Health Diagnostics "Interactive Consultations" Software – Instructions for Use (IFU)

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Owner: Peter Roberts| Reviewed by: Ellie Shackleton

Purpose: This Instructions for Use (IFU) document provides healthcare professionals in the UK with the information required to safely and effectively use *Health Diagnostics' "Interactive Consultations"* software. It details the device identification, intended use, operating instructions, safety warnings, maintenance procedures, and disposal guidelines, as mandated by the UK Medical Devices Regulations 2002 (SI 2002 No. 618, as amended) which transpose the requirements of the EU Medical Device Directive (93/42/EEC). All safety and performance information relevant to users is included, and any residual risks are described. **Read this document carefully before using the software** to ensure proper use and to prevent harm to patients or users.

Health Diagnostics Ltd, Suite C1, The Quadrant,Sealand Road, Chester CH1 4QR

T: 01244 669700 **F:** 01244 373173 **E:** info@healthdiagnostics.co.uk **W:** www.healthdiagnostics.co.uk

Company Registration 4649183

1. Device Identification

Device Name: *Interactive Consultations* – a cloud-based software application for clinical use.

	This software is Medical Device Software (SaMD) **Device classification:** Class 1 (Rule 12) **UK Responsible Person:** Not applicable (UK manufacturer) **UDI-DI:** UDI not required for this device class
	UKCA marked medical device in accordance with the UK Medical Devices Regulations 2002 (as amended) **UK Responsible Person:** Not applicable (UK manufacturer) **UDI-DI:** UDI not required for this device class
	Health Diagnostics Ltd. Mentor House, Ainsworth Street, Blackburn BB1 6AY
	Important to consult the Instructions for Use prior to operation of this Medical Device

Regulatory Status: *UK*CA-marked medical device, classified as **Class I** (General Medical Device) under the UK Medical Devices Regulations 2002 (UK MDR 2002), which reflects the EU MDD classification. This indicates the software meets applicable essential requirements and has been assessed for safety and performance by the manufacturer. The device has been registered with the MHRA (UK Medicines and Healthcare products Regulatory Agency) as required for all medical devices placed on the Great Britain market. (If the manufacturer were based outside the UK, a UK Responsible Person's name and address would be provided on the product labelling or in this IFU, in accordance with UK regulations. In this case, as a UK-based manufacturer, no separate UK Responsible Person is required.) The UKCA marking and relevant device information can be found on the software's "About" screen or accompanying electronic documentation.

Software Type: *Software as a Medical Device (SaMD) – delivered as a Software as a Service (SaaS)*. The software is cloud-hosted on secure servers managed by Health

Diagnostics and accessed via a web browser interface. There is no need to install special software on local computers; users run *Interactive Consultations* through a standard internet browser over a secure connection (see Section 5 for system requirements). The software does not include any physical components or consumables. Health Diagnostics maintains the backend servers and infrastructure that host the application and patient data.

Language: This IFU is provided in English (UK), intended for professional users. In the UK, English is the required language for medical device documentation for healthcare professional use. If this software is supplied in other regions or languages, official translations of the IFU will be provided as necessary.

Note: *Interactive Consultations* is a medical device as defined in UK law (a software intended for diagnosis, prevention, monitoring, or support of patient care). It should be used in accordance with this IFU and under relevant medical device regulations. The software is designed to conform to the Essential Requirements for safety and performance set out in UK MDR 2002 (which corresponds to MDD Annex I requirements). By affixing the UKCA mark, the manufacturer declares that *Interactive Consultations* meets all applicable requirements. (Under UK regulations, certain low-risk devices in Class I or IIa might not require detailed IFUs if they can be used safely without them, but due to the complexity and clinical nature of this software, a full IFU is provided to ensure safe use.) Health Diagnostics, as the manufacturer, is responsible for the device's compliance and has ensured that all necessary information for safe use is supplied here.

For completeness: Software may have been previously CE-marked under the EU MDD prior to the UK's departure from the EU, and CE marking may still be present alongside UKCA marking during the transition period. However, primary certification for Great Britain is now UKCA. The device's Declaration of Conformity and Technical Documentation are maintained by Health Diagnostics and can be made available upon legitimate request by regulatory authorities or clients. Each instance of the software (version/build) is identified on the login page or "About" menu for traceability. Users should always ensure they are using an officially released version.

2. Intended Use

Intended Purpose: *Interactive Consultations* is a clinical decision-support and workflow software tool intended for use by qualified healthcare professionals (e.g. doctors, nurses, pharmacists, or other licensed clinicians) during patient consultations. The software is designed to support in conducting and documenting patient health assessments, by guiding the user through structured consultation steps, suggesting evidence based prompts or calculations, and recording relevant patient data. It aims to improve the consistency, quality, and efficiency of consultations by integrating patient information and clinical guidelines into an interactive digital format.

