RIS RESPIRATORY INNOVATION SUMMIT

4Dx

XV (XRAY VELOCIMETRY) A NEW MODALITY FOR FUNCTIONAL LUNG IMAGING

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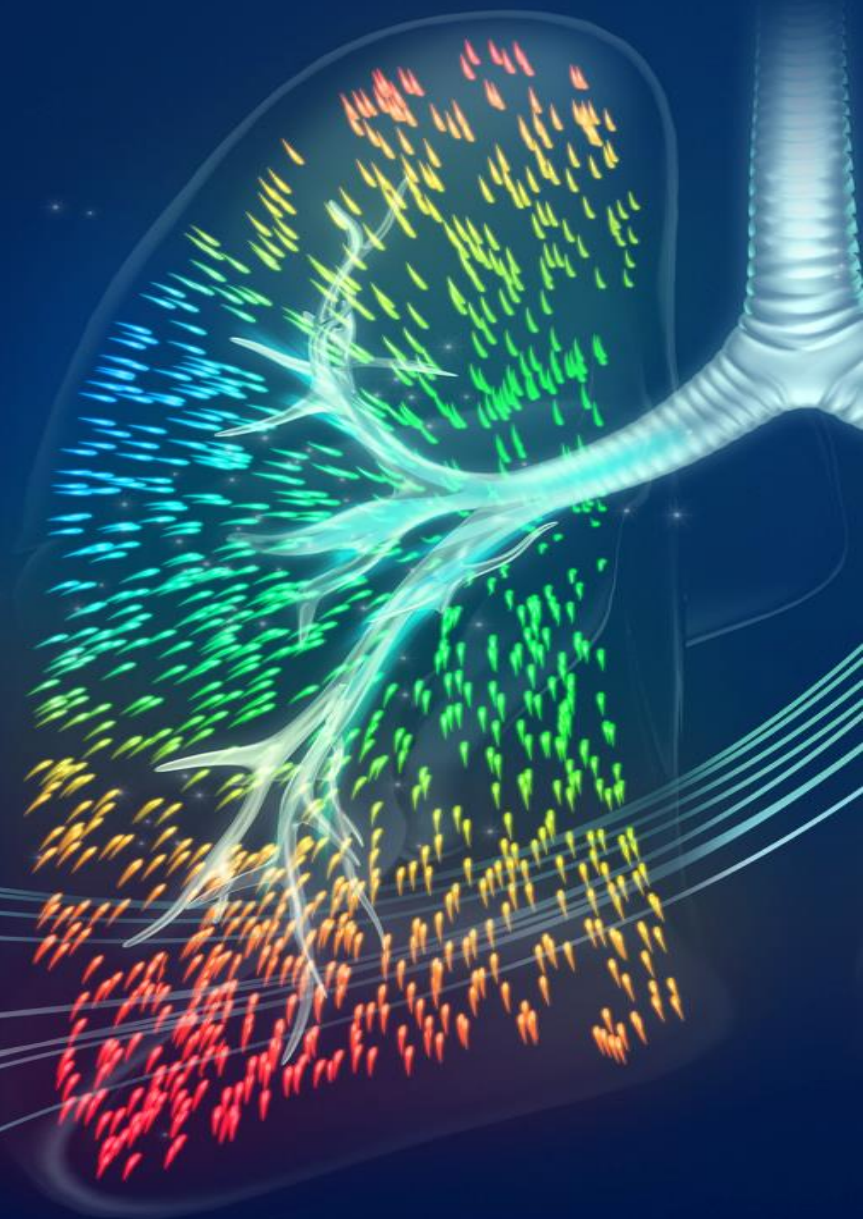
FOUNDER, CEO 4Dx



