

imbio

IQ-UIP

v2.1.0

THE PRODUCT DESCRIBED IN THIS MANUAL IS
INTENDED FOR INVESTIGATIONAL USE ONLY.

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1 Introduction

Caution: This product is for investigational use only.

1.1 Scope of Manual

This user manual was written for the Imbio IQ-UIP software (FOR INVESTIGATIONAL USE ONLY).

This user manual was written for the Imbio IQ-UIP software. IQ-UIP is accessible via multiple deployment options, including various distribution partners or Imbio's Core Computing Platform (ICCP). Usage of these platforms and deployment options are outside of the scope of this manual. Contact support@imbio.com for more information.

1.2 Product Overview

Imbio's IQ-UIP software device uses an artificial intelligence algorithm to automatically analyze a qualifying chest computed tomography (CT) scan. The device performs image classification to identify if a chest CT scan contains findings suspicious for the radiological usual interstitial pneumonia (UIP) pattern and generates a summary output to report positive findings in parallel to and separate from the standard of care radiological image interpretation. The software does not recommend treatment or provide a diagnosis. It is a tool to assist ILD clinics in identification of patients with radiological UIP within their hospital system. The final radiological determination is provided by a thoracic radiologist after reviewing the original scans on the clinical PACS. The final clinical ILD diagnosis and/or treatment strategy is determined after consultation with clinicians from other clinical units, via a multidisciplinary team discussion (MDT/MDD) or other similar process in accordance with the institution's procedures.

Imbio IQ-UIP does not interface directly with any CT or data collection equipment, does not require user input, provides no image viewing capabilities, does not route images, and does not annotate images. Instead, the software imports data files previously generated by CT and is designed to function using information entirely derived from the CT images alone.

The Imbio IQ-UIP software utilizes high-resolution, non-contrast, inspiration, chest/lung CT images in DICOM format as input to the software.

Imbio IQ-UIP software outputs are sent to Imbio's web-based Portal, or similar application from commercial distribution partners. An IQ-UIP Report is

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automatically generated and added to a designated worklist if a scan is flagged as scan containing findings suspicious for UIP Pattern.

The outputs from Imbio IQ-UIP software are not to be used in the primary radiology clinical workflow. The standard-of-care radiology workflow (i.e. reviewing and reporting the findings that initiated the request for CT) continues unaffected by the parallel workflow of the lung health program. For clarity, the IQ-UIP device does not flag/prioritize cases within the standard, clinical radiology workflow.

1.3 Contact Imbio



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2 Intended Use and Requirements (For Investigational Use Only)

Caution: This product is for investigational use only.

2.1 Indications for Use

Imbio IQ-UIP is a computer-aided software indicated for use in 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.

Imbio 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 Imbio IQ-UIP are intended to be used in conjunction with other 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.

2.2 Intended Users

This product is not for clinical use. Users should use this product for investigational use only.

2.3 Intended Patient Population

This product is not for clinical use. Device inputs should be designated as for investigational use only.

2.4 Scan Protocol Requirements

The ability of the Imbio IQ-UIP software to analyze an chest CT scan is dependent on the field-of-view and image resolution. Therefore, it is important to analyze the scan's field-of-view and resolution. The field-of-view and resolution can be determined by assessing the acquisition protocols from the DICOM data as well as visually assessing the images themselves. The DICOM data provides information on the basic acquisition parameters used and can be compared with Imbio's required parameters. The scan should also be visually assessed to ensure that there are no artifacts or missing information.

2.4.1 Acquisition Parameter Requirements

The Imbio IQ-UIP software will not generate outputs for scans with acquisition parameters that do not meet the requirements as outlined in the table below.

DICOM Tag	Name	Required Value
(0008,0060)	Modality	CT
(0028,0030)	Pixel Spacing	$\leq 2.0 \times 2.0$ mm
(0018,9305)	Revolution Time	≤ 1.0 s (if present)
N/A	Slice Spacing	≤ 3.0 mm
(0018,0050)	Slice Thickness	≤ 3.0 mm
N/A	Field of View	$\geq 10.0 \times 10.0 \times 20.0$ cm
(0028,1054)	Rescale Type	HU (if present)
(0020,0032)	Image Position Patient	Present and not empty
(0020,000E)	Series Instance UID	Present and not empty
(0010,1010), or (0010,0030) AND (0008,0020)	Patient Age	≥ 22 years
(0018,0010)	Contrast Bolus Agent	Empty or not Present
(0002,0010)	Transfer Syntax UID	$\neq 1.2.840.10008.1.2.2$ (Explicit VR Big Endian)

