

| Document Title       | <br>X-on Health<br>an SCG company | Version |
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| Instructions For Use | INSTRUCTIONS FOR USE FOR WORKFLOW AGENT                                                                             | 1.0     |

# Workflow Agent

Manufacturer: X-on Health Ltd



## Instructions For Use

June 2026

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# 1. Product Identification & Manufacturer Details

## 1.1. Device Identification

Workflow Agent, V06.2026

## 1.2. Manufacturer Information

X-on Health Ltd of Glebe Farm Down Street, Dummer, Basingstoke, Hampshire, RG25 2AD, United Kingdom

## 1.3. UDI-DI Reference

UDI-DI: 5056932800008

UDI-PI: (01)5056932800008(11)260730(8012)06.2026



## 1.4. Contact/Support Information

Users can report malfunctions, errors, or unexpected clinical events by using the "Thumbs Up/Thumbs Down" wherever the Workflow Agent summarisation is presented, this is supplemented by the addition of a context capture box, a mandatory comment field for "Thumbs Down" to allow users to specify if the error was a Hallucination, Omission, or Inaccuracy (or add any context they deem relevant). This mechanism then feeds into X-on Health's centralised reporting for internal investigation.

Users are also encouraged to report more critical problems via the Support Portal (24/7 online platform, <https://support.x-onweb.com/login>) or by contacting Support on 0333 332 6633 (working hours) or 0333 555 8999 (out of hours), available 24/7.

As this is a registered medical device, users are requested to report any serious adverse incidents (this includes the death of a patient/user/or other person, the temporary or permanent serious deterioration of a patient/users/or other persons state of health, and a serious public health threat) involving this software directly to the Medicines and Healthcare products Regulatory Agency (MHRA).

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Reports should be submitted via the official MHRA Yellow Card Scheme (Available at: <https://yellowcard.mhra.gov.uk/>). When submitting the report, users must ensure they provide the software name, version number, and the manufacturer name (X-on Health).

## 2. Intended Purpose & Clinical Scope

### 2.1. Intended Purpose

The subject device is intended to automate the collection, transcription, and summarisation of preliminary patient consultation data. It is intended for use by General Practice (GP) Surgeries to gather patient clinical history, symptom descriptions, and administrative details from patients for the purpose of initiating follow-up communication.

### 2.2. Indications for Use

The target patient population for the subject device is primary care patients.

The subject device is used in the field of primary healthcare administration and triage.

### 2.3. Target Users

The device is intended to be used by General Practice staff within a primary healthcare setting.

### 2.4. Contraindications

The device is explicitly not for emergency use. It is contraindicated for any patient experiencing symptoms requiring immediate medical attention. The system logic includes a specific warning step to exclude these patients, directing them instead to A&E or 999. But if they still chose to use the Workflow Agent, despite the warning in place, they will not receive or be escalated to any emergency services.

While not listed as a strict medical contraindication, the device's reliance on voice interaction creates functional contraindications for unclear speech, where patients that may be unable to do so may fail to complete the Workflow Agent process.

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## 3. Technical & Environmental Requirements

### 3.1. Hardware Requirements

i3 processor minimum, 4GB RAM, 2GB disk space, 1366×768 minimum display (1920×1080 recommended).

### 3.2. Software Operating Environment

Windows 10+, supported browsers (Edge, Chrome, Firefox, Safari), cloud-hosted SaaS — no local server needed

### 3.3. Connectivity Requirements

Stable internet required (minimum 4Mbps), no offline capability, X-on Health advanced cloud telephony dependency (Surgery Connect) required.

## 4. Operational Instructions (Step-by-Step)

### 4.1. Installation & Deployment: Clear guidance on how to download, install, or access the Workflow Agent

Installation can take place either using a Regular installer for individual PCs and Laptops or via Group Policy using an MSI installer.

The Workflow Agent requires the X-on Health Phonebar (Surgery Connect) to be installed on the PC. Step-by-step guidance on how to install this application is provided here:

<https://help.x-onweb.com/en/collections/43128-phonebar-installation-and-set-up>

### 4.2. Account Setup & Security: Instructions on creating user profiles, setting secure passwords, and data privacy protocols.

As the Workflow Agent is embedded into the Surgery Connect product, user profiles, passwords, and data privacy protocols are stored within the Service Delivery Console.

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### 4.3. Core Functionality Guide

For guides to all of our core functionality surrounding the X-on Health Workflow Agent, please visit the X-on Health Help Centre for various step-by-step guides on navigating the product UI, and the inputs required from the user. Link: <https://help.x-onweb.com/en/>

### 4.4. Data Input/Output Quality: Specifications regarding the format and quality of data inputs and outputs

There are input dependencies present such as speech clarity and line quality that may impact results of the Workflow Agent. Despite our ongoing post market surveillance of the Workflow Agent and high-standard of benchmarks to allow the Workflow Agent to pass its software verification and validation testing, we must acknowledge the output quality may be affected by inaccuracies, omissions, and hallucinations of the summarisations generated. X-on Health advises that the user always reviews the Workflow Agent's generated content.

