4DMedical™

IQ-UIP™

A New Approach to UIP Identification for IPF Management

FDA "Breakthrough Device:" Advancing Early Detection and Intervention

IQ-UIP is innovative software that uses deep learning to accurately classify Usual Interstitial Pneumonia (UIP) and predict patient survival, matching expert CT readers.[1] It integrates with inspiratory CT scans for instant analysis, significantly improving the efficiency of UIP identification. FDA-cleared in 2024, IQ-UIP sets a new benchmark in pulmonary diagnostics.

The Time Challenge

Diagnosing UIP is difficult and often delayed—patients typically see ≥3 doctors, undergo 3 CT scans[2], and wait an average of 2 years[3] for a correct diagnosis. UIP, most often linked to idiopathic pulmonary fibrosis (IPF), reduces life expectancy to just 3–5 years[4] after diagnosis. Because most patients face a 1–2-year delay from symptom onset, much of their limited survival time is lost before treatment begins.[2]

Early detection with IQ-UIP is vital for improving survival rates.

The Accuracy Challenge

UIP symptoms often mimic other lung conditions like COPD or asthma[5], and conventional imaging adds to delays and misdiagnoses—over 50% are misdiagnosed, shortening lifespans[2].

A Cutting-Edge Solution

IQ-UIP leverages AI to automatically screen CT scans and flag patients for specialty referral, making timely expert care more accessible.

Expert Performance

IQ-UIP's performance aligns with expert-level standards, showing 90.2% sensitivity and 91.5% specificity in detecting UIP patterns,[6] benchmarked against a multi-reader panel of thoracic radiologists.

IQ-UIP Advantage for Pulmonology Specialists

1 Enhanced Accuracy and Speed: Swift identification of UIP patterns, such as sub-pleural fibrosis and honeycombing, to expedite patient management, optimizing care pathways.

2 Prompt Intervention: Automated referrals ensure patients reach ILD specialists quickly for urgent care.

3 Expanded Access: Consistent, reliable screening across all healthcare settings, improving access for under-served patients.

4 Potential to Extend Lifespans: Early detection supports timely intervention, potentially extending survival and improving quality of life.

IQ-UIP transforms UIP diagnosis and care by enabling proactive, timely, and expert intervention—helping you deliver life-saving diagnoses and reshape outcomes for patients with IPF.

1 Chung JH, Chelala L, Pugashetti JV, Wang JM, Adegunsoye A, Matyga AW, Keith L, Ludwig K, Zafari S, Ghodrati S, Ghasemiesfe A, Guo H, Soo E, Lyen S , Sayer C, Hatt C, Oldham JM. A Deep Learning-Based Radiomic Classifier for Usual Interstitial Pneumonia. Chest. 2024 Feb;165(2):371–380. doi: 10.1016/j.chest.2023.10.012. Epub 2023 Oct 14. PMID: 37844797; PMCID: PMC11026174.

2 Cosgrove, G.P., Bianchi, P., Danese, S. et al. Barriers to timely diagnosis of interstitial lung disease in the real world: the INTENSITY survey. BMC Pulm Med 18, 9 (2018). https://doi.org/10.1186/s12890-017-0560-x

3 Hoyer, N., Prior, T.S., Bendstrup, E. et al. Risk factors for diagnostic delay in idiopathic pulmonary fibrosis. Respir Res 20, 103 (2019). https://doi.org/10.1186/s12931-019-1076-0

4 Khor YH, Ng Y, Barnes H, Goh NSL, McDonald CF, Holland AE. Prognosis of idiopathic pulmonary fibrosis without anti-fibrotic therapy: a systematic review. Eur Respir Rev. 2020 Aug 4;29(157):190158. doi: 10.1183/16000617.0158-2019. PMID: 32759374; PMCID: PMC9488716.

5 Collard HR, Tino G, Noble PW, et al. Patient experiences with pulmonary fibrosis. Respir Med. 2007;101(6):1350-1354. doi: 10.1016/j.rmed.2006.10.002

6 https://www.accessdata.fda.gov/cdrh_docs/pdf24/K242467.pdf

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| NAME: 0NXEG3Z6V276 | SEX: Unknown | STUDY DATE: January 18, 2024 |
| PATIENT ID: 0NXEG3Z6V276 | DOB: Unknown | REPORT DATE: August 20, 2024 |

MANUFACTURER: SIEMENS KERNEL: B30f SLICE THICKNESS: 1.0 TUBE CURRENT AVG KVP: 200 mA, 120 kV

Suspicious for UIP pattern.
Review by specialist recommended.