Clinical Application: The software assists in screening, assessing, and recording patient information during a consultation. For example, a health professional using *Interactive Consultations* can be guided through standardised questionnaires for medical history and lifestyle, automatically calculate health risk scores (such as cardiovascular risk via QRISK3, if applicable), and receive alerts or suggestions based on the data entered. The software can present reference information (like relevant care recommendations) or highlight abnormal values to the user in real-time. This supports clinical tasks such as preventative health checks (e.g., NHS Health Check assessments), routine GP consultations, or specialty specific evaluations, depending on how the software is configured and deployed. Importantly, *Interactive Consultations* does not itself make clinical decisions or diagnoses; rather, it provides information (risk indicators, data summaries, etc.) to inform and support the health professionals own judgment. All final diagnoses, treatment decisions, and advice to the patient are to be determined by the healthcare professional in charge, taking into account the software's output alongside other clinical findings and professional judgement.

Intended Users and Use Environment: The device is intended for professional use only. Users should be licensed healthcare practitioners trained in basic computer use and familiar with the clinical workflows relevant to their practice. Training or orientation on the software's use should be completed before using it with patients (see Section 4, *Warnings and Precautions*). This software is not intended for use by patients or the general public. The typical use environments include hospitals, GP surgeries, clinics, community health centres, or other healthcare settings – essentially any setting where a professional consultation with a patient takes place. Because *Interactive Consultations* is accessed via the internet, an appropriate computing device (desktop or laptop computer, or a tablet) with a secure internet connection is required. The environment should be indoors and professional, e.g. consultation rooms or offices, with standard conditions (comfortable ambient temperature, controlled privacy, and network connectivity). The software can be used during in person face to face consultations or in telehealth scenarios (e.g., the user uses it while on a video call with a patient), as long as the user has access to the software and the patient's information securely.

The software's cloud-based nature means multiple users in different locations (within the organisation) can use it concurrently, and data entered is centrally stored. Healthcare organisations may integrate the software into their existing IT setup (for instance, accessing it over an NHS network, possibly integrating with electronic health record systems). *Interactive Consultations* is suitable for point of care use, but relies on network availability; thus in certain field environments (mobile clinics without connectivity), its use may be limited unless offline arrangements are made (see Section 4 and Section 5 for contingency considerations).

Patient Population: There are no absolute restrictions on patient population from the software's perspective – it can be used for adult or paediatric consultations, male or female patients, etc., provided the content within the software is configured appropriately for that population. Typically, it is used for adult patients in general practice or community health check programmes (for instance, ages 18 and above, or specifically 40-74 in the case of NHS Health Check programs for cardiovascular risk) as its default workflows align with adult health assessments. The software does not directly interact with patients (they do not operate it; the health processional does), so factors like patient mobility or dexterity do not affect its operation. However, if using *Interactive Consultations* for children or special populations, the healthcare provider must ensure that any clinical reference ranges or risk algorithms in use are valid for those groups (e.g., certain risk score calculators apply only to certain age ranges, such as QRISK3 being typically for ages 25–84). In summary, *Interactive Consultations* can be applied to any patient group so long as the healthcare professional uses the software's outputs flexibly and appropriately for that patient's context.

Contraindications and Limitations of Use: There are no medical contraindications to using the software, since it does not involve a physical intervention on the patient. The main limitations are situational and procedural:

- *Not a Standalone Diagnostic:* The software must not be used as the sole basis for making a diagnosis or prescribing treatment (see Warnings in Section 4). It is an adjunct tool. For critical conditions or where the software's suggestions conflict with clinical observations, the user should rely on standard medical evaluation and judgment.
- *Emergency Situations:* In acute or emergency scenarios (e.g., a patient needing immediate resuscitation or urgent care), do not delay treatment to use the software. *Interactive Consultations* is not intended for real-time monitoring of vital signs or critical decision support in emergencies; it's optimised for structured assessments typically lasting several minutes. In emergencies, priority should be given to hands-on medical intervention. The software can be used afterwards for documentation if appropriate.
- *Device/Network Downtime:* Do not attempt to use the software if it is not fully functional, for example if you encounter a system outage, network failure, or obvious malfunction. In such cases, follow your organisation's downtime procedures (e.g., switch to paper forms to capture information) rather than trying to force use of the software. If internet connectivity is lost during a consultation important data might not save to the server – thus it's better to pause and ensure the connection is restored, or record information offline and enter it later. (The manufacturer provides guidance and an offline template for rare extended outages – see Section 5 and 4 for contingency instructions.)