## 5. ⚠ Warnings, Precautions, & Residual Risks ⚠

### 5.1. Disclaimers

The device does not provide clinical diagnoses, recommend treatments, or make triage decisions. The device is strictly a data-collection and summarisation tool.

### 5.2. Warnings

The device utilises AI for the summarisation of the patient provided information and conversation with the Workflow Agent. Summarisation errors or misinterpretations may occur therefore; the user must review all summarisation outputs before making any clinical decisions based on them.

### 5.3. Precautions

The device is not intended for use in medical emergencies. It incorporates specific logic to warn patients that the system is for non-urgent issues and points them to emergency services (999/111) if required.

### 5.4. Residual Risk

A comprehensive risk analysis was conducted for the Workflow Agent. All identified risks have been mitigated and evaluated for acceptability based on their severity and probability of occurrence.

#### 5.4.1. Clinical Benefit vs. Risk Justification

The overall residual risk of the Workflow Agent has been officially evaluated and deemed acceptable when balanced against the significant clinical benefits provided by the device.

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#### Key Clinical Benefits:

- Enables highly effective post-consultation summarisation of preliminary patient consultation data.
- Delivers improved efficiency in preliminary patient triage workflows.
- Enhances overall patient and clinician satisfaction metrics.

#### Safety Evaluation Measures:

Because all individual risks were found to be inherently acceptable and firmly positioned within the safe zone, no further device modifications, changes to intended use, or additional risk controls were required. No hazardous clustering or borderline risk accumulation is present in the device design.

#### 5.4.2. Clinical Safety Compliance (DCB0129)

The DCB0129 standard (NHSE clinical risk management standard in the manufacture of health IT systems) shares similar emphasis on residual risk and mitigating this down to an acceptable level for the purpose of patient safety. X-on Health maintains a dedicated DCB0129 Clinical Risk Management Plan and Hazard Log. In alignment with the core product risk assessment detailed above for the Workflow Agent as a Class I Medical Device, all clinical residual risks evaluated under the DCB0129 framework were similarly deemed acceptable. The complete DCB0129 documentation suite is available for download and review via our secure Trust Centre

(Link: <https://surgeryconnect.academy/trust-centre/>)

## 6. Troubleshooting & Maintenance

### 6.1. Troubleshooting

For general troubleshooting queries, please refer to the X-on Health help centre for assistance.

<https://help.x-onweb.com/en/>

Beyond this, please raise a ticket on the X-on Health Support portal (<https://support.x-onweb.com/login>) to access 24/7 support.

### 6.2. Software Updates

X-on Health delivers all software updates centrally through its cloud-hosted, thin-client architecture. Because the platform operates as a Software as a Service (SaaS) solution, updates are applied server-side, users do not need to download, install, or manually apply patches to receive the latest version of the software.

Customers are alerted to software changes through multiple channels:

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- In-application notifications: Alerts and banners displayed within the Surgery Connect User Console and Phonebar to inform active users of updates, outages, or end-of-life products.
- Email notifications: Registered System Administrators receive targeted communications detailing changes, their impact, and any required actions.
- Help Centre guides: Detailed guides, release notes, and updated training materials are published in the X-on Health Help Centre and Academy.

## 6.3. Data Backup & Recovery

### Architecture & Compliance

X-on Health uses a resilience-first architecture certified under ISO 22301 (Business Continuity) and ISO 27001 (Information Security) to ensure data protection and continuous uptime.

### Data Storage & Redundancy

- Location: 100% hosted within the UK across four Tier 3 data centres
- Quadruple Redundancy: Each site holds 100% of configuration and audit data (e.g., call recordings), ensuring zero data loss. Replication latency is typically 2–3 seconds (max 30 seconds).
- Infrastructure: Features N+1 component redundancy (power, cooling, hardware) and elastic auto-scaling to handle demand surges.

### Backup Schedule

- Daily: Full nightly backup of database servers and data to a remote location.
- Weekly: Full backup of virtual machines.
- Security: All backups are encrypted using AES-256 within UK jurisdiction (UK GDPR compliant).

### Failover & Disaster Recovery

- Automated Failover: Traffic automatically and instantly re-routes via load balancing if a data centre or path fails.
- Manual Override: Senior engineers can force a "Site Switch" during partial disruptions. Tests are conducted monthly.
- Uptime SLA: 99.99% availability guarantee, backed by contractual service credits.

### Monitoring & Incident Notification

- Status Dashboard: Real-time, traffic-light component visibility via the Support Portal.
- In-App Alerts: Immediate connectivity warning banners inside the Surgery Connect User Console.
- Admin Alerts: Targeted emails sent to System Administrators for high-severity incidents.

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- Post-Incident: Full Root Cause Analysis (RCA) published for major outages.