Digital Twins for Organ Preservation Devices

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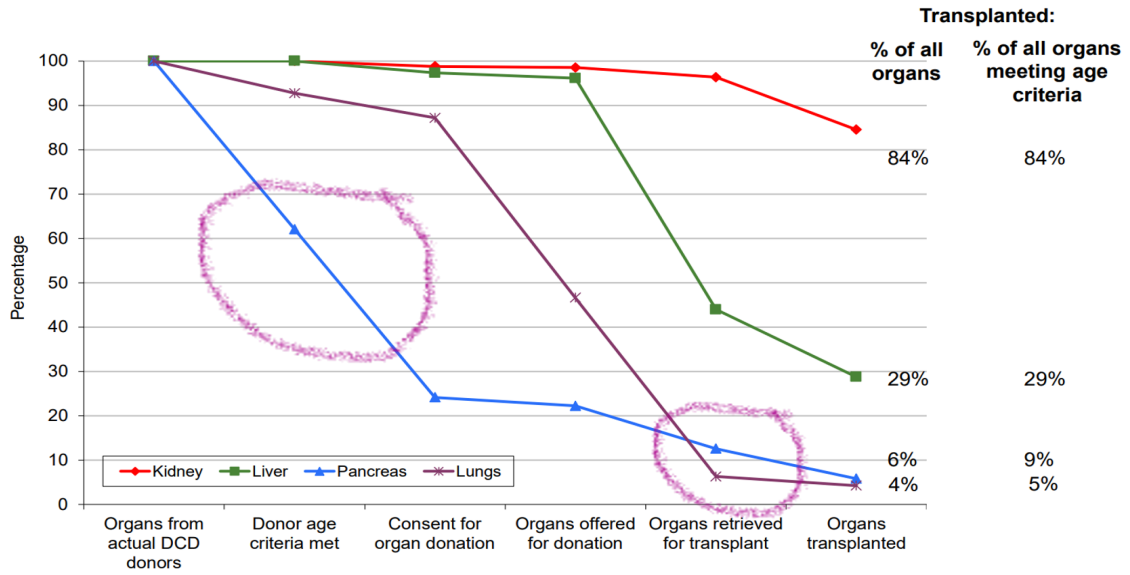
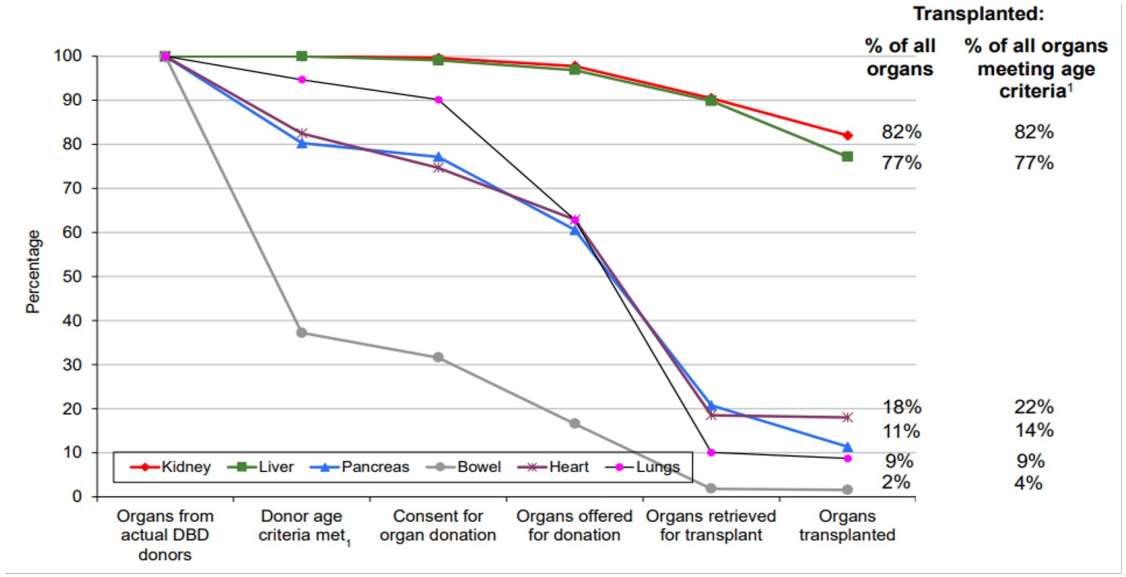
scubatx
ORGAN PRESERVATION TECHNOLOGIES

Organ Preservation

- Organ demand is outpacing supply
- Acceptable criteria are stretched
- Many viable organs go unused
- Increase of cardiac death donation
- **Advanced organ preservation techniques are required**
- Requiring use of complex devices





NHSBT. The National Organ Retrieval Service and Usage of Organs Report 2020/21, 2021

