

Instructions for Use (IFU) – OrQA-L deployed through TransplantPath

Product Name:	OrQA-L
Model Number:	Model 3
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Revision History

Version Number	Changed Section	Change Description & Rationale	Date of Change	Author of Changes
V1.0	All	New Document	04.07.2025	Bryan Lister
V2.0	All	Refining of content after NHSBT CTU review 10.12.25. Minor changes to contraindications. Footer added final page	09.01.2026	Colin Wilson, George Kourounis, Bryan Lister



INSTRUCTIONS FOR USE (IFU)

OrQA-L - Liver Quality Assessment Support Tool integrated into TransplantPath

For clinical investigation use only

Date of Issue: 09.01.26

1. DEVICE NAME

OrQA-L – Liver Quality Assessment Support Tool deployed within TransplantPath.

2. INTENDED PURPOSE

Summary

OrQA-L is a clinical decision-support software tool designed to assist transplant professionals by providing an objective assessment of liver quality. The system uses digital photographic images of the donor liver, captured as part of routine practice during organ retrieval in line with NHSBT protocols, to produce a quality score which is intended to support but not replace clinical judgement regarding organ suitability. OrQA-L is a Software as a Medical Device (SaMD).

In detail

OrQA-L is an algorithm accessed from within TransplantPath, designed to assist transplant professionals in assessing liver quality for transplantation decisions. The SaMD uses a machine learning model (a form of Artificial Intelligence or 'AI') that has been trained upon surgeon-scored image data to assist with the visual assessment of the fatty appearance of the liver. Digital photographic images, uploaded from a mobile device through the DonorPath platform, are used to generate a score for a subject organ, returned through TransplantPath. This score correlates with the opinion of multiple expert surgeons, i.e. the consensus assessment. This computational task provides individual transplant professionals with an indication of how a consensus of surgeons would visually evaluate the fattiness of the subject organ. The SaMD is intended for use by liver transplant professionals at the time of organ retrieval, specifically in the operating theatre after the cold organ preservation flush. Users of this device are expected to have the necessary expertise and training in liver transplantation organ procedures.

OrQA-L assesses organ quality on a standardised continuous scale of 0 – 4, corresponding to the categories: "None" (0-1), "Mild" (1-2), "Moderate" (2-3) and "Severe" (3-4), derived from expert surgeon consensus opinions during training of the algorithm. The performance evaluation indicates mean absolute error of 0.46 with a 95% confidence interval of 0.432 – 0.490.

3. PATIENT POPULATION

OrQA-L is intended for use with any donated liver with back-bench images being considered for transplantation. The model was developed using a dataset of anonymised photographs taken at the time of organ retrieval from routine UK clinical transplant practice, which included both adult and paediatric donors. Due to anonymisation, the exact distribution of donor characteristics such as age, sex, and ethnicity in the training set is not known. The model was developed and validated using data representative of real-world clinical variation and is therefore not limited to any specific demographic profile.

4. INTENDED USER

Transplant professionals based in Great Britain and working within the organ donation pathway.

5. INTENDED USE ENVIRONMENT

The environment is the NHS organ transplant network across hospitals in England, Scotland and Wales, under standard organ retrieval conditions according to the standard practice *NHSBT MPD1100/11 - Guidance and Principles – Donor Related Images and Video*.

6. DEVICE DESCRIPTION

OrQA-L is an algorithm accessed from within the NHSBT TransplantPath system. It analyses digital photographic images of donor livers taken intraoperatively and uploaded to DonorPath which are then released to the TransplantPath environment. Using machine learning algorithms, it provides an aggregate quality score that corresponds to visual grades of hepatic steatosis.

7. IMAGE ACQUISITION INSTRUCTIONS

Required Equipment:

- Apple iPad with high-resolution rear camera (standard issue by NHSBT)
- Access to DonorPath for image upload and TransplantPath for return of OrQA score
- Clean white surgical swab
- Ice bowl containing liver

Photographing the Liver:

As per NHSBT guidance document MPD1100/11, take a minimum of four photographs of the liver in the ice bowl with white swab on the table to the left of the liver as viewed by the photographer:

1. Anterior View
2. Posterior View
3. Posterior surface left lobe (rotated)
4. Posterior surface right lobe (rotated)

Photographic Image Standards:

- Ensure the liver is placed in a clean ice bowl (minimal blood/contamination) with a white swab included in the frame to assist with colour calibration
- Theatre room lights should be ON but direct the operating lights away from the liver to minimise glare and reflections
- Maintain a consistent distance (~30–50 cm) and angle for all photographs to improve image analysis accuracy
- Avoid shadows, obstructions, or fluid on the camera lens
- Ensure all four images are sharp and properly focused with no patient identifiable data in the image

8. IMAGE UPLOAD INSTRUCTIONS

- Confirm correct patient and case identifiers before submission
- Upload all images using the existing standard workflow for organ photograph submission
- Within TransplantPath photographs will be transferred via an API link for assessment using the OrQA-L module. The number of images transferred per liver will range from a minimum of one to a maximum of five

9. SCORE CALCULATION

The decision to accept a liver for transplantation from a deceased donor depends on multiple factors, including the donor's medical history, mode of death and biochemical markers of liver injury taken prior to retrieval. Importantly, subjective visual assessment of the liver surface texture and level of steatosis plays a key role in assessing the viability of a retrieved liver. Implanting surgeons depend on the retrieval surgeons' assessment of a liver to inform the decision to implant the organ.