Imbio IQ-UIP is a computer-aided software indicated for use in passively notifying specialists at an ILD center of radiological findings that may be consistent with UIP. The results of Imbio IQ-UIP are intended to be used in conjunction with additional patient information and based on the user's professional judgment, to assist with the review of medical images. Notified clinicians are responsible for viewing full image series and making final clinical determinations.

IQ-UIP Score: 9

See Imbio IQ-UIP user manual for information on the IQ-UIP Score.

Official ATS/ERS/JRS/ALAT 2022 Clinical Practice Guidelines: High-Resolution Computed Tomography Scanning Patterns

	UIP Pattern	Probable UIP Pattern	Indeterminate for UIP	CT Findings Suggestive of an Alternative Diagnosis
Confidence level for UIP histology	Confident (>90%)	Provisional high confidence (70–89%)	Provisional low confidence (51–69%)	Low to very low confidence (<=50%)
Distribution	Subpleural and basal predominant. Often heterogeneous (areas of normal lung interspersed with fibrosis). Occasionally diffuse. May be asymmetric	Subpleural and basal predominant. Often heterogeneous (areas of normal lung interspersed with reticulation and traction bronchiectasis/bronchiolectasis)	Diffuse distribution without subpleural predominance	Peribronchovascular predominant with subpleural sparing (consider NSIP). Perilymphatic distribution (consider sarcoidosis). Upper or mid lung (consider fibrotic HP, CTD-ILD, and sarcoidosis). Subpleural sparing (consider NSIP or smoking-related IP)
CT Features	Honeycombing with or without traction bronchiectasis/bronchiolectasis. Presence of irregular thickening of interlobular septa. Usually superimposed with a reticular pattern, mild GGO. May have pulmonary ossification	Reticular pattern with traction bronchiectasis/bronchiolectasis. May have mild GGO. Absence of subpleural sparing	CT features of lung fibrosis that do not suggest any specific etiology	Lung findings • Cysts (consider LAM, PLCH, LIP, and DIP) • Mosaic attenuation or three-density sign (consider HP) • Predominant GGO (consider HP, smoking-related disease, drug toxicity, and acute exacerbation of fibrosis) • Profuse centrilobular micronodules (consider HP or smoking-related disease) • Nodules (consider sarcoidosis) • Consolidation (consider organizing pneumonia, etc.) Mediastinal findings • Pleural plaques (consider asbestosis) • Dilated esophagus (consider CTD)

Adapted from: Raghu G, et al. Am J Respir Crit Care Med, 2022. 205(9): p. e18-e47.

Definition of abbreviations: CT = computed tomography; CTD = connective tissue disease; DIP = desquamative interstitial pneumonia; GGO = ground-glass opacity; HP = hypersensitivity pneumonitis; HRCT = high-resolution computed tomography; ILD = interstitial lung disease; IP = interstitial pneumonia; LAM = lymphangioleiomyomatosis; LIP = lymphoid interstitial pneumonia; NSIP = nonspecific interstitial pneumonia; PLCH = pulmonary Langerhans cell histiocytosis; UIP = usual interstitial pneumonia.

ADDITIONAL INFORMATION

ⓘ IQ-UIP testing has shown **90.2% Sensitivity** and **91.5% Specificity** for detecting UIP pattern on qualifying CT scans.

ⓘ User manual for IQ-UIP dev can be found at https://www.imbio.com/support-documentation.

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Indication

IQ-UIP is a computer-aided software indicated for use in passively notifying specialists associated with interstitial lung disease (ILD) centers of radiological findings suggestive of radiological usual interstitial pneumonia (UIP) in non-contrast, chest CT scans of adults. IQ-UIP uses an artificial intelligence algorithm to analyze images and identify positive findings on a worklist application separate from and in parallel to the standard of care radiological image interpretation. Identification of positive findings include summary reports with a clinical guideline reference for the definition of UIP pattern that are meant for informational purposes only. The device does not alter the original medical image and is not intended to be used as a diagnostic device.

The results of IQ-UIP are used to notify specialists at an ILD center of radiological findings that may be consistent with UIP. These specialists are qualified clinicians experienced in evaluating chest CTs for ILD. Input images originate from within the same hospital network associated with the ILD center. The results of IQ-UIP are intended to be used in conjunction with additional patient information and based on the user's professional judgment, to assist with the review of medical images. Notified clinicians are responsible for viewing full image series and making final clinical determinations.