Organ Preservation

STATIC COLD STORAGE

HYPOTHERMIC MACHINE PERFUSION

https://www.organ-recovery.com/lifeport-kidney-transporter/

NORMOTHERMIC MACHINE PERFUSION

https://www.organox.com/

PERSUFFLATION

https://www.scubatx.com/

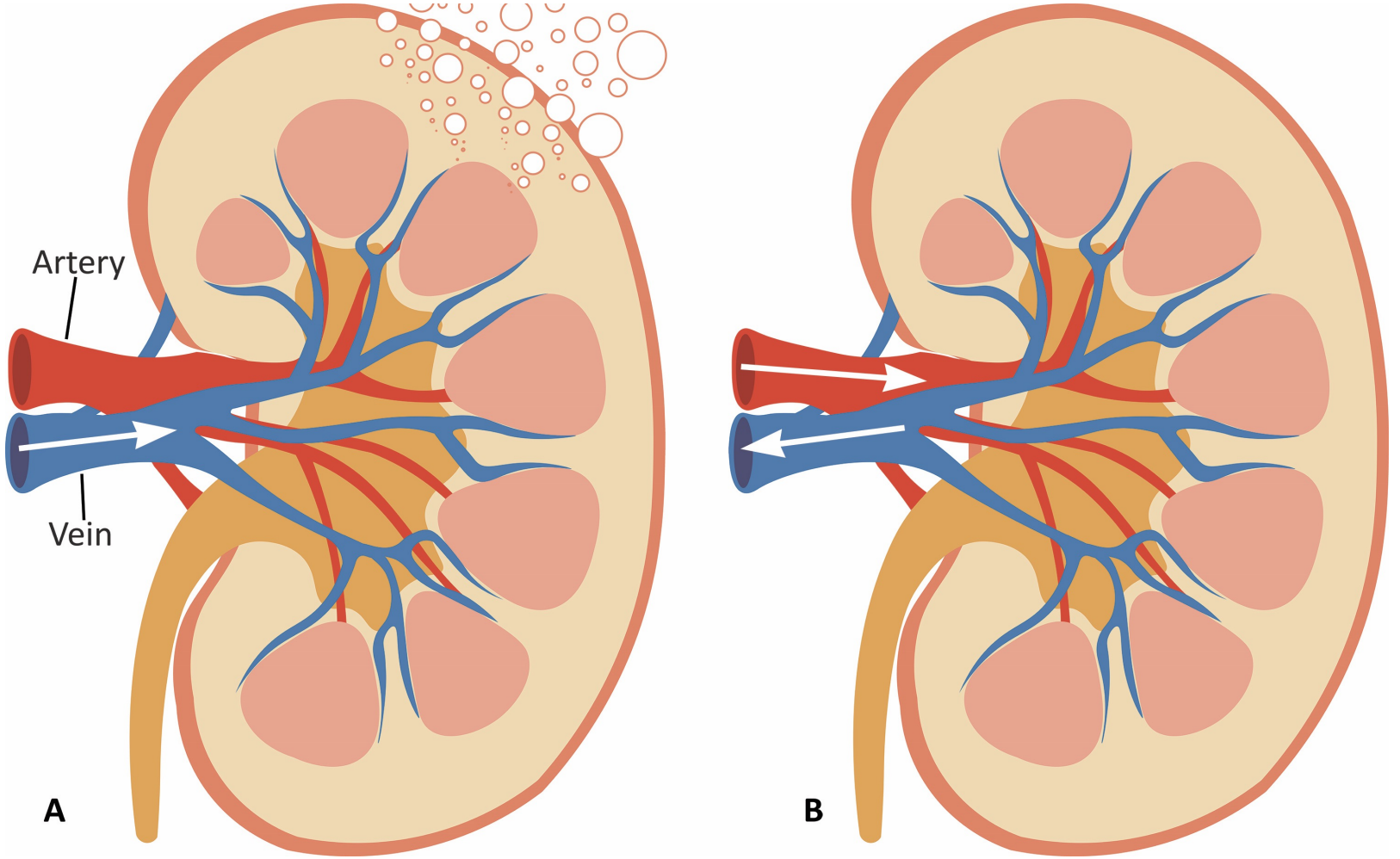
Passive Techniques