EXISTING TECHNIQUES FAILING US

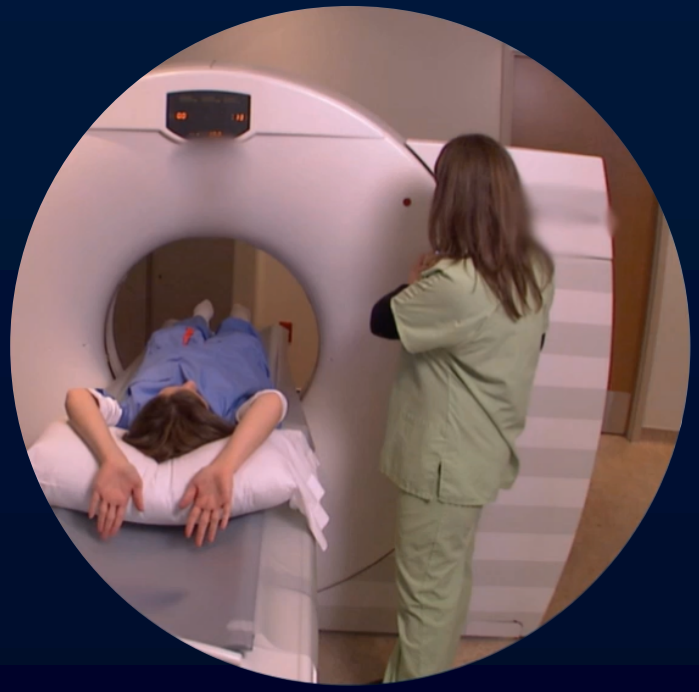
Spirometry

1850s
1D

X-ray

1890s
2D

CT



1970s
3D

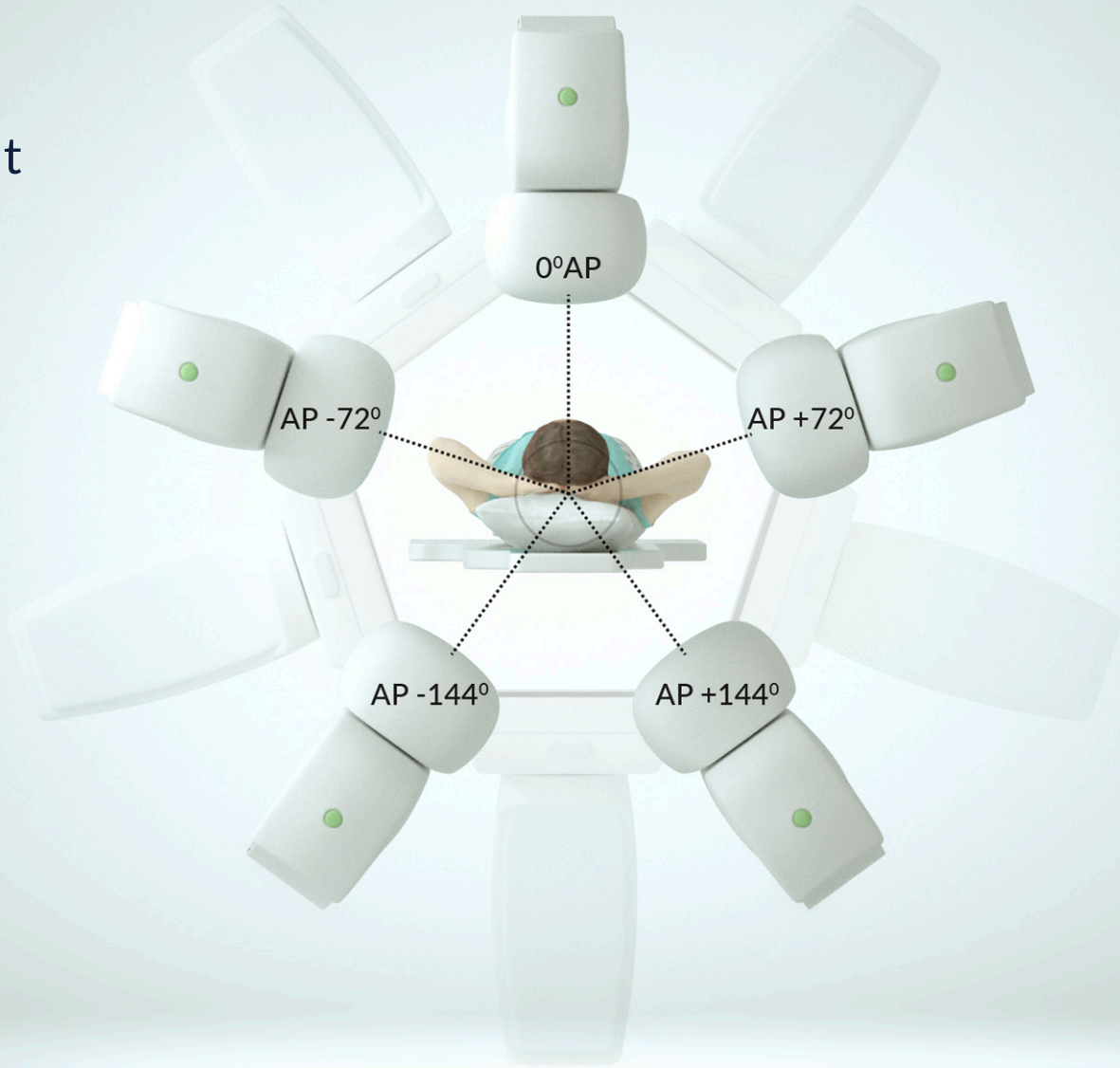
TECHNOLOGY BREAKTHROUGH

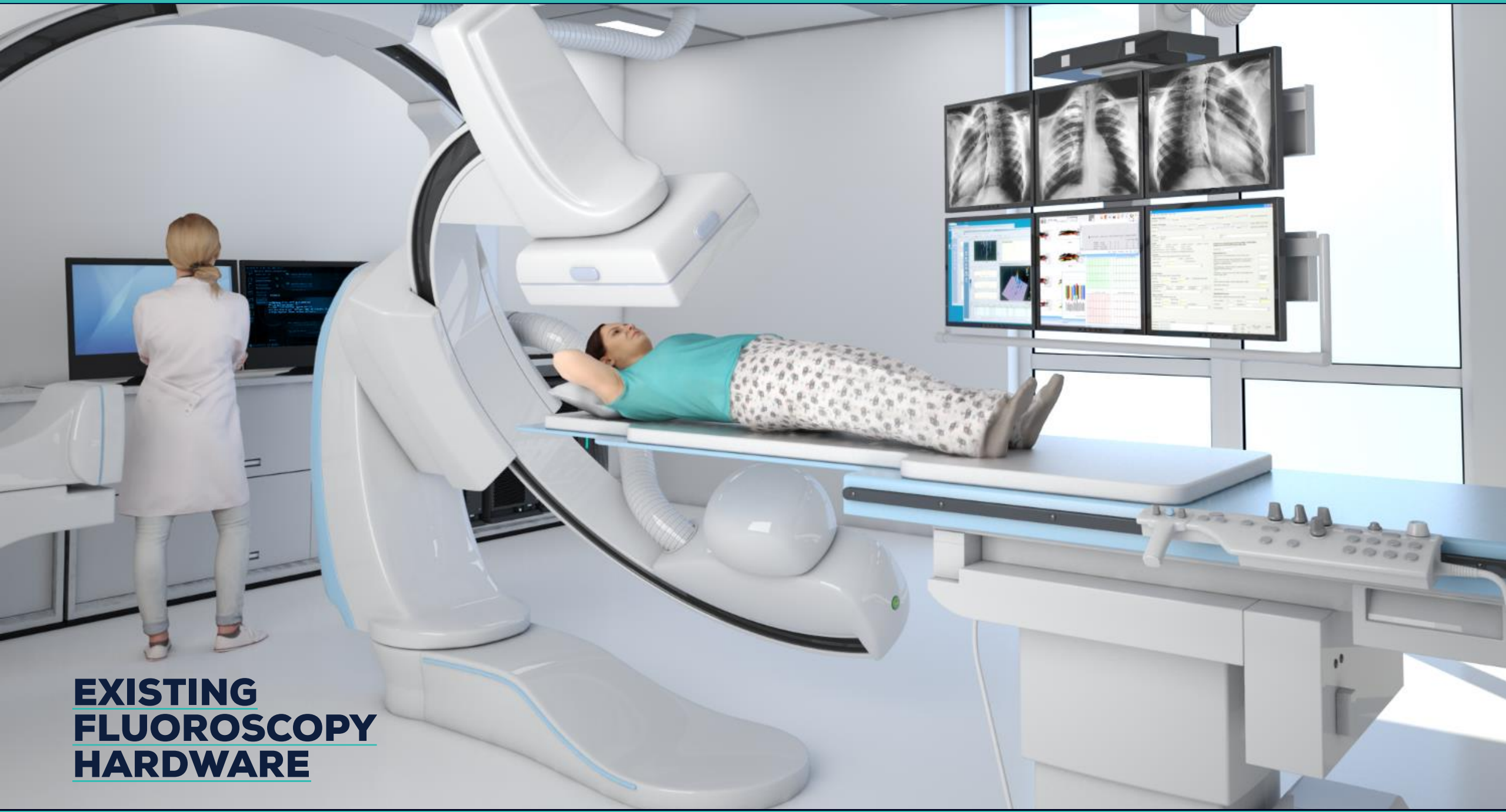
INTRODUCING:
XV TECHNOLOGY

A NEW MODALITY FOR FUNCTIONAL LUNG IMAGING

TECHNOLOGY BREAKTHROUGH

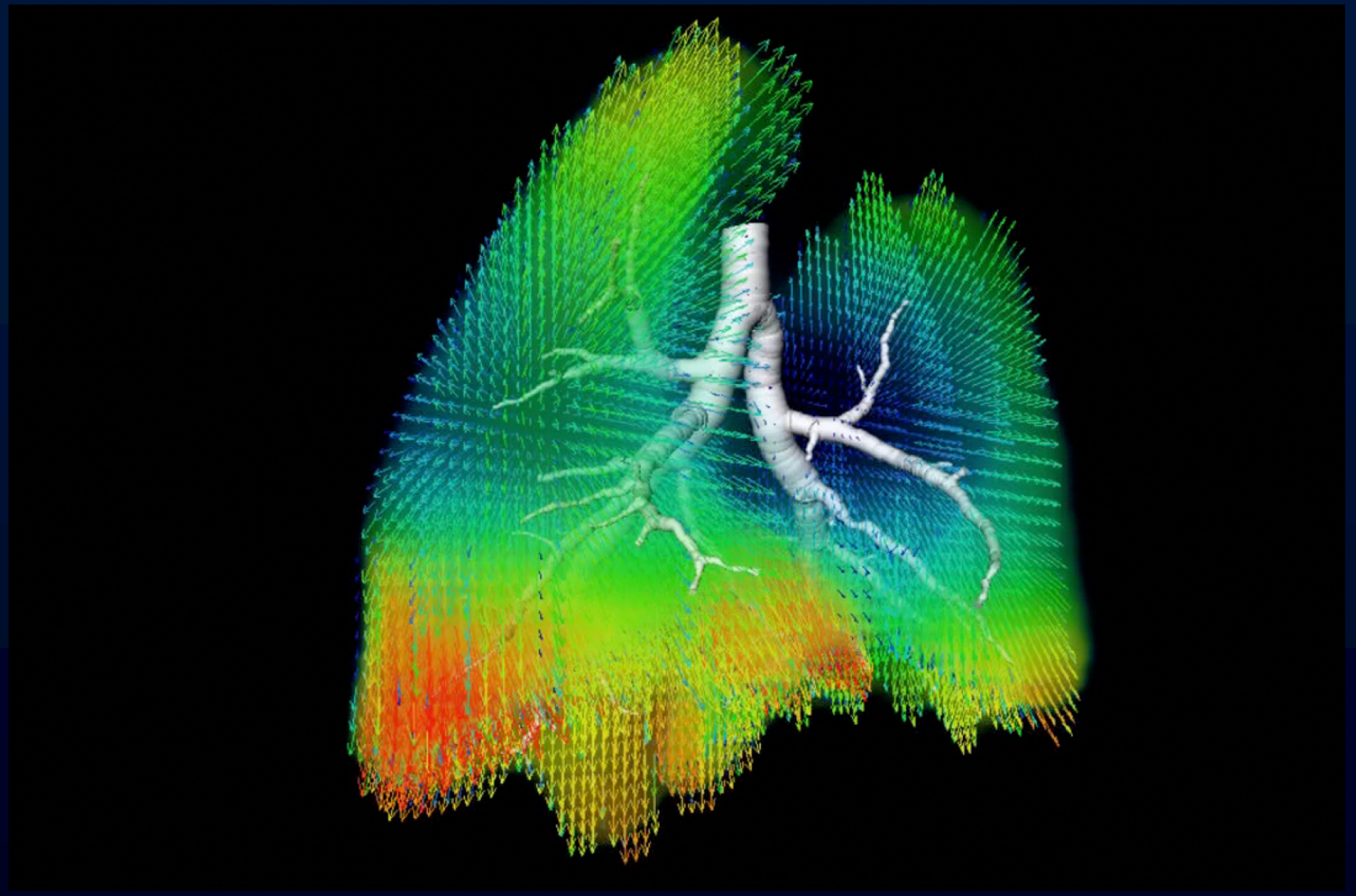