2.4.2 Imbio Recommended Protocol

For the Imbio IQ-UIP software, Imbio recommends a 3D volumetric acquisition with pixel spacing less than 1 mm and slice thickness less than 3 mm for the input inspiration scan. Imbio also recommends that the patient lies in the supine position. Imbio IQ-UIP software will automatically reject contrast enhanced acquisitions. Example protocols are listed in the table below. The protocols accepted by Imbio IQ-UIP software are not limited to the scanners and protocols in the table, but the acquisition parameters should be similar. Failure to observe

2 INTENDED USE AND REQUIREMENTS

the recommended scan protocol could limit the software's ability to properly segment lungs.

Scanner Make	GE	SIEMENS	PHILIPS	TOSHIBA/ CANON
Scanner Model	VCT 64	Sensation-64	64 Slice	Aq64
Scan Type	Helical	Spiral	Helical	Helical
Rotation Time (s)	0.5	0.5	0.5	0.5
Det. Configuration	64 x 0.625	64 x 0.6	64 x 0.625	64 x 0.5
Pitch	0.984	1.0	1.0	0.828
kVp	120	120	120	120
mA	200	200	200	150
Reconstruction				
Kernel	Standard†	B35f†	B†	FC13†
Thickness (mm)	0.625	0.75	0.67	1
Spacing (mm)	0.5	0.5	0.5	0.5
DFOV(cm)	Lungs*	Lungs*	Lungs*	Lungs*

†More reconstruction kernels are considered acceptable than the kernels listed in this table. See table below listing all recommended and not recommended reconstruction kernels.

*Reconstruction field of view should encompass the widest diameter of the lung.

2.4.3 Recommended Reconstruction Kernels

Imbio does not provide an exhaustive list of acceptable reconstruction kernels due to the large number of reconstruction kernels available and the implementation of new kernels. The performance assessment of IQ-UIP software, as further described below in Section 4.3, primarily utilized datasets with the SOFT (7.8% of test datasets), STANDARD (53.9% of test datasets), BONE (1.7% of test datasets), and LUNG (36.6% of test datasets) reconstruction kernels or equivalent kernels for non-GE vendors.

2.5 Hardware Requirements

Hardware requirements for running Imbio IQ-UIP software are as follows:

- 4 CPU Cores
- 8 GB RAM
- 50 GB Storage

3 Quality Assessment / Clinical Workflow

Caution: This product is for investigational use only.

Scan quality and possible artifacts must be assessed before utilizing the results produced by the Imbio IQ-UIP software.

3.1 Precautions

This software is designed to run on any input data that satisfies the criteria in Section 2.4.1 and it does not perform any additional quality checking. **It is the responsibility of the medical professional who is using the application to ensure that the input data is of adequate quality.** If the input data is not of adequate quality, the application's results should be disregarded. Imbio IQ-UIP software is not intended for use as a primary tool for disease detection and/or diagnosis.

IQ-UIP was designed and validated on adult lungs and has not been validated on children.

4 IQ-UIP Software

Caution: This product is for investigational use only.

4.1 Device Input

The Imbio IQ-UIP software requires a single DICOM format, non-contrast, chest CT image series as input.

The Imbio IQ-UIP software will not generate outputs for scans with acquisition parameters that do not meet the requirements as outlined in Section 2.4.1.

4.2 Device Outputs

4.2.1 IQ-UIP Report

When analyzed with appropriate input data, the IQ-UIP Software generates an IQ-UIP Report (as a PDF-formatted file) if, and only if, a CT scan contains features suspicious for radiological UIP pattern. The output IQ-UIP Report is accessible to view within the dedicated worklist application.

IQ-UIP software does not generate outputs if a CT case is not flagged as suspicious for radiological UIP pattern.