Active Techniques

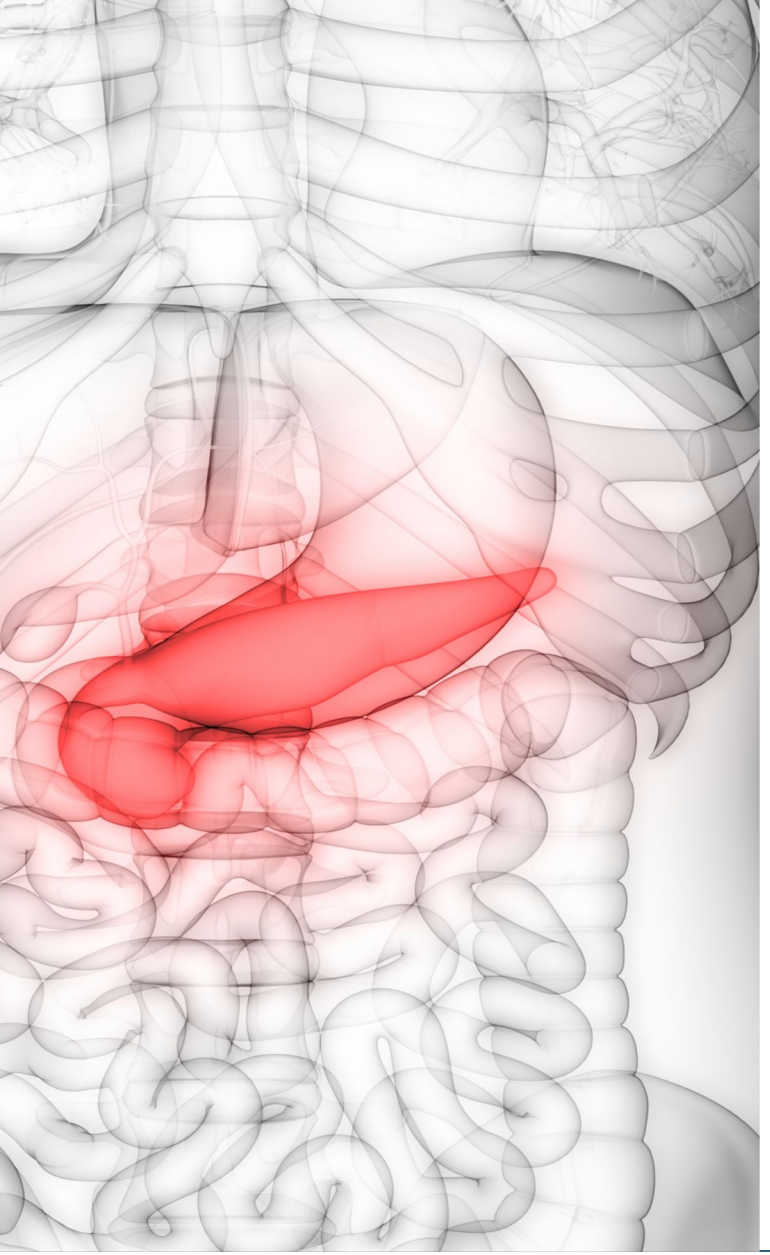
Case Study: The ScubaTx™ Device

Persufflation

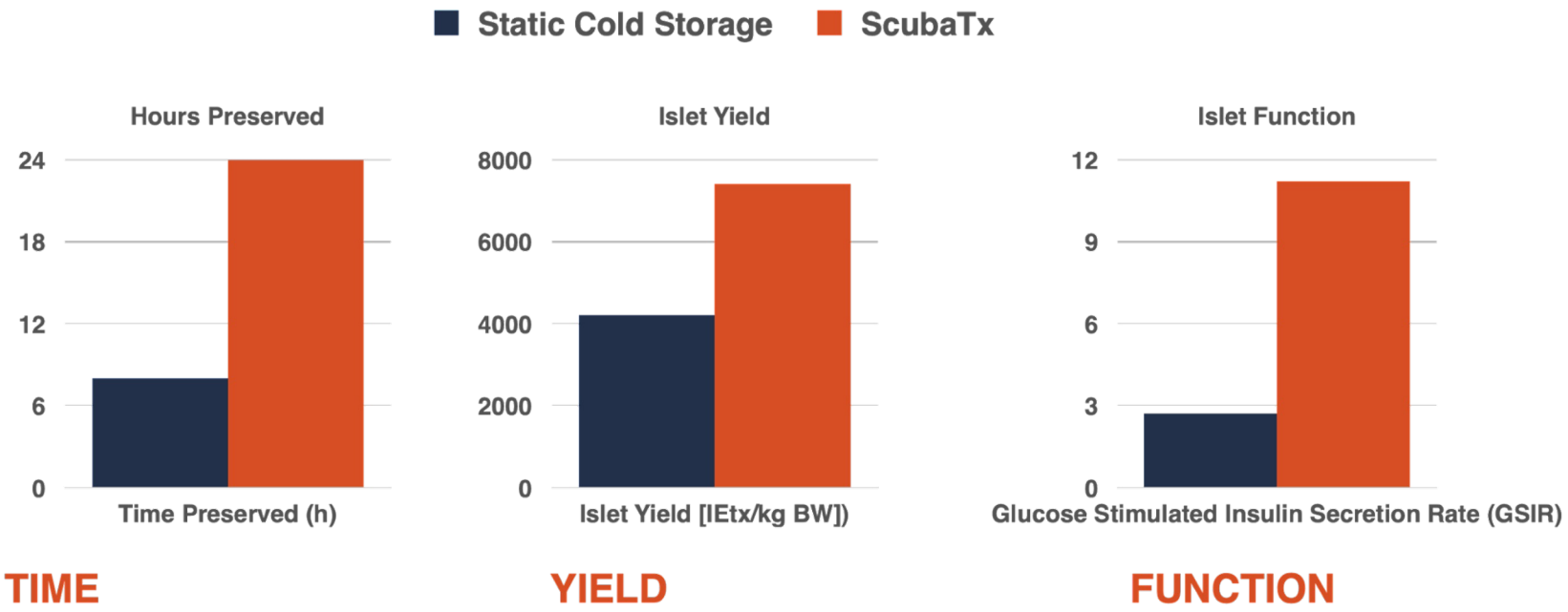
- Uses humidified oxygen gas to perfuse the organ
- Hypothermic preservation
- Multi-organ
- Two types
  - Retrograde PSF (A)
  - Anterograde PSF (B)