- Directly reconstructs 3D motion field without reconstructing a 3D image
  - Directly measure (quantify) ventilation
  - Low to very low dose



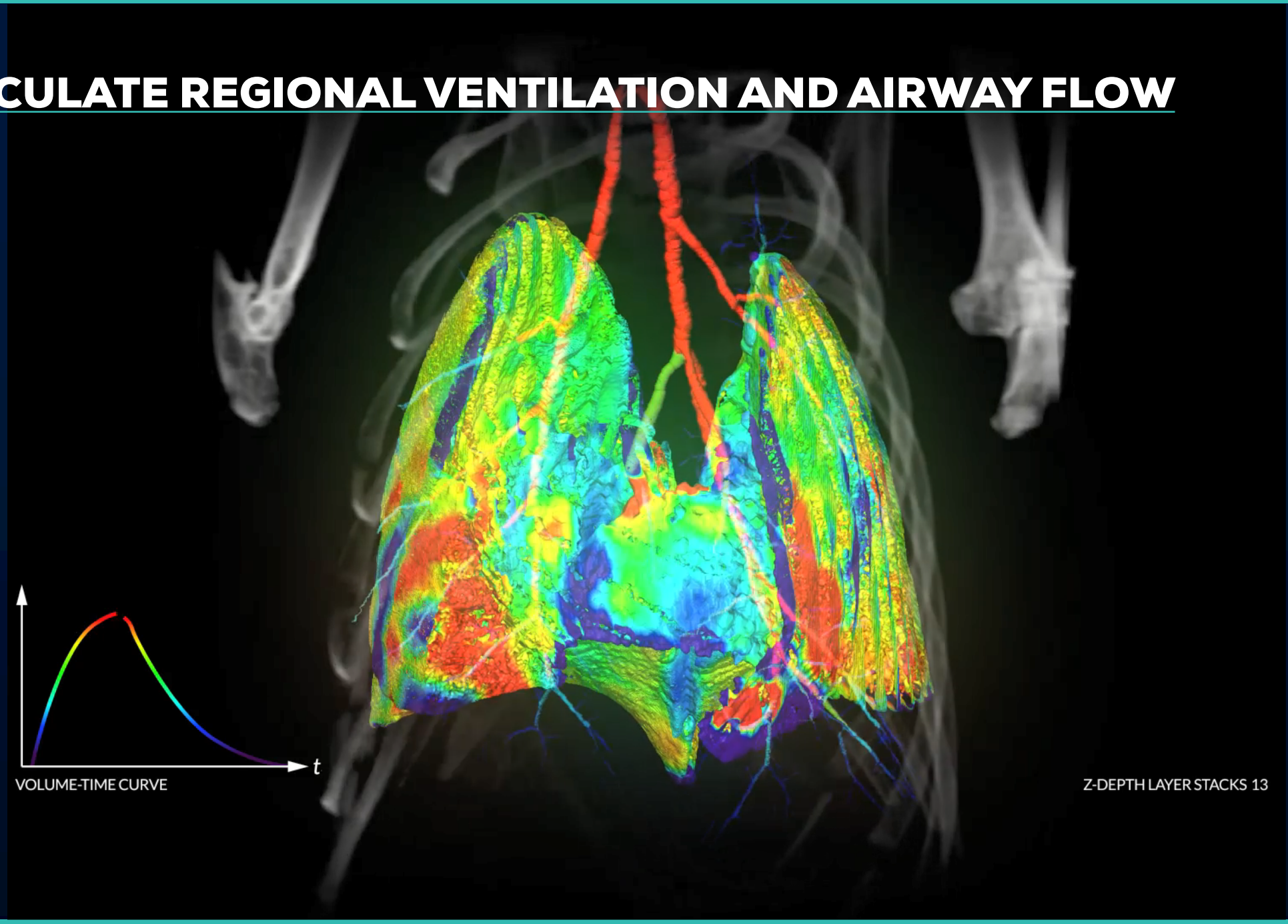


EXISTING FLUOROSCOPY HARDWARE

MEASURE REGIONAL LUNG MOTION



CALCULATE REGIONAL VENTILATION AND AIRWAY FLOW



EXTENSIVE AND GROWING VALIDATION

Extensive technological validation:

- Physics
- Preclinical studies
- Ongoing program of clinical trials

CLINICAL CASE STUDIES

- Data selected from “HIFI” study conducted at Cedars Sinai under direction from PI Stephen L Shiao MD PhD
- Admission criteria: substantial radiation delivered to lung as a result of RTx to any thoracic cancer
- XV scans acquired in combination with PFT, CT and other diagnostics over 13-month period following RTx admission
- Endpoints:
  - Interim: Is clinical data generated using XV consistent with gold standard measures and other clinically available measures?
  - Complete: is XV predictive over other measures for the onset of radiation induced pneumonitis and/or pulmonary fibrosis?

CASE A

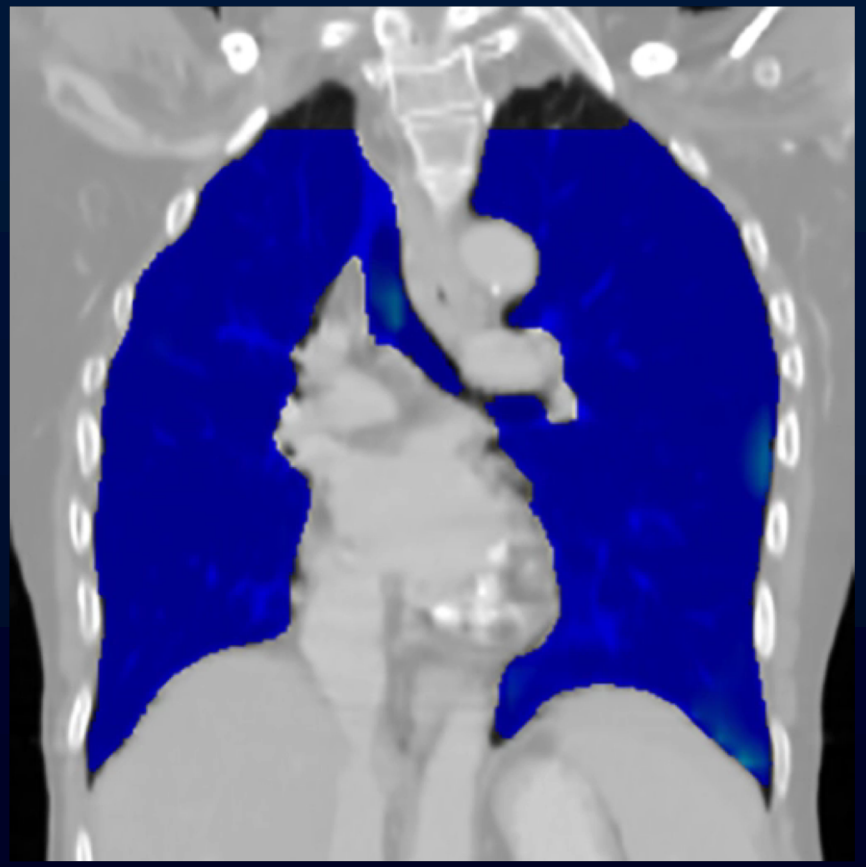
Key patient data:

- FEV1(% of expected) : ≥ 100%
- FVC (% of expected) : ≥ 100%
- FEV1 / FVC : 1.11