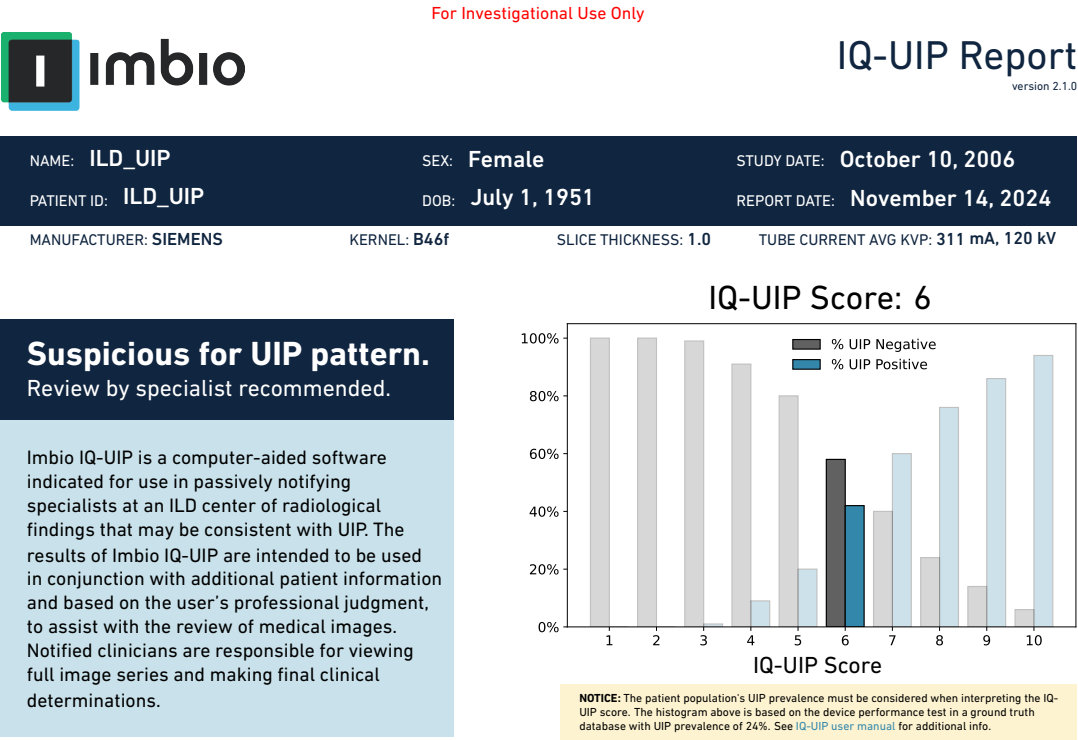
The report has been designed to communicate essential information to the user while reducing risks of improper use of the device. Each section of the report will be discussed in detail. An example of the IQ-UIP Report is shown below.

Header: The header section contains patient identifiable data, such as Patient Name, Patient ID, Patient Sex, and Patient Date of Birth, study information such as Study Date and Report Date, along with image acquisition/reconstruction information such as CT Manufacturer, Reconstruction Kernel, Slice Thickness, Tube Current, and kVp as available in the DICOM tags.

Notification Result: A report is only produced in the event that findings suspicious for radiological UIP pattern are identified in the input CT image series. Therefore, all reports will have the following messaging:

"Suspicious for UIP Pattern. Review by specialist recommended."

This message communicates the results of the IQ-UIP analysis to the user and also drives the intended clinical workflow for users to review the input CT scans for patients with a positive IQ-UIP result. IQ-UIP is not intended to deliver a final diagnosis or be a sole trigger for initiating additional testing or treatment. It is



intended only to identify CT image series that warrant a review by specialized clinicians with experience evaluating CTs for ILDs and who are involved in an ILD specialty clinic. An abbreviated version of the device's indications for use (IFUs) are also included below the notification result.

IQ-UIP Score: The IQ-UIP score is displayed is an integer between 1 and 10 where a score of 1 means very likely UIP negative and a score of 10 means very likely UIP positive. The IQ-UIP score is not a probability of UIP but is intended to be analyzed relative to IQ-UIP scores generated based on the datasets included within the IQ-UIP Standalone Performance Assessment with known ground-truth. The IQ-UIP score, in combination with other information, may be used in the help characterize a dataset as being UIP positive and may be used as one input to clinical decision making when following published clinical guidelines.

The histogram plot displays all IQ-UIP scores in 10 bins for the population in the and relative amounts of ground-truthed UIP+ or UIP- datasets. The performance datasets used to generate the IQ-UIP Score histogram plot were not used in model training and consist of a UIP prevalence of 24%. The highlighting colorization of the bars within the histogram plot coincide with the output IQ-UIP score calculated from the input dataset for easier identification.

Notice: The population used to test the device's performance was enriched for UIP as well as other fibrotic, UIP-mimicking diseases. Users must consider their patient population's UIP prevalence when interpreting the IQ-UIP score. In real-world prevalence(s), which is expected to have a lower UIP prevalence, equivalent IQ-UIP scores may have a lower percentage of true UIP positives.