Buhagiar, A.J., Freitas, L., Scott, W.E.: Persufflation - current state of play. Transplantology (Sep 2021). https://doi.org/10.3390/transplantology2030035



Pancreas preservation breakthrough: standard care x improvements



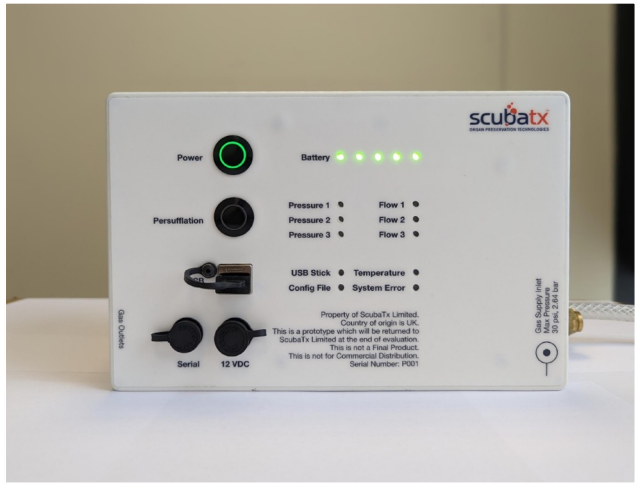
TIME **YIELD** **FUNCTION**

- University of Arizona collaboration constitutes a breakthrough for pancreas preservation, taking islet yield well above the current cut-off limit for transplantation.

- If translated into clinical practice, offers the promise for significant improvements in yield (>2x) and function (>4x) of Pancreatic Islet transplants for Type 1 Diabetes.

ScubaTx Device

- Uses PSF
- Multi-organ
  - Pancreas
  - Liver
  - Kidney
  - Heart
  - Composite tissue (hand + face)
- Active oxygen flow control
- Passive temperature monitoring

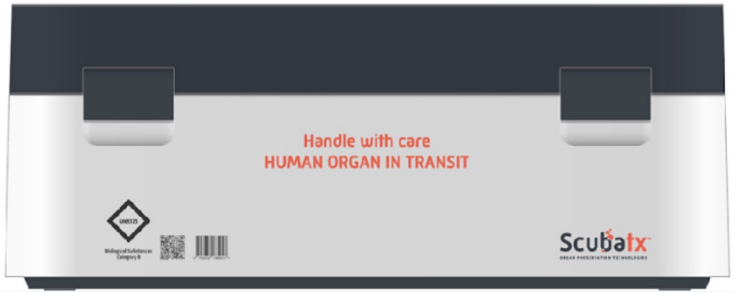


DOCK - control system

VOYAGE – retrieval system

Device in Action

scubatx™
ORGAN PRESERVATION TECHNOLOGIES



Prof. Derek Manas	(left)	Transplant Surgeon	Clinical Director NHS Blood and Transplant
Sam Tingle	(middle)	Transplant Fellow	Newcastle Surgical Fellow
Dr. Bill Scott	(right)	ScubaTx CSO	Newcastle Senior Lecture

Evaluation of the ScubaTx DOCK device on recovered human Pancreas @ 30th May 2022.

Extended preservation windows designed for commercial application

HYPOTHERMIC
Cooling organs reduces impact of hypoxia. Ice blocks means it's simple, low cost, & function even if battery fails.

OXYGENATED
Oxygen-rich air is bubbled through the organ's vasculature. Maintains organ function.

HUMIDIFIED
Avoids desiccation of delicate organ vasculature.

MODULAR
One unit serves all organs: reduced acquisition costs, greater return on capital, wider distribution of units.

ULTRA-PORTABLE
Small, stackable. Takes up little space = lower storage and transport costs.

INTELLIGENT FEEDBACK
Pertinent & timely detail to clinicians/transporters. Faster clinical decision-making.

AUTOPILOT
Simple UI means no additional staff required and minimises training = reduced costs, easier to deploy. NFC-enabled consumable simplifies machine operation, hence minimising user error.

