

## Due Diligence for Automated Tools – Guidance for LMCs

### Background

NHS England has recognised the potential benefits of technologies that can record, transcribe, and summarise consultations (referred to as *ambient voice technologies* or AVTs). They have made clear that all NHS organisations must ensure that any AVT solution adopted complies with published NHS standards in their [Guidance on the Use of AI-Enabled Ambient Scribing Products in Health and Care Settings](#) (a summary of which has been provided for LMCs).

A number of AVT suppliers are actively approaching GPs with AI-driven “ambient scribe” products. However, many of these suppliers have not yet demonstrated compliance with core NHS governance requirements — including securing ICB approval, providing MHRA clinical safety and technical/cyber assurance, and evidencing proven benefit within NHS settings.

On 9 June 2025, NHS England issued “*Priority Notification: Ensuring Safe and Assured Adoption of AI Scribe Technology*” (copy attached).

LMCs have already received a summary of this notification. For ease of reference, the key obligations for practices considering the implementation of these technologies are set out again below.

### Key points for practices and LMCs:

1. Do not use AVT solutions that do not meet NHS standards.
2. AVT solutions require MHRA Class 1 medical device status.
3. Practices/GPs must complete a clinical safety risk assessment and DPIA before deployment as part of their legal responsibilities (DCB0160).
4. Liability for using non-compliant solutions sits with the deploying organisation or individual user.

### Risks of non-compliance:

- Clinical safety breaches.
- Data protection violations.
- Financial penalties & liabilities.

### Minimum Requirements for AVT Adoption:

#### 1. Core Requirements

- **Technology & Security:** Must meet Digital Technology Assessment Criteria (DTAC), Data Security and Protection Toolkit (DSPT), Cyber Essentials Plus, and have CREST-approved pen testing.
- **Data Protection:** Must follow ICO standards, have local ICB/Trust approval including DPIA.
- **Clinical Safety:** Have a named accountable Clinical Safety Officer(s).
- **Privacy:** End-to-end encryption and GDPR compliance.

- **Safe Use:** No unsafe functionality.
- **System Integration:** Must integrate with NHS systems.
- **Translation Accuracy:** Supplier is responsible and user must check for accuracy.

## 2. Enhanced Requirements

- **Medical Device Status:**
  1. If the system summarises medical info → MHRA Class 1.
  1. If it gives diagnoses, management plans, referrals, or calculations → At least MHRA Class 2a.
- 1. **Data Handling:**
  1. Patient session data should be auto deleted unless required by law.
  1. Follow UK GDPR and Data Protection Act 2018 principles.
- 1. **System Integration:**
  1. Must fit with existing NHS IT infrastructure to enable automated workflows.

## 3. Clinical & Operational Benefits

- Must have evidence of real-world clinical validation of benefits in the NHS care setting proposed and clear economic justification and workforce impact.

### Immediate required actions:

1. Pause, reject, or stop engagement with any non-compliant AVT supplier.
2. Stop implementation/use of AVT if standards are not met.
3. Engage with ICB and regional teams for assurance.

NHSE is developing a **national delivery proposal** to enable safe, standardised AVT rollout across England.

Practices considering the adoption of Ambient Voice Technologies (AVTs) must carry out thorough due diligence. **Completing a Data Protection Impact Assessment (DPIA) alone will not be sufficient to demonstrate compliance with NHS requirements.**

LMCs should be aware that some practices have already escalated concerns about specific AVT suppliers to NHSE and GPCE. At present, access to AVT suppliers that appear to meet NHS standards is uneven across GP IT systems (Optum (EMIS) and SystemOne), owing to delays within NHS digital teams in granting IM1 approval for certain suppliers.

The IM1 onboarding process is a structured, NHS England managed pairing approach designed to ensure that products integrating with GP IT systems are subject to appropriate due diligence. This process is carried out in collaboration with Foundation GP Suppliers and covers areas such as technical conformance, clinical safety, and information governance.

For products containing artificial intelligence (AI), this means a review of the whole product documentation will have been undertaken during pairing.

This includes:

DCB0129 Clinical Safety Case and Hazard Log

Data Protection Impact Assessment (DPIA)

Confirmation of medical device registration, where applicable

Hazard Log and Safety Case documentation from any Sub Processors, may also be required as part of their assurance review.

To support LMCs in advising their constituent GPs, a draft template letter is provided below. This can be adapted as needed and sent directly to potential suppliers as part of the practice's due diligence process:

**Subject: Request for Compliance and Assurance Information – Ambient Voice Technology**

Dear [Supplier Name],

Our practice is currently reviewing options for ambient voice technologies and, as Data Controller, we are required to ensure that any product we use is lawful, secure, and compliant with NHS and data protection standards.

To support our due diligence, we would be grateful if you could provide clear responses and supporting documentation in relation to the following areas:

**GDPR and Data Processing**

1. How long is patient voice data (including audio recordings and transcripts) retained and where is the data retained?
2. What mechanisms are in place to ensure data can be deleted promptly — including if requested by the Data Controller?
3. What is your current security posture (overall readiness and ability to identify, defend against, respond to, and recover from cybersecurity threats and risks), and can you share a roadmap of any planned security improvements? Please provide evidence.
4. Do you apply pseudonymisation or anonymisation to patient voice data or transcripts?
  - If yes, what methodology(ies) are used, and at what stage of processing does this occur?
5. Are you using special category patient data for secondary purposes (e.g., for AI training, product improvement, or commercial purposes)? If so, what is your lawful basis for doing so?

**NHS Assurance and Documentation**

6. Is your ambient voice technology covered by valid IM-1 or other relevant NHS assurance approval?
7. Can you provide authenticated assurance documents (e.g., Certificate of Assurance, IM-1 Supplier Conformance Assessment List (SCAL) and associated risk assessments) that explicitly cover this product?
8. Does your NHS assurance documentation cover all functions of the product, including transcription, summarisation, coding, and integration into clinical systems?

**Engagement and Transparency**

9. How do you ensure that compliance commitments made to customers are tracked and delivered?
10. Will you provide up-to-date GDPR, DTAC, and clinical safety documentation on request, and ensure these are maintained as the product evolves?

We would be grateful if you could respond within [X] weeks to enable us to complete our assessment. Thank you for your assistance, and we look forward to your reply.

Yours sincerely,  
[Your Name]  
[Your Role]  
[Practice Name]