Clinical Guidelines for UIP Pattern: A detailed excerpt from the 2022 clinical guidelines for the definitions of radiological UIP pattern on high-resolution CT is included on the bottom half of the report. The UIP radiological patterns are defined according to the American Thoracic Society/European Respiratory Society/Japanese Respiratory Society/Latin American Thoracic Association (ATS/ERS/JRS/ALAT) publication [1]. The excerpt from the clinical guidelines is meant for informational purposes only and is not intended for diagnostic use. The guidelines explain the four UIP pattern subtypes in terms of confidence level for UIP histology, distribution of findings, and CT features observed in the CT images.

Footer: A report footer contains additional information such as device performance in terms of sensitivity and specificity based on the device's performance assessment along with possible warnings and hyperlinks to the IQ-UIP User Manual.

4.2.2 Input Check Failure Report

The Input Check Failure Report can also be output in a DICOM-compatible format. The cause(s) of the input check failure can be identified by the red 'X' mark in the Result column of the Input Check Failure Report. In the figure below, the offending parameters are the modality. Note the yellow triangle warning signs indicate sub-optimal parameters or parameters that are missing from the input meta data (Revolution Time or Rescale Type). These warnings will not result in an input check failure, but should be noted, nonetheless.

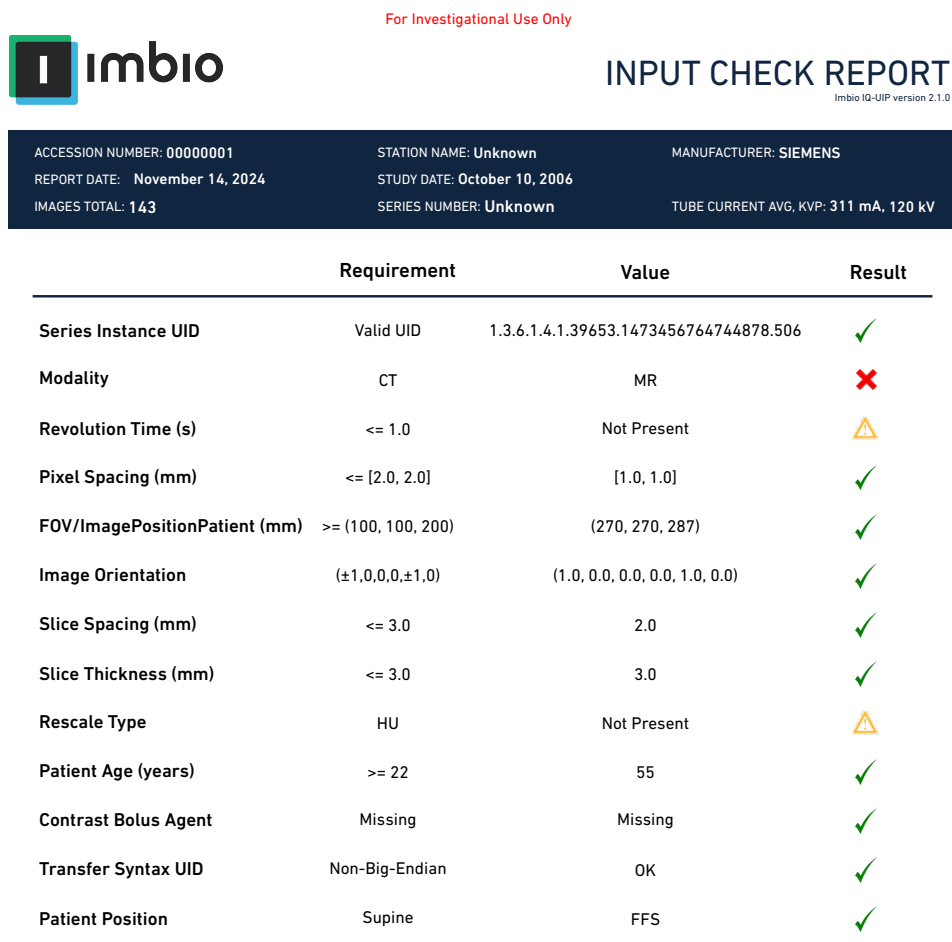


Figure 2: Example Input Check Failure Report

4.3 Algorithm Performance

The purpose of the device's standalone performance assessment is to demonstrate the effectiveness of the Imbio IQ-UIP software compared to a

clinically acceptable, reference standard (i.e., ground-truth dataset) to make a binary determination for the presence of the radiological UIP pattern in qualifying chest CT image series.