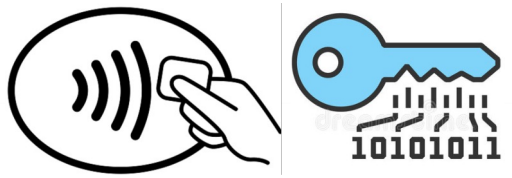
MISRA

eC ESCHER C VERIFIER

D-RISQ SOFTWARE SYSTEMS

5 patents filed ed, 2 imminent)

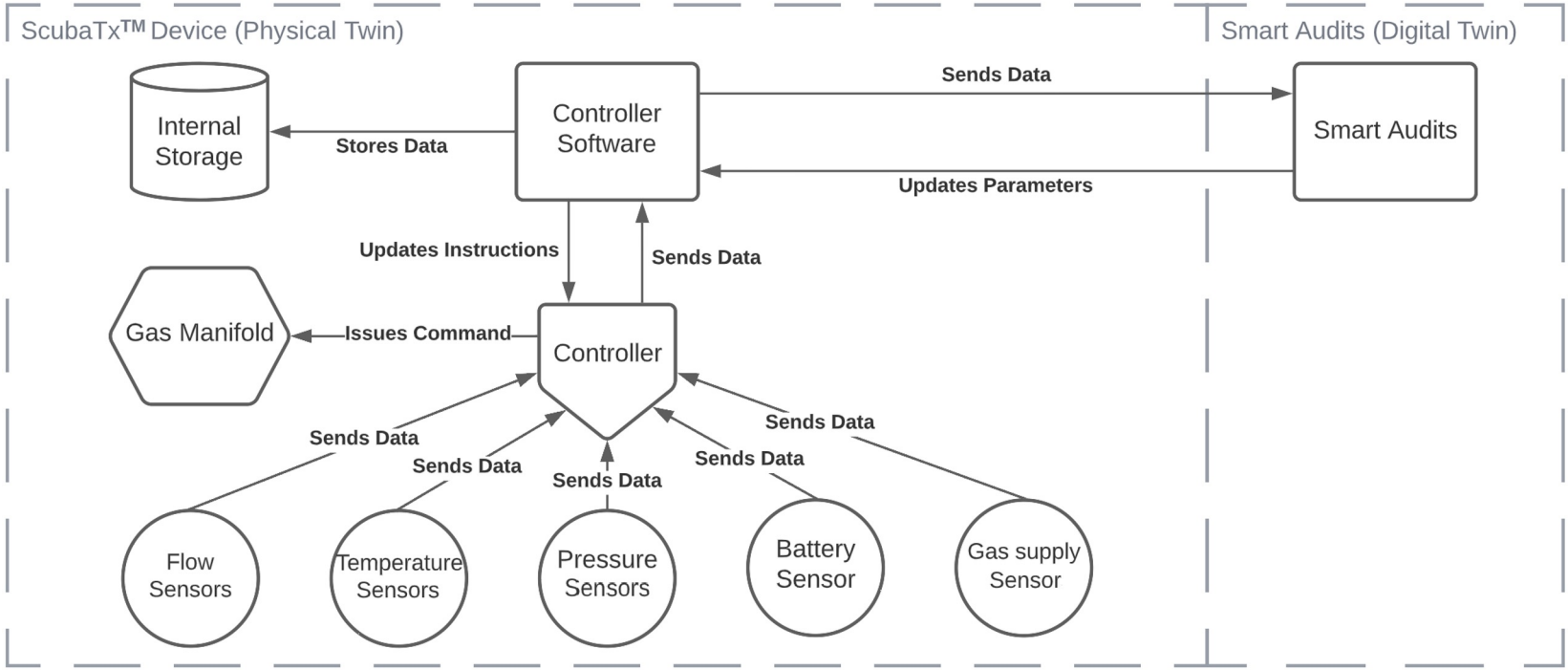
PROPRIETARY
Only functions with genuine ScubaTx disposables.



Digital Twins

Data Communication

- Information closed control loop
- Operating parameters re-configuration
- Secure connection between device and the digital twin for
  - Preventing misuse scenarios
  - Treatment traceability
  - Security and Authenticity
  - Business model protection



Buhagiar A., Freitas L., Scott W., Larsen P. G., Digital Twins for Organ Preservation Devices, ISoLA, LLNCS 13704, Oct. 2022 https://doi.org/10.1007/978-3-031-19762-8_3

Models

ACTIVE MODELS (Digital Twin)

- Oxygen flow/pressure
- Organ-under-preservation
  - Pancreas
  - Kidney
  - Liver
  - Heart
  - Composite tissue
- Environment