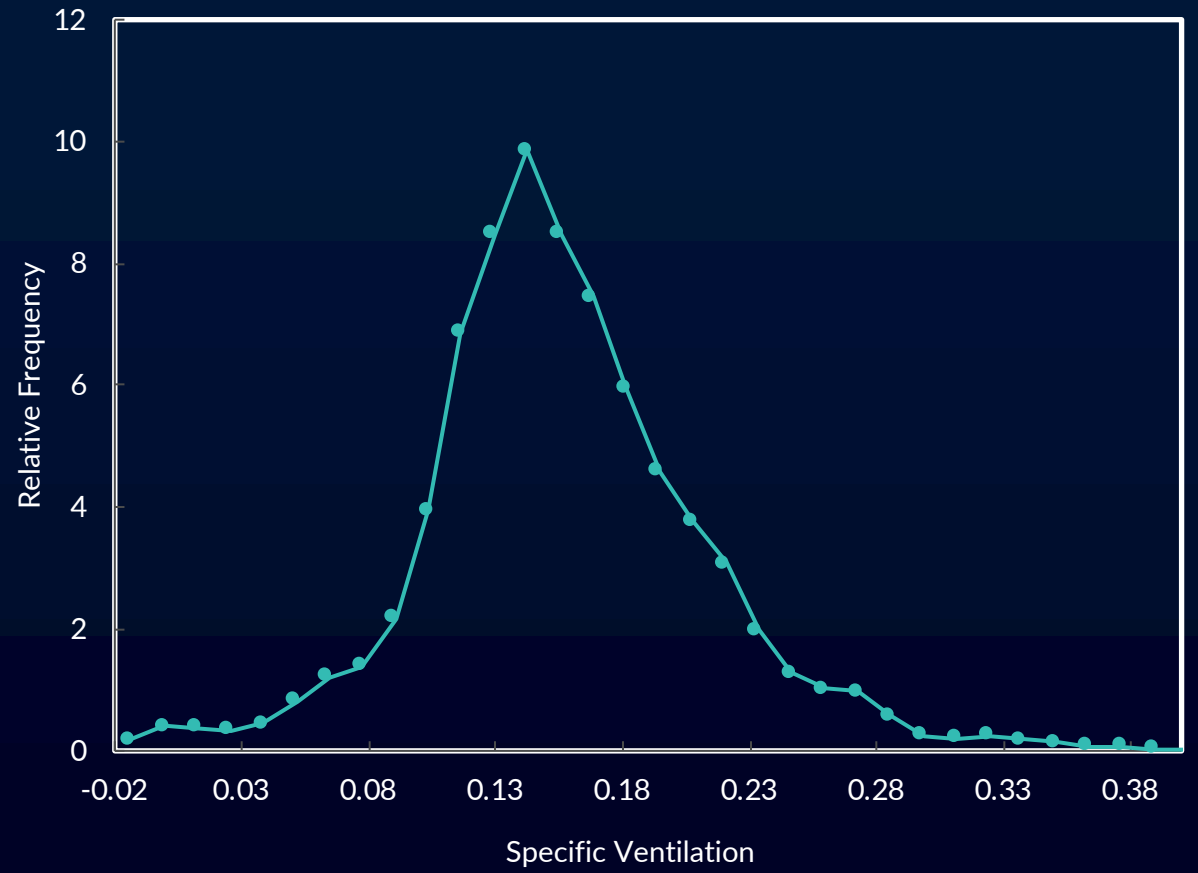
Summary: Normal lung function

CASE A

Ventilation map

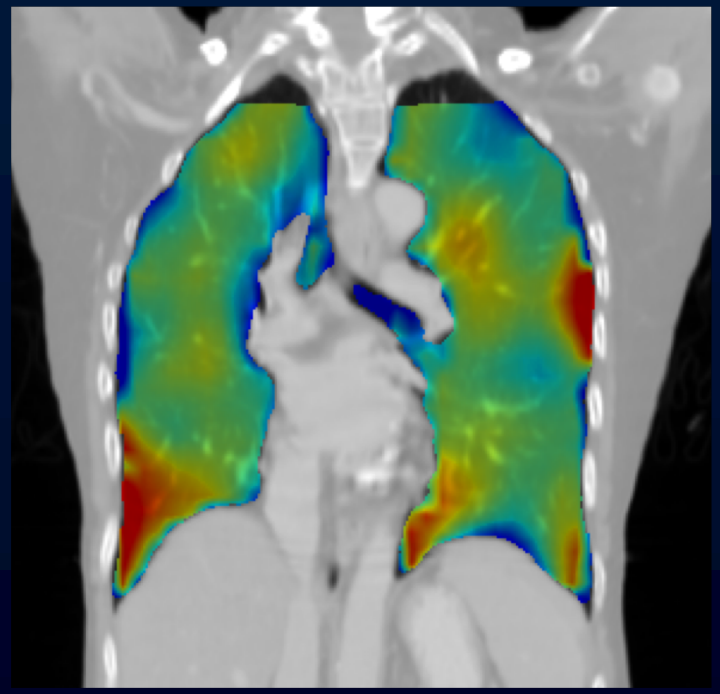


Ventilation Frequency Distribution

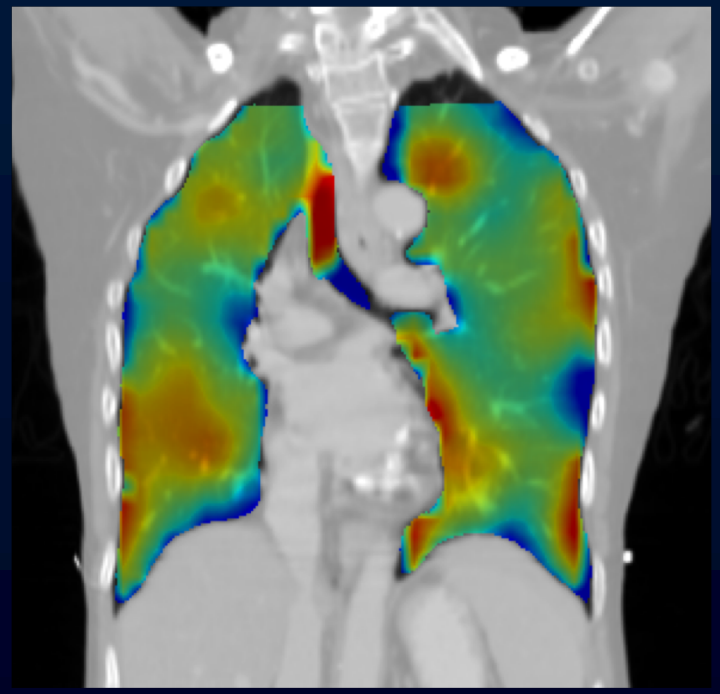


CASE A

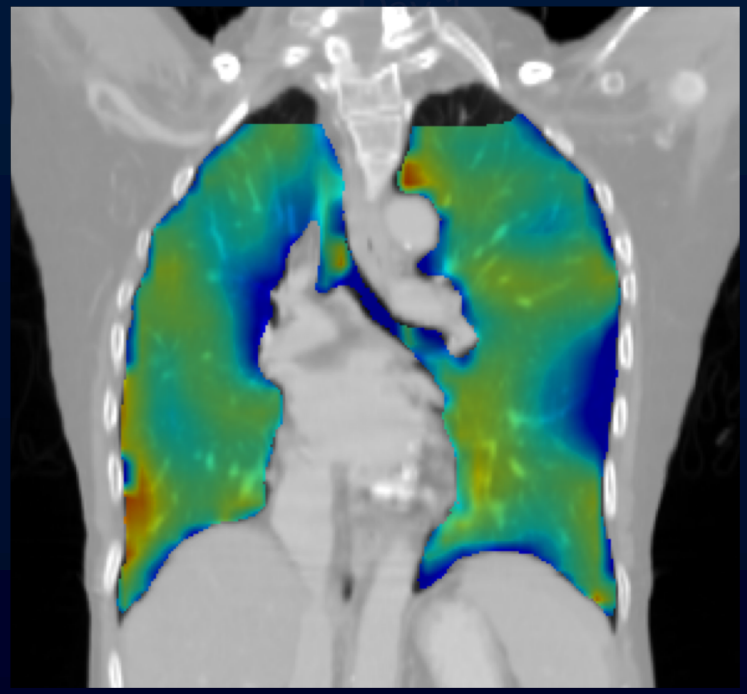
Repeatability analysis



Scan 1



Scan 2



+2 weeks

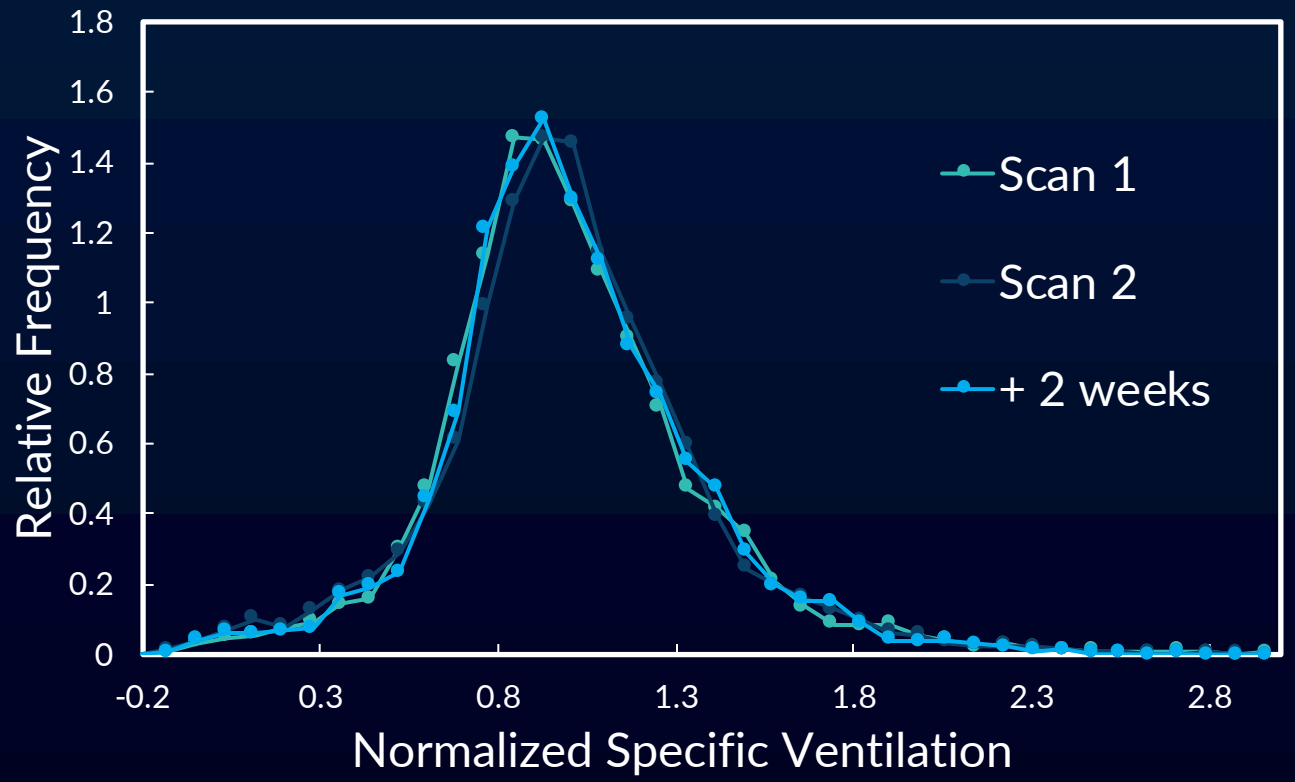
CASE A

Repeatability analysis

XV scan summary statistics

	Scan 1	Scan 2	+2 wks
Tidal Volume (L)	0.61	0.58	0.52
Global Specific Ventilation	0.22	0.21	0.18