IQ-UIP software's performance was evaluated on 804 anonymized, chest CT datasets collected from multiple hospitals, clinical imaging centers, and imaging databases, both private and publicly available, to have a representative distribution of varying CT scanner vendors, slice thicknesses, convolution kernels, and lung disease subtypes. All datasets were quarantined from the datasets used in the device's model training and validation (i.e., model tuning). The population of CT datasets was selected to represent a large cross-section of lung disease observed in a screening population. The population is enriched with cases with radiologist-confirmed UIP pattern to more accurately measure the efficacy of the IQ-UIP software.

Datasets with obvious metal or high attenuation artifacts, severe motion artifacts, undergone prior lung transplant or with a missing lung were excluded from the study.

The average age of subjects in the performance dataset was 64.1 +/- 11.9 years including 300 females, 437 males, and 67 subjects with gender unavailable.

The breakdown for the number of datasets from each database and number of clinically diagnosed IPF subjects is included. IPF prevalence was determined to be 29%. All datasets used in the standalone performance assessment were quarantined from model training with no overlap in imaging site or subject ID (i.e., site and subject-level independence).

Database	Datasets (N)	IPF+ Datasets (N)
OSIC	242	118
COPDGene	186	0
RIFF	98	98
FocuSSced	20	0
SegMed Insights	59	0
MIDRC RiCORD	16	0
NLST	70	0
UC-Davis	36	18
CCIC	77	0

Important cohorts were subdivided by the dataset's clinical diagnosis label from the associated database into four groups: IPF-only, Non-IPF Fibrotic, Non-Fibrotic, Normal. The cohorts included the following diagnoses:

- **IPF-only:** datasets with an IPF clinical diagnosis label (MDT or pulmonologist determined)

- **Non-IPF Fibrotic:** idiopathic nonspecific interstitial pneumonia (iNSIP), fibrotic NSIP (fNSIP), unclassifiable idiopathic interstitial pneumonia (uIIP), unclassifiable interstitial lung disease (uILD), sarcoidosis, chronic/fibrotic hypersensitivity pneumonitis (cHP/fHP), rheumatoid-arthritis interstitial lung disease (RA-ILD), sarcoidosis, exposure-related ILDs, combined pulmonary fibrosis and emphysema (CPFE).
- **Non-Fibrotic:** emphysema (COPD), bronchitis (COPD), carcinoma, lymphoma, organizing pneumonia (OP), acute HP, pleuroparenchymal fibroelastosis (PPFE), respiratory bronchiolitis ILD (RB-ILD), Systemic sclerosis (SSc), bronchiolitis, pneumonia.
- **Normal:** datasets without any apparent lung abnormalities or pathologies.

4.3.1 Overall Performance

The software's performance was compared against a ground truth determined by majority opinion from five, expert, U.S. board-certified radiologists ("truthers") practicing within the United States. Each truther had a minimum of 5+ years' experience evaluating chest CTs for ILDs and a clinical familiarity with using the ATS/ERS/JRS/ALAT diagnostic categories for radiological UIP pattern. Each truther evaluated and categorized all 804 datasets into 1 of the 4 diagnostic categories (i.e., UIP, Probable UIP, Indeterminant for UIP, and Alternative Diagnosis) for radiological UIP pattern. For analysis, a binary (two-category) radiological UIP pattern ground truth label was generated by defining UIP positive (UIP+) as UIP or Probable UIP and UIP negative (UIP-) as either Indeterminate for UIP or Alternative Diagnosis. The device's overall performance in terms of area-under-the-curve (AUC) of the receiver operating curve (ROC), accuracy, sensitivity, specificity, positive predictive values (PPV), and negative predictive values (NPV) are reported below compared to ground truth labels. Device performance metrics and 95% confidence intervals (CI) are reported for all groups/subgroups unless the number of datasets needed for computation is ≤ 5 , no True Positives (for determining device specificity) are present, or no True Negatives (for determining device sensitivity) datasets are not present. "N/A" will be reported instead in these cases.

Metric	Value	95% CI
AUC ROC (%)	96.6	[95.4, 97.7]
Sensitivity (%)†	90.2	[86.2, 94.3]
Specificity (%)†	91.5	[89.2, 93.7]
Accuracy (%)†	91.2	[89.1, 93.0]
PPV (%)††	77.0	[72.2, 82.0]
NPV (%)††	96.7	[95.5, 98.1]

†Performance was assessed using an IQ-UIP model binary threshold of 0.395. This threshold algorithmically determines the cut-off for deciding between UIP+ and UIP-.

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††Performance was assessed using an ground-truthed UIP+ prevalence of 24% within the assessment cohort.