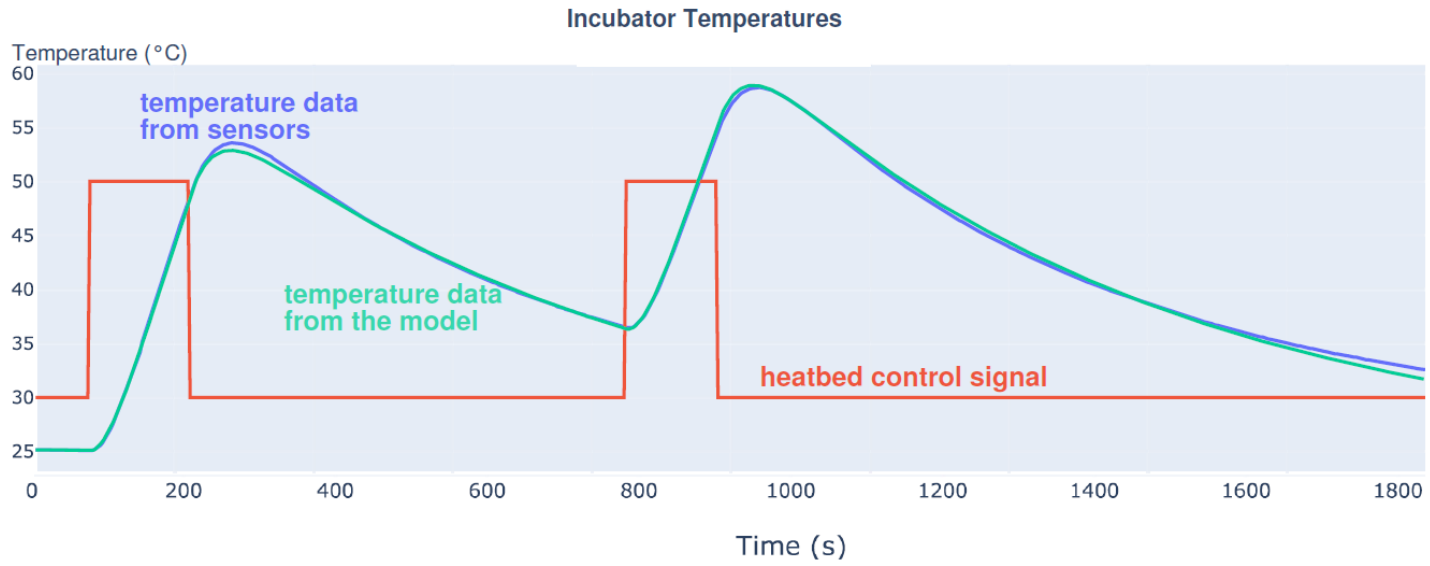
PASSIVE MODELS (Digital Shadow)

- Temperature
- Humidity
- Battery consumption
- Gas supply

Case Study: The ScubaTx™ Device

Visualisations

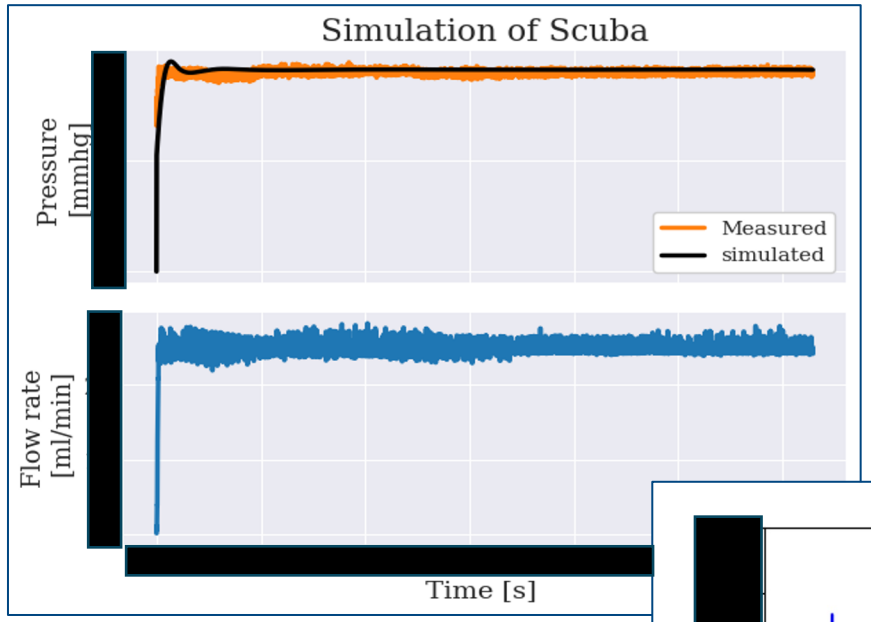
- Digital twins offer the possibility of enhanced visualisations
  - Predictive visuals
  - Articulated reporting
- Improved alarms



H. Feng, C. Gomes, C. Thule, K. Lausdahl, A. Iosifidis and P. G. Larsen, "Introduction to Digital Twin Engineering," *2021 Annual Modeling and Simulation Conference (ANNSIM)*, 2021, pp. 1-12, doi: 10.23919/ANNSIM52504.2021.9552135.

