

## NEED/BACKGROUND

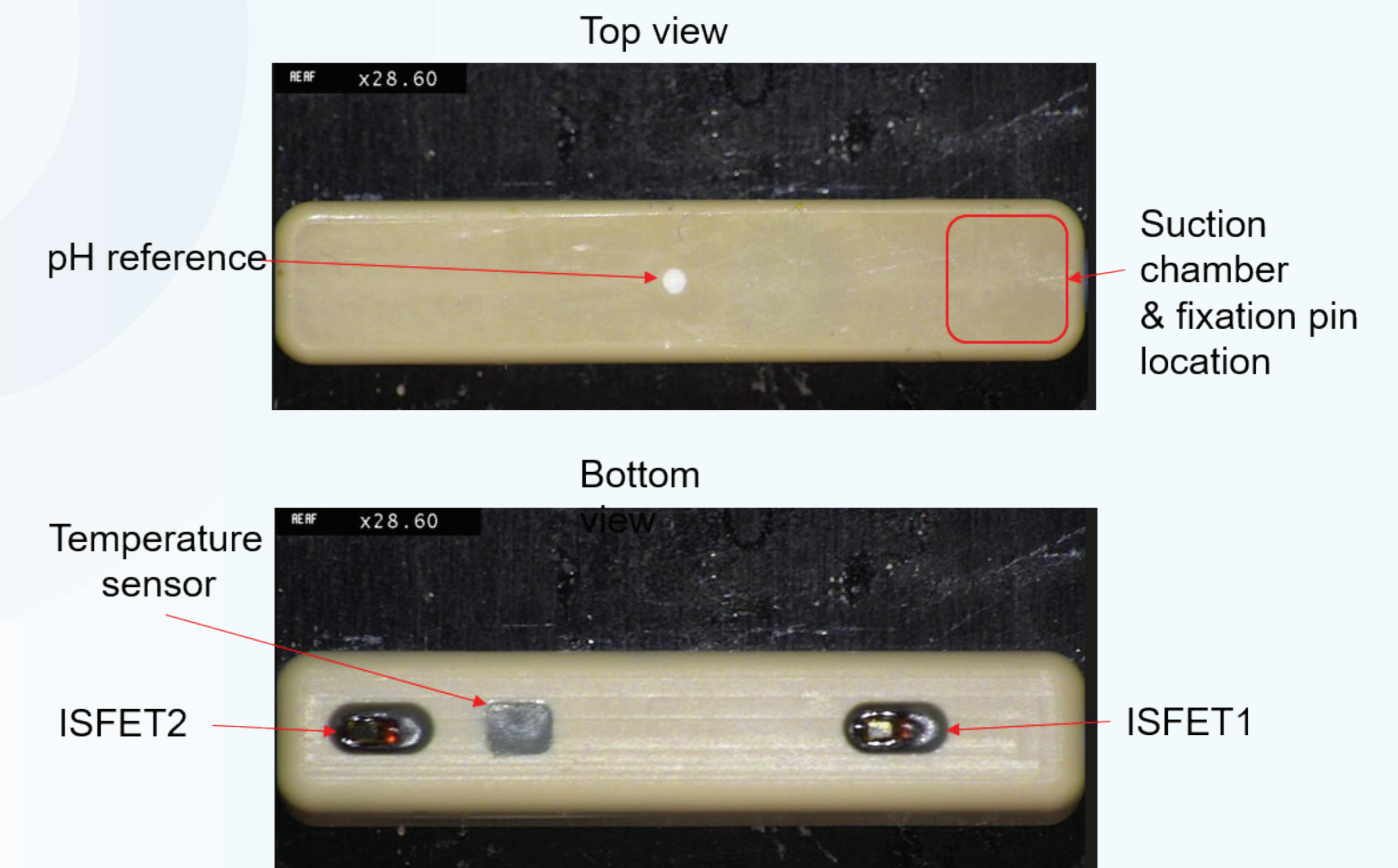
- Ambulatory pH testing is the gold standard for the diagnosis of GERD – a highly prevalent and potentially dangerous disease with varying clinical symptoms.
- pH testing, +/- impedance for non-acid reflux, was developed in the 1970's and is currently either a transnasal catheter 24hr test or a 48hr capsule test (pH only). The test involves placement of sensors in the distal esophagus, a RF data collection device and manual patient input of symptoms and activities using a paper diary.
- Patients violently dislike the transnasal test – capsules are rapidly gaining preference despite lower accuracy (sampling only every 6 seconds) and lack of impedance for non-acid reflux.
- Due to patient dislike, high set-up costs, and an inefficient medical workflow, only 2% of patients who meet Society recommended criteria for pH testing currently receive it.

## TECHNOLOGY

- **In 2022, a consortium of 9 academic and industrial partners received an EU grant to develop a solution for the technical failings of current pH testing systems. An intensive R&D program has been conducted, building on a preliminary design and patent prototype (TRL4) that the IHU-Strasbourg had previously completed.**
- **The development specifications for the system:**
  - **endoscopically implantable capsule with similar dimensions to current pH capsules**
  - **no need for external suction for attachment**
  - **directional flow detection (impedance equivalent)**
  - **more frequent pH sampling (3 sec vs 6 sec) for improved accuracy**
  - **patient position (upright/supine)**
  - **temperature (for device passage)**
  - **use of standard Bluetooth data transmission to communicate directly with patients' smartphones**
  - **an e-health platform including a patient focused interactive app to allow intuitive, icon driven and quantified patient symptom input with automated prompts**
  - **cloud based data integration and interpretation – including automated data editing**
  - **clinician able to personalize the test for each patient and download the test report from the cloud in a customizable format.**

## PRECLINICAL EXPERIENCE

- After 2 years of extensive development, all design goals have been achieved in a prototype format (TRL 6) and extensively validated on benchtop testing.
- Preclinical tests in 2 living porcine models and one human cadaver have preliminarily validated capsule placement without external suction and the ability to transmit usable sensor data from the animal and human models to an external receiver via Bluetooth.
- Further preclinical tests in animals and cadavers in early 2025 to further validate other design parameters.
- Human clinical evaluation with a TRL7 level device scheduled in France, Ukraine and Kenya in 2025-26.



## FUTURE DIRECTION

A new paradigm of a digital, intelligent, user friendly pH testing tool developed and pre-clinically validated in Europe. The device is entering regulatory approval phase with the goal of clinical testing and commercialization in the near future. It is hoped this will advance GERD diagnostics from its current unscalable analogue version to a patient centered e-health tool and improve access to this important tool in the treatment of reflux disease.