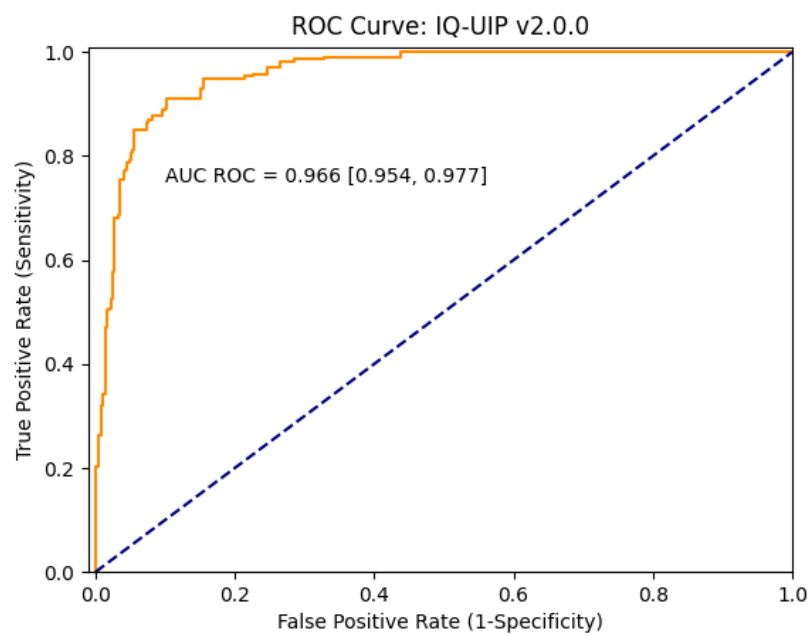


Figure 3: Receiver Operator Curve (ROC) for the IQ-UIP Performance Assessment. AUC = Area-under-curve.

The PPVs and NPVs using the default binary threshold were simulated across all possible UIP disease prevalences ranging from 0 to 100% using the IQ-UIP device's performance. The 95% confidence intervals were estimated using bootstrapping with replacement. The simulated curves are shown in the Figure below.

The expected UIP/IPF prevalence were estimated in the following device-use locations: ILD clinic, specialty center, primary care / emergency department and lung cancer screening.

Device Use Locations	Expected UIP Prevalence	PPV (%)	NPV (%)
ILD Clinic [2][3]	25.0%	77.9 [73.3, 82.8]	96.5 [95.2, 98.0]
Specialty Clinic	10.0%	54.1 [47.8, 61.6]	98.8 [98.4, 99.3]
LCS [4]	1.0%	9.7 [7.7, 12.7]	99.9 [99.8, 99.9]
Primary Care/ED [5]	0.6%	6.0 [4.7, 8.0]	99.9 [99.9, 100]

LCS = Lung Cancer Screening. ED = Emergency Department. 95% CI included for PPV and NPV values.

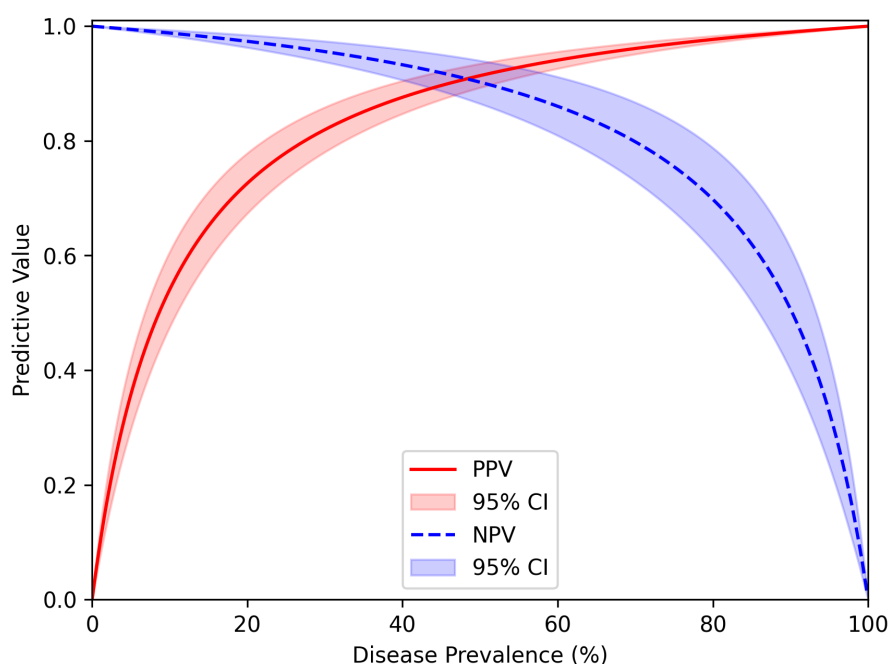


Figure 4: Simulated positive and negative predictive values (PPV, NPV) and their 95% confidence intervals (CI) with varying UIP+ disease prevalences from the IQ-UIP Performance Assessment.