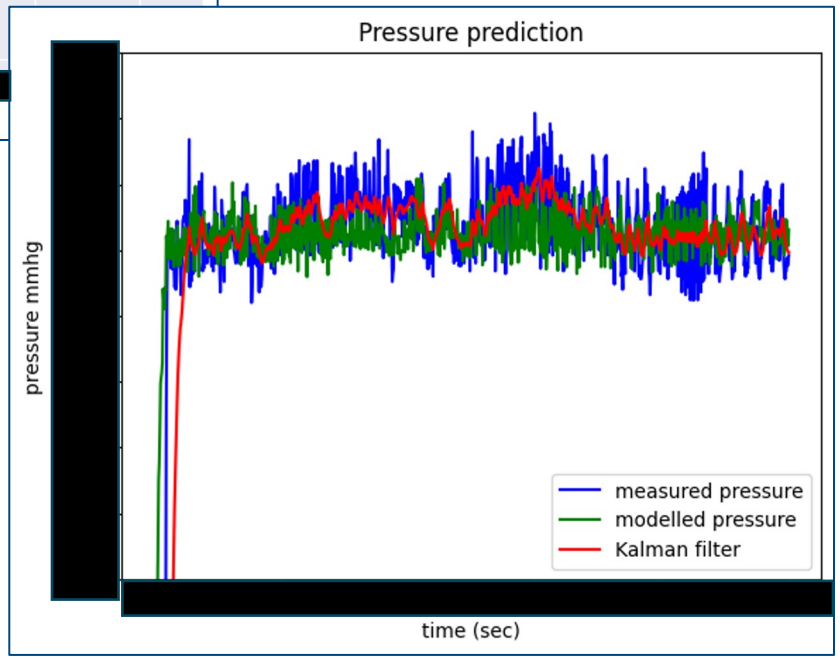
Oxygen Flow/Pressure Models

- Collaboration with AU/Denmark
  - Accurate predictions
  - Hardware-based
- (Kalman) filters used
  - To predict expected pressures and flow



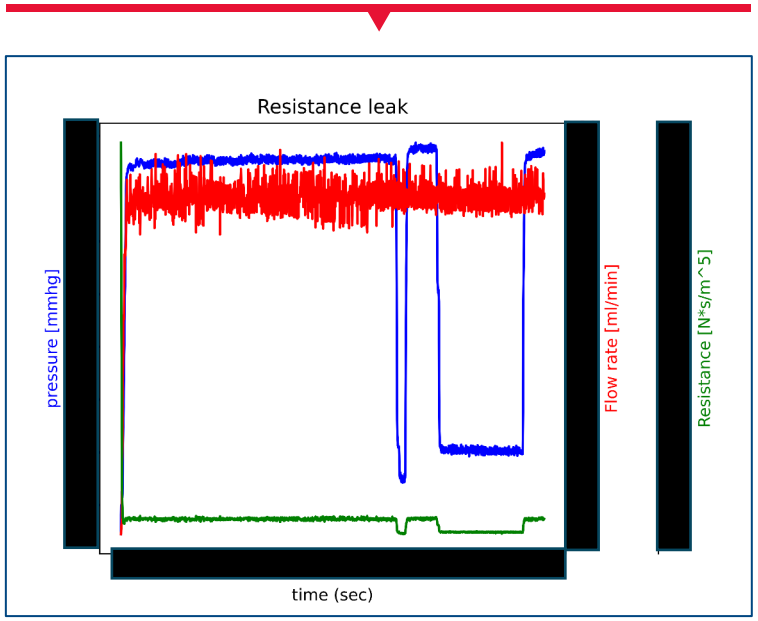
Simulated pressure using model for a preservation period

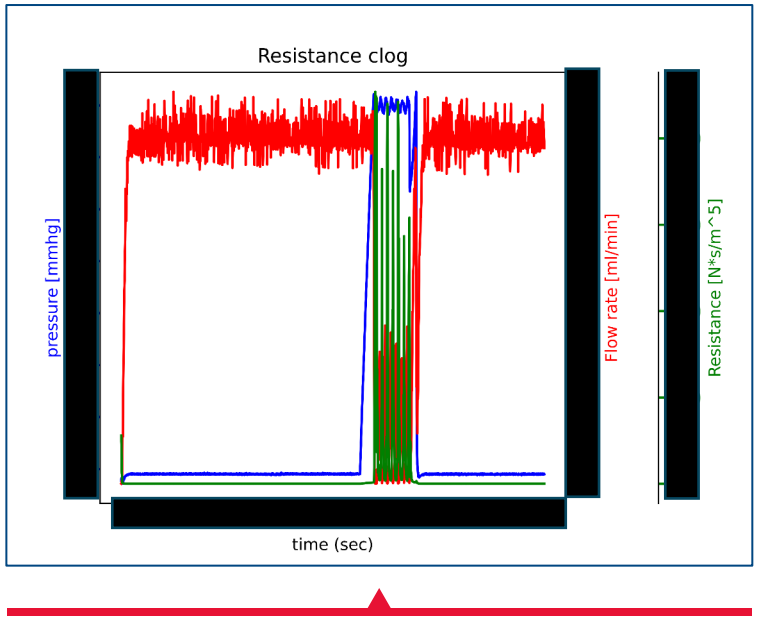
Predicted pressures for preservation period