Heterogeneity Index (%)	38.9	38.4	38.6
Ventilation Defect Percentage (%)	2.09	3.01	2.40

Ventilation Frequency Distribution



CASE A

Assessment of XV

- XV consistent with PFT/spirometry:
  - In subject with normal lung function, no ventilation defects apparent
  - Statistics and maps show homogenous ventilation

- Repeatability analyses demonstrate high degree of agreement between scans:
  - Scan 1 vs +2 weeks, $\Delta < 2\%$

CASE B

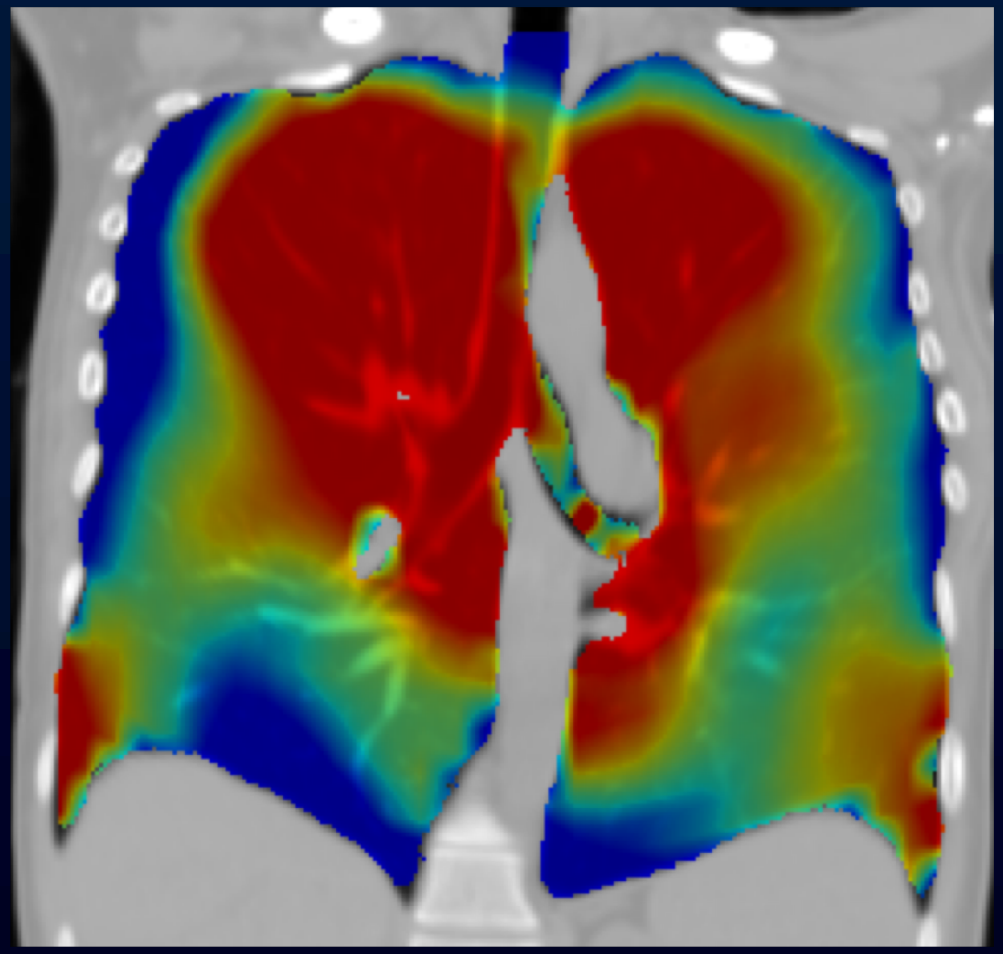
Key patient data:

- FEV1 (% of expected) : 75 %
- FVC (% of expected) : 89 %
- FEV1 / FVC : 0.84

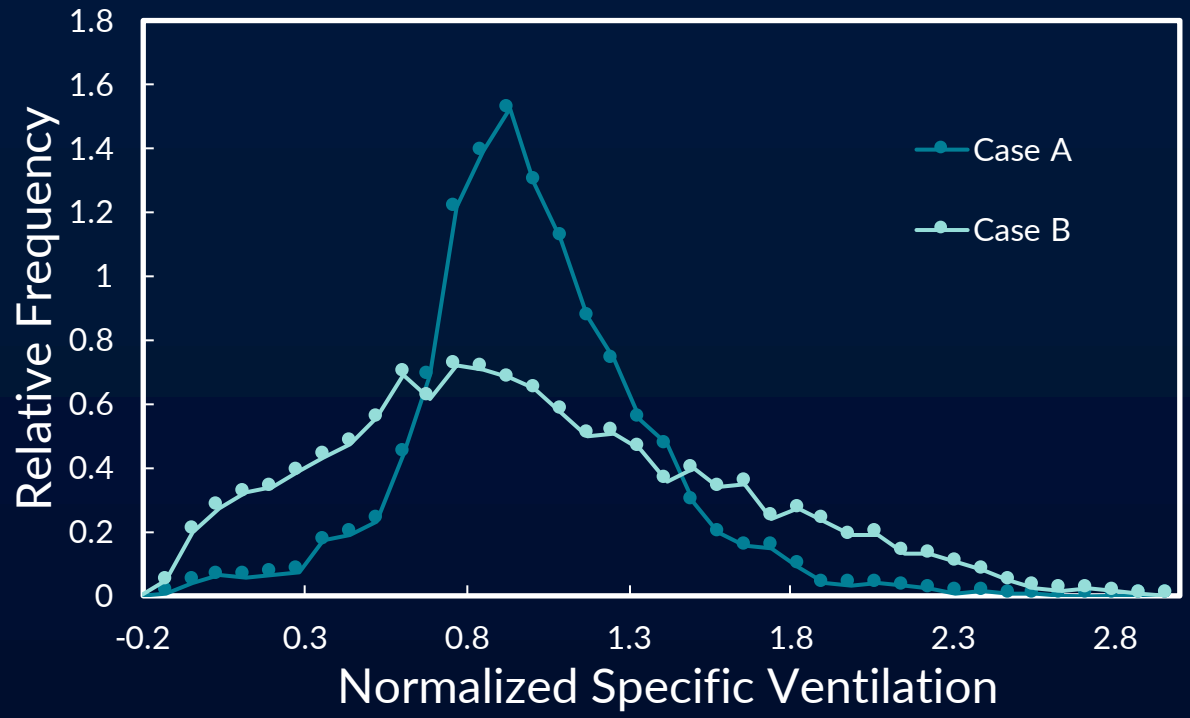
Summary: Moderate lung function on PFT

CASE B

Considerable ventilation heterogeneity detected



Ventilation frequency distribution
(Moderate (A) vs normal (B) lung function)



	Case A	Case B
Heterogeneity Index (%)	38.6	79.5
Ventilation Defect Percentage (%)	2.4	16.1

CASE B

Assessment of XV

- XV consistent with spirometry:
  - In subject with moderate lung function, significant inhomogeneity of lung function

- Additionally:
  - XV presents spatial and temporal locations of ventilation defects
  - Demonstrates advantage of XV based regional function analysis over classical PFT

CASE C

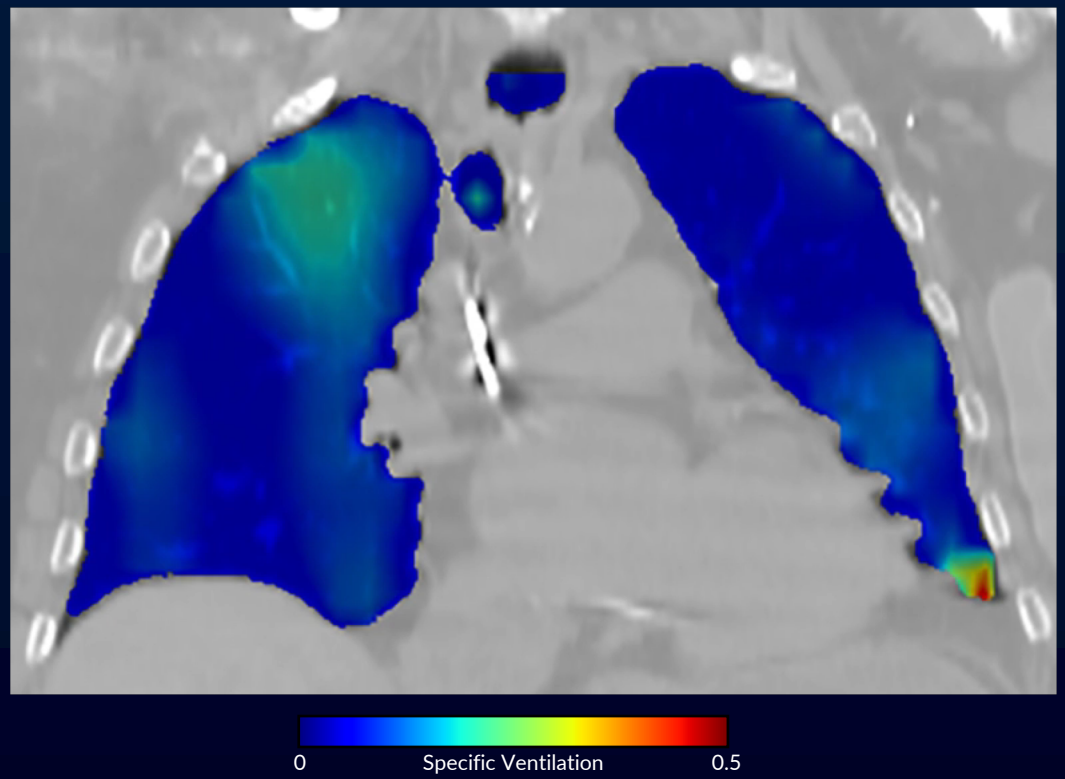
Key patient data

- 4 months post treatment
  - FEV1 (% of expected): ≥ 100%
  - FVC (% of expected) : ≥ 100%
  - FEV1 / FVC : 1.07
- 12 months post treatment
  - FEV1 (% of expected): 81%
  - FVC (% of expected) : 91%
  - FEV1 / FVC : 0.89