4.3.2 Subgroup Performance

To understand the generalizability of the device's performance in cohorts and possible confounders, a subgroup analysis was performed to evaluate the device for sensitivity and specificity for across these subgroups including lung disease, manufacturer, reconstruction kernel, and slice thickness. The tables below show the performance across subgroups.

Cohort	IPF-Only	Non-IPF Fibrotic	Non-Fibrotic	Normal
Datasets (N)	234	228	202	140
UIP+ / UIP- (N)	181 / 53	12 / 216	0 / 202	0 / 140
Sensitivity (%)	94.5 [91.1, 97.3]	25.0 [0.0, 53.8]	N/A	N/A
Specificity (%)	41.5 [28.6, 55.1]	92.6 [88.9, 96.2]	97.5 [N/A]	100 [100, 100]
TN, FN, TP, FP (N)	22, 10, 171, 31	200, 9, 3, 16	197, 0, 0, 5	140, 0, 0, 0

Manufacturer	GE Medical	Siemens	Canon/Toshiba	Philips
Datasets (N)	232	296	89	187
UIP+ / UIP- (N)	45 / 187	37 / 259	30 / 59	81 / 106
Sensitivity (%)	82.2 [70.0, 92.9]	89.2 [77.3, 97.6]	90.0 [77.8, 100]	95.1 [89.5, 98.9]
Specificity (%)	94.1 [90.4, 97.3]	95.0 [92.2, 97.3]	93.2 [86.4, 98.4]	77.4 [69.2, 84.7]
TN, FN, TP, FP (N)	176, 8, 37, 11	246, 4, 33, 13	55, 3, 27, 4	82, 4, 77, 24

Notice: User(s) should be aware of performance differences observed in chest CT scans originating from Philips manufacturer as shown in the Manufacturer table above.

Recon. Kernel†	SOFT	STANDARD	BONE	LUNG
Datasets (N)	63	433	14	294
UIP+ / UIP- (N)	28 / 35	49 / 384	7 / 7	109/185
Sensitivity (%)	89.3 [76.9, 100]	83.7 [72.9, 92.7]	85.7 [55.6, 100]	93.6 [88.9, 98.1]
Specificity (%)	82.9 [69.7, 94.1]	97.4 [95.7, 98.7]	100.0 [100, 100]	80.5 [74.1, 86.2]
TN, FN, TP, FP (N)	29, 3, 25, 6	374, 8, 41, 10	7, 1, 6, 0	149, 7, 102, 36

†Reconstruction kernels across vendors were grouped according to a "GE Medical equivalent" best match.

Slice Thickness†	< 1.5 mm	≥ 1.5 & <3.0 mm	= 3.0 mm
Datasets (N)	664	100	40
UIP+ / UIP- (N)	180 / 484	12 / 88	1 / 39
Sensitivity (%)	91.7 [87.4, 95.4]	75.0 [44.4, 100.0]	0.0 [0.0, 0.0]
Specificity (%)	90.3 [87.6, 93.0]	95.5 [90.8, 98.9]	97.4 [92.1, 100.0]
TN, FN, TP, FP (N)	437, 15, 165, 47	84, 3, 9, 4	38, 1, 0, 1

5 Possible Encountered Exceptions

Caution: This product is for investigational use only.

The Imbio IQ-UIP software produces notifications and errors when an exception is encountered within the algorithm. Below are possible errors generated by the software with further descriptions and probable causes of the exceptions.

5.1 Input Errors

ERROR: Input data invalid

This error occurs if one or more acquisition parameters do not meet Imbio's requirements. For the details on each required parameter, see Section 2.4.1.

ERROR: [DIRECTORY] contains more than one series

This error occurs if the input contains more than one images series.

5.2 General Errors

ERROR: "No Lungs Detected"

This error indicates the lungs could not be detected. Possible causes include the input image does not contain the lung, input image is noisy, or there is not coverage of the lungs within the image field-of-view.

6 Considerations to Reduce Risk

Caution: This product is for investigational use only.