Fault Detection and Generation of additional information

- Flow remains constant even when a leak occurs
- System/Organ internal resistance is calculated using the model





- Results observed for air supply blockage
- Flow difficult to maintain when blockage occurs

Digital Twinning Benefits for Scuba's device

1. **Emulation** of the device provides more data without reliance on organ availability
2. Dynamic **calibration** of the preservation process during runtime
    - Bespoke treatment provided to each organ
    - Realtime adaptation to environmental changes (e.g. turbulence, speed bump, etc.)
    - Limiting possible harmful scenarios (e.g. leaks, overpressure, etc.) on research organs
3. **Maintenance** scenarios prediction and monitoring
4. User **decision support** by providing optimal context
    - Accurate battery consumption readings
    - Gas leak management
    - Temperature management

Technical Challenges

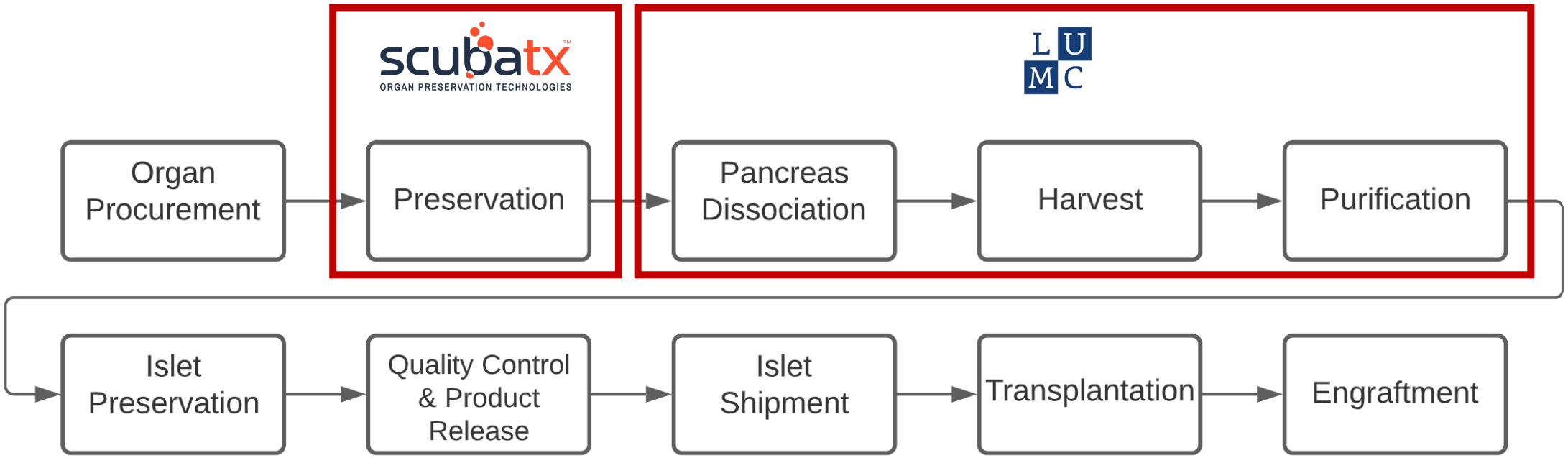
- Development of accurate models
  - Organ under preservation models
  - Environment models
- Calibration of models using real-world data
  - Many scenarios to test
  - Limited access to organs
  - Logistics (e.g., clinical constraints)
- Regulatory pathway challenges
  - Novel technique
  - Dynamic nature
  - Interacts with the preservation process

Medical Challenges

1. Medical device automation and streamlining
2. Increased throughput without increasing cost
3. Regenerative medicine solutions (e.g., personalized [car-t] cancer treatment)
4. Distributed devices across health care
5. Clinical trials will not uncover various (software) issues
6. Increased need for formal modelling and better/clearer regulation on software
7. New formal methods for variety of healthcare industries
8. Formal methods that can teach medical device engineers as it has in other areas

Beyond Organ Preservation

Pancreas Islet Cells Manufacturing



Possible application of Digital twins

Summary

- Digital twins can be greatly beneficial for organ preservation devices
  - Optimised preservation process
  - Improved visualisation
  - Better device evaluation
- Many challenges involved in adopting digital twins for medical devices
  - Regulatory pathways
  - Model design
  - Data gathering for model calibration
- Applications beyond organ preservation