Summary: Moderate loss of lung function detected by PFT at twelve months RTx

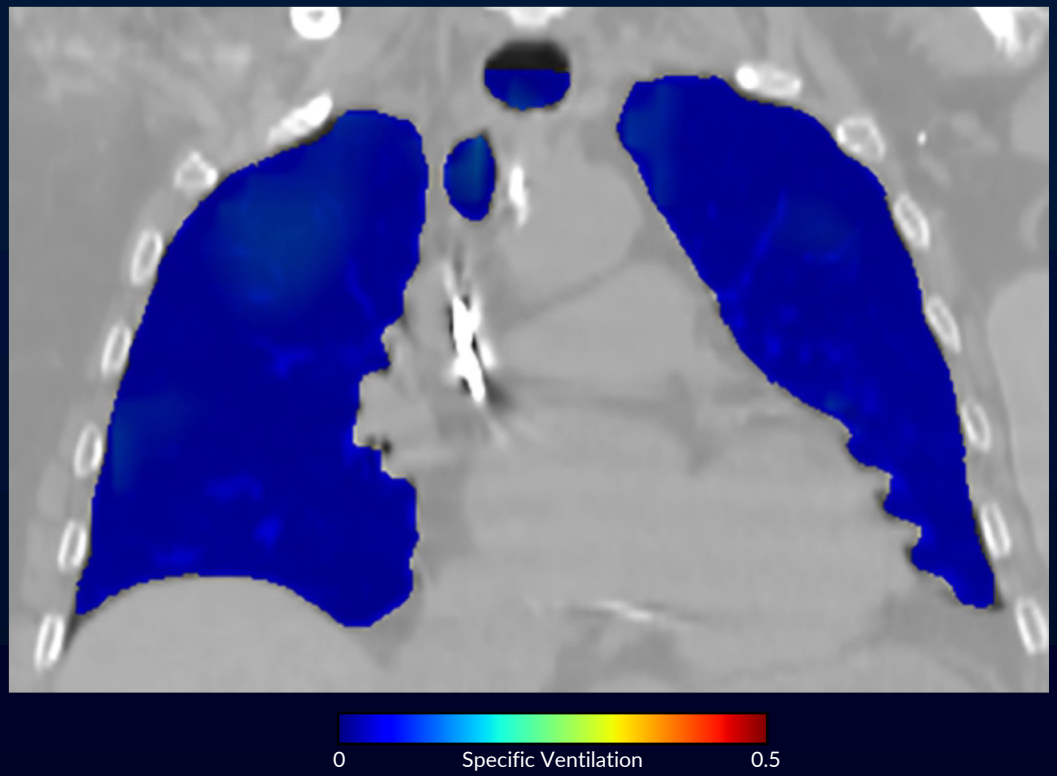
CASE C

Ventilation map



4 months post treatment

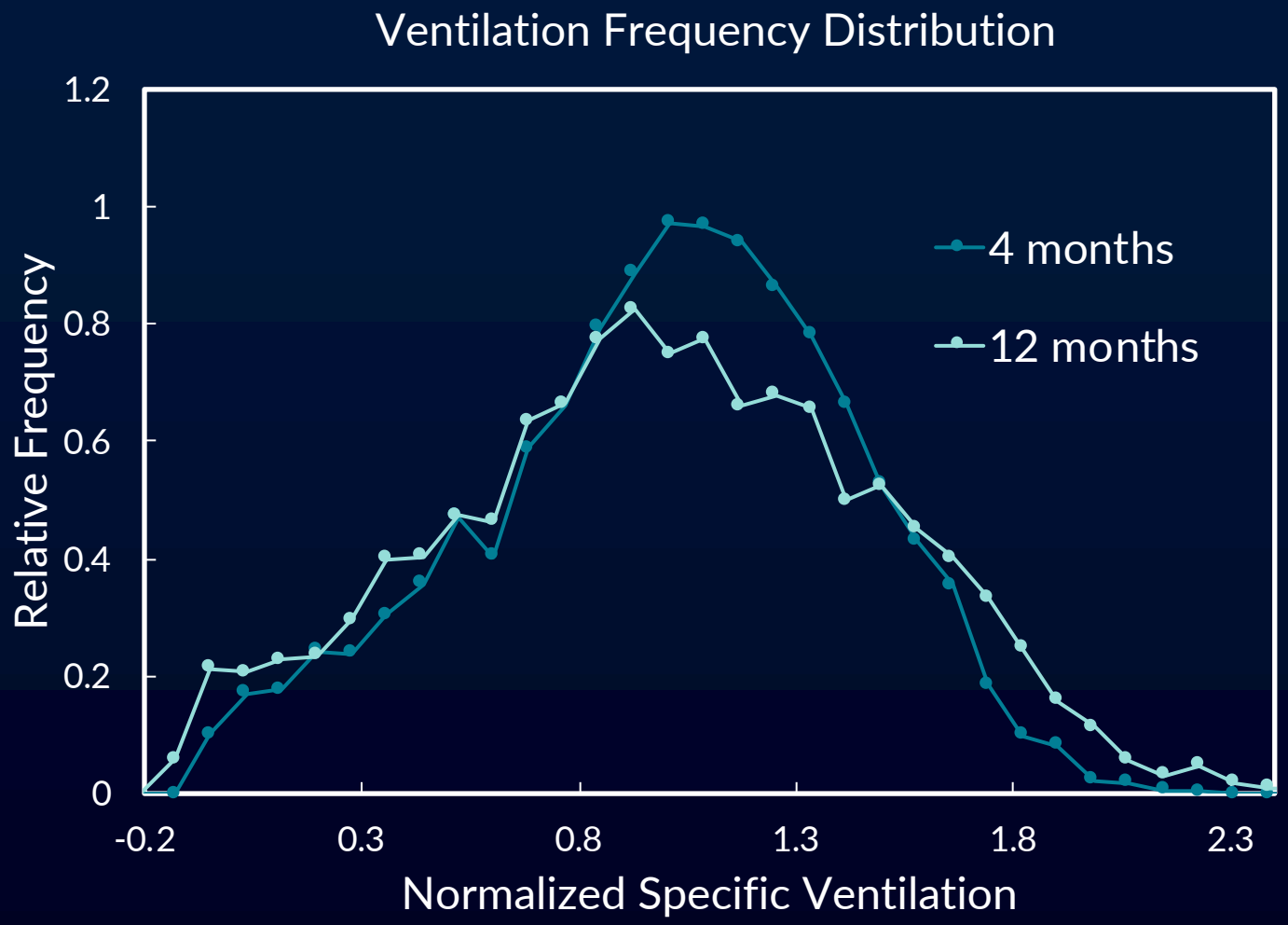
Ventilation map



12 months post treatment

Ventilation defect becomes apparent in lower right lung at 12 months post treatment (RTx)

CASE C



Ventilation defect results in significant observations, including quantification of:

- extent, severity, and location of ventilation defect
- increase in ventilation heterogeneity
- significant compensation

CASE C

Quantitative and Qualitative Assessment of XV

- XV vs PFT/spirometry (current gold standard)
  - In subject with lung function changing from normal to moderate, XV consistent with spirometry:
    - significant increase in inhomogeneity of lung function
    - appearance of significant ventilation defects

- Additionally:
  - Ventilation XV provides rich observations not available via PFT, including quantification of:
    - extent, severity and location of ventilation defect
    - increase in ventilation heterogeneity
    - significant compensation

SUMMARY

- XV provides functional insight of PFT
  - 3D Nature of CT
  - Dose and availability of X-ray
- Clinical validation
  - Primary study complete
  - XV is accurate and repeatable
  - Ventilation defects quantified and identified
  - Changes in regional lung function observed over time
  - Additional studies online, with more coming

THANK YOU