Imbio IQ-UIP does not interface directly with any CT or data collection equipment; instead the software imports data files previously generated by such equipment. Furthermore, Imbio IQ-UIP provides no image viewing capabilities. Instead, Imbio IQ-UIP writes files out that can be viewed by other commercial viewing applications. The device does not alter the original medical image and is not intended to be used as a diagnostic device.

6.1 Protocol

For optimal results, users should follow the CT protocol as outlined in Section 2.4. It is important to work with the IT administrator to set up access to the separate, dedicated worklist/workstation; either to the Imbio Portal worklist or similar application from Imbio's distribution partners.

6.2 Algorithm Limitations

The Imbio IQ-UIP software checks input parameters and notifies users with warnings or error messages. Even so, there are a small number of cases where no warning or error is given and the output report is generated with potentially misleading results. The Imbio IQ-UIP software should only be used by intended users as specified in Section 2.2.

Users are responsible for reviewing each exam on a diagnostic viewer according to the current standard of care. IQ-UIP is limited to the notification of specialists associated with ILD Centers of radiological findings suggestive of radiological UIP pattern in chest CT scans of adults. IQ-UIP does not provide any diagnostic information, does not remove or alter original medical images, and should not be used in lieu of full patient evaluation, or relied upon to make or confirm diagnosis.

The results of Imbio IQ-UIP are intended to be used in conjunction with other 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.

The outputs from Imbio IQ-UIP software are not be used in the primary radiology clinical workflow. The standard-of-care radiology workflow (i.e., reviewing and reporting the findings that initiated the request for CT) continues unaffected by the parallel workflow of the ILD program. For clarity, the IQ-UIP

6 CONSIDERATIONS TO REDUCE RISK

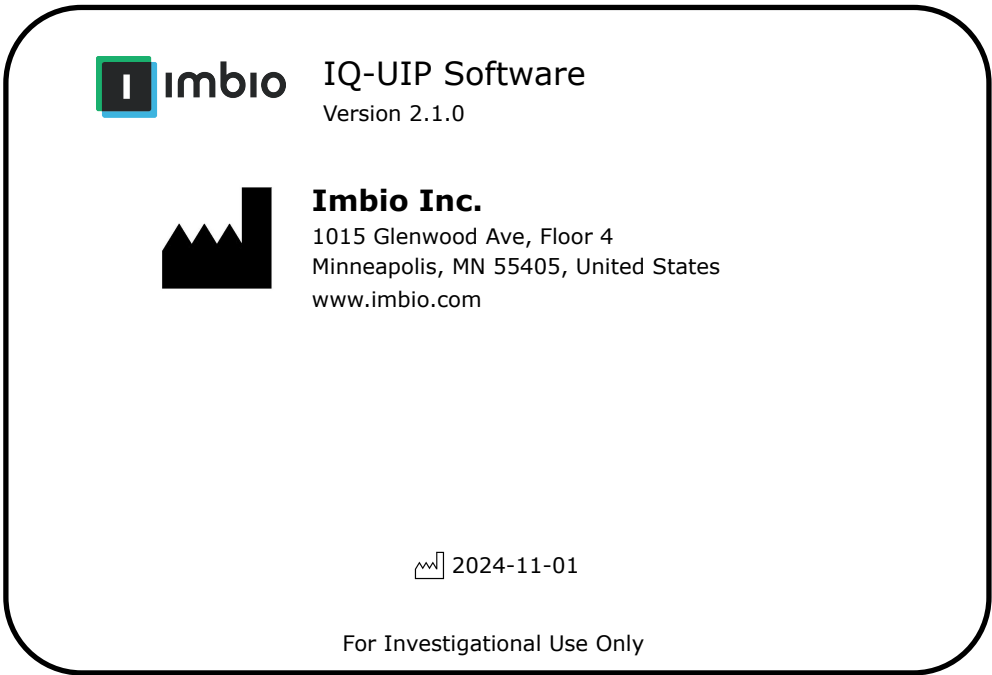
device does not annotate original medical image, make diagnoses, or flag/prioritize cases within the standard, clinical radiology workflow.

6.3 Cybersecurity Recommendations

When deploying systems on which this application will run, please consider the following technical security guidelines:

- Ensure only permitted users are able to sign into the system, using at minimum, a username and strong password.
- Ensure that system firewalls are configured in such a way as to only allow needed traffic to ingress the system.
- Ensure that operating system patches are kept up-to-date, and monitor operating system vendor communications for security and patching-related announcements.

7 Software Label



8 Bibliography

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