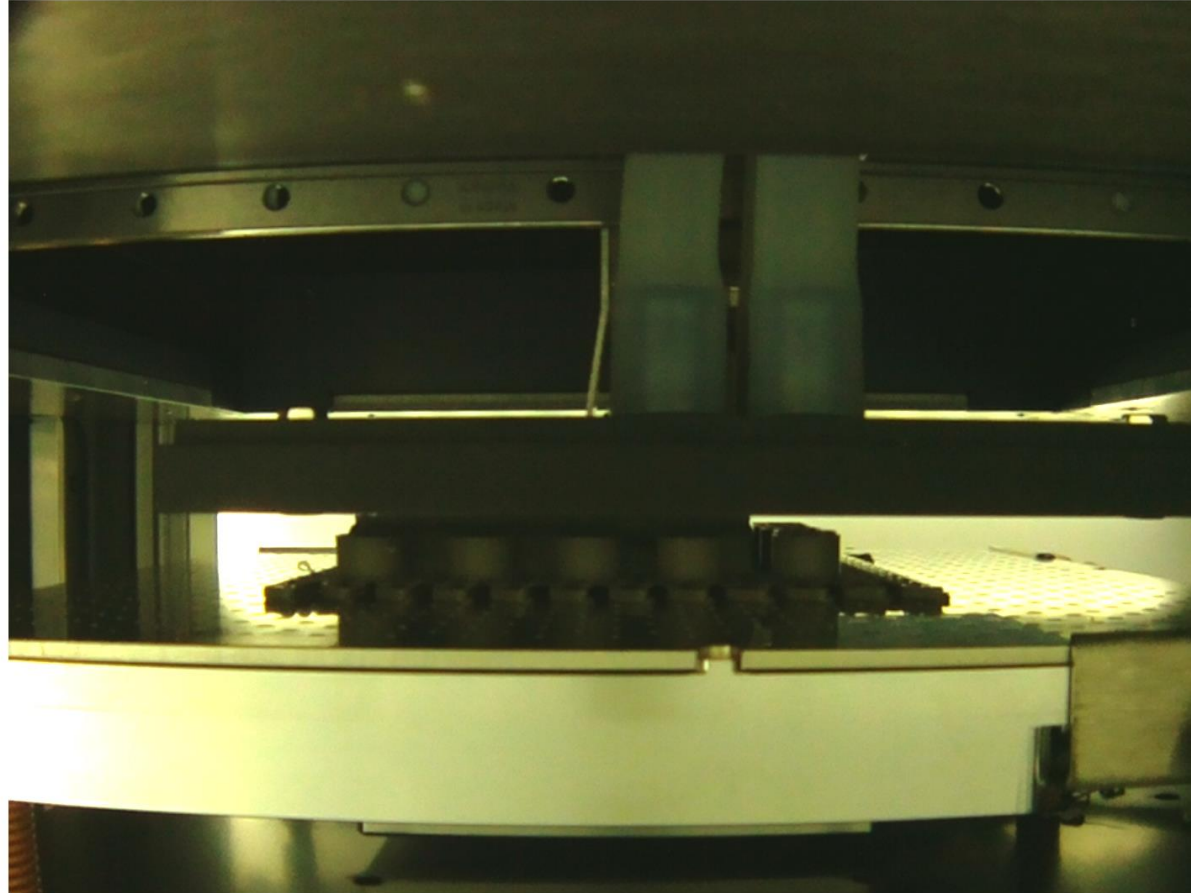


Workflow



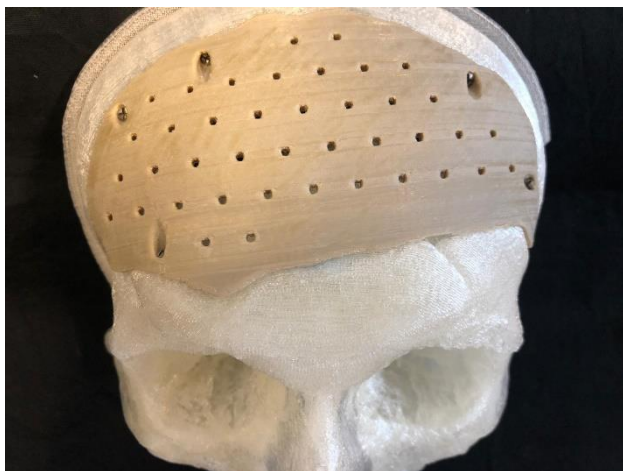
2019-02-21 18:52

2 of 4



Printed Part

Printed Examples



The examples were created by the cranio maxillo facial department from the university hospital Basel.

Ref:



Dr. med. Dr. med. dent. Florian
M. Thieringer, MHBA
Kaderarzt/Co-Leiter 3D-Print
Lab
Tel.061 328 72 37
florian.thieringer@usb.ch