Upon receipt, each digital photographic image will be individually processed by the OrQA-L module. The first stage involves an image quality assessment to confirm the image depicts a liver and meets photographic acceptance criteria (exposure, focus, white balance). If an image fails this check, then it will not be used for any further OrQA-L assessments. If the image passes the quality checks it will proceed to the assessment phase of the module.

For accepted images, the OrQA-L module will generate a score and a 95% confidence interval per image. The individual OrQA-L scores and their 95% confidence intervals will be combined to generate an overall OrQA-L score and confidence interval for the liver. A weighted average approach will be applied, where the weight of each image is determined by the square root of the inverse of its confidence interval (i.e. images with narrower confidence intervals will be weighted more strongly for the overall assessment).

If all images pass the image quality step, the final average OrQA-L score and its 95% confidence interval will be sent to TransplantPath and displayed alongside each corresponding image. In cases where some images pass (scorable images) while others fail, only the average OrQA-L score from the scorable images will be sent and linked to all of the images. When this occurs, no error messages are displayed to users, but they are recorded within the OrQA-L and TransplantPath API.

10. CLINICAL INTERPRETATION & LIMITATIONS

- OrQA-L is not a diagnostic tool and does not replace expert clinical evaluation, histology, or macroscopic judgement.
- The score is one factor to be considered alongside other factors, for example: donor history, visual inspection, and laboratory findings.
- Implanting surgeons must trust their own clinical judgement especially if their assessment of organ quality disagrees with OrQA-L.

11. WARNINGS AND PRECAUTIONS

- All organ images must be captured according to NHSBT standard practice MPD1100/11 to be suitable input data for analysis by OrQA-L
- The recipient surgeon should be conversant HTA 'A' Liver Quality Scale and how it maps to the OrQA-L output
- Whilst OrQA-L is intended to support clinical decision making, it does not replace clinical decision making.

12. MAINTENANCE AND TROUBLESHOOTING

- Ensure iPad operating software is up to date
- Use secure Wi-Fi/ mobile data to upload to DonorPath
- In certain situations, no score may be possible. Only the first batch uploaded currently will be analysed as part of the OrQA-UK trial

13. DATA PRIVACY AND SECURITY

OrQA-L complies with the UK General Data Protection Regulation (UK GDPR), and the Data Protection Act 2028. All images are processed securely within NHS-approved systems. No patient-identifiable data is stored within OrQA-L.

14. SAFETY INFORMATION

Contraindications

OrQA-L is an organ quality assessment tool intended to support clinical decision making when digital photographic images are presented together with an OrQA score and associated confidence interval information. It should not be used in situation where the tool's use could be detrimental to the patient or workflow, where the user does not understand the score or its context, or where the user considers the information returned as being potentially unreliable. OrQA-L should also not be used where the liver remains in situ and has not yet undergone cold preservation flushing, or where the liver surface cannot be clearly visualised (e.g. due to obscuration or inadequate exposure).

Warnings and Remaining Risks

OrQA-L is an investigational software as a medical device. Where a device deficiency (for example a technical failure) or a use error has occurred or is suspected, these should be reported via the OrQA Trial website:

- <https://www.nhsbt.nhs.uk/clinical-trials-unit/trials-and-studies/organ-donation-and-transplantation/orqa-uk/>

Reporting a Serious Incident

Incidents that may have an adverse effect upon organ donation and/or transplantation should be reported through the NHSBT Datix system in accordance with the ODT Clinical Governance incident reporting process by completing a NHSBT Incident Submission Form at:

- <https://safe.nhsbt.nhs.uk/IncidentSubmission/Pages/IncidentSubmissionForm.aspx>

Where an incident is deemed urgent, this will also be reported by telephone to the ODT Hub Operations as described:

- <https://www.odt.nhs.uk/odt-structures-and-standards/governance-and-quality/tell-us-about-an-incident/>

15. DEVICE REGISTRATION AND REGULATORY COMPLIANCE

OrQA-L is an investigational medical device and not available for clinical use outside of this study.

16. MANUFACTURER INFORMATION



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These instructions should be referred to as required by all users during image acquisition and upload procedures.