- *Unintended User Groups:* The software is not intended for patients or laypersons to use directly. Patients should not be given control of the software interface, and they cannot be expected to interpret its medical content correctly. Similarly, any non-clinical staff should not use it to make clinical assessments. The interface may contain medical jargon and requires clinical knowledge to navigate.
- *Scope of Clinical Logic:* The decision support content (like alerts or calculators) within *Interactive Consultations* is based on general guidelines and typical scenarios. Patients with unusual or complex conditions might fall outside the scope of the software's built-in logic. For example, a patient with a very rare metabolic disorder might not trigger any of the software's standard prompts but still requires special assessment – the user must recognise such situations and proceed with appropriate care beyond what the software provides. The software's suggestions do not encompass every possible condition or nuance. Always adhere to local clinical protocols and use the software as a supplement.
- *Data Privacy and Consent:* Use of the software should comply with patient consent and data protection regulations. If a patient declines to have their data recorded electronically, the user should respect that and not force use of the software for that patient. (This is not a contraindication per se, but a legal and ethical consideration.)

By understanding these intended use conditions and limitations, healthcare providers can use *Interactive Consultations* in appropriate scenarios to enhance patient care, while avoiding misuse in situations for which it is unsuited.

3. Instructions for Operation

Overview

The *Interactive Consultations* software has been designed to integrate smoothly into routine clinical workflows. Because it is delivered as a web-based service, operation largely involves accessing the system through a web browser on a compatible device and following on screen prompts. Prior to first use in a clinical setting, ensure that you have been set up with a user account and that your environment meets the requirements (see Section 5, *Maintenance and Storage*, for technical prerequisites such as internet access and supported browsers). Users should also complete any training provided by Health Diagnostics or their organisation, so they are familiar with the interface and features (see Warnings in Section 4 regarding training).

Always use the software on approved, secure systems to guarantee performance and patient data security (for example, use it on your workplace computer or tablet that is managed by your healthcare organisation's IT department, rather than an

unsecured personal device). Never use an untrusted or public computer to access patient data via the software.

Follow these typical steps for operating *Interactive Consultations* in the context of a patient consultation:

1. Access and Login:

On your clinic computer or tablet, open a supported web browser (e.g., Google Chrome, Microsoft Edge, Safari – see Section 5 for details) and navigate to the *Interactive Consultations* login page. This is a secure URL provided by Health Diagnostics (often a unique web address for your service or region, e.g., https://consultations.healthdiagnostics.co.uk/login). The exact access method may vary depending on integration; some sites have single sign-on via their intranet. Log in using your authorised user credentials. Each user will have a unique username (or email) and password, or an NHS single sign-on, depending on your organisation's setup. The software uses these credentials to ensure only trained healthcare professionals can access it. Do not share your login details with anyone (each user should use their own account). Upon successful login, you will typically see a dashboard or main menu.

2. Patient Selection

Once logged in, select or identify the patient who is the subject of the consultation. The software may interface with your organisation's patient records system; for example, you might be able to search for a patient by name, NHS number, or date of birth and load their record (if the system is integrated with the GP or hospital registry). Alternatively, for a new patient, you may create a new record by entering their demographics. Verify the patient's identity on screen (confirm you have the correct record loaded by cross-checking name, DOB, address, etc.) before proceeding, to avoid documentation errors (e.g., writing notes in the wrong person's chart). This step is analogous to pulling the correct paper file or opening the right EHR record. Many clinics have a policy of asking the patient to confirm key identifiers – continue to follow those safety practices even when using the software.

3. Initiate Consultation Session

With the patient's record ready, start a new "consultation" or "session" within the software. Depending on configuration, you might click a button like "Start Consultation" or choose a type of consultation from a list (for instance, *General Health Check*, *Follow-up Visit*, etc.). Some implementations automatically start a session when you open a patient's record. At this stage, fill in basic encounter details if prompted: date (usually auto filled), your

name or identifier (if not automatic), and the consultation type or reason (if the software asks for it). The software will then present the user interface for entering consultation data, often structured in tabs or pages following the workflow of a typical consultation. For example, tabs might include sections like *History*, *Examination*, *Risk Calculation*, *Summary*.

4. Data Entry and Interactive Guidance

Work through the consultation steps as guided by the software:

- **Medical History & Lifestyle:** The software may prompt you to enter the patient's medical history, current symptoms, and lifestyle factors. This could be done through checkboxes, dropdown selections, or free-text entry. For instance, there might be fields for smoking status, exercise frequency, diet, family history of certain diseases, etc., as relevant to the consultation. Ask the patient the questions as needed and record their responses. The interface is designed to be user-friendly: some fields may only appear based on earlier answers (branching logic). For example, if you indicate the patient may be at risk of Type 2 diabetes, additional questions about diabetes risk might appear. Fill these in diligently. **Tip:** If the patient has existing records, some information might be pre-populated for you (e.g., existing conditions or medications could display). Verify any such information with the patient for accuracy.
- **Physical Measurements:** Enter vital signs and examination findings. The software will typically have dedicated fields for metrics like blood pressure, heart rate, height, weight (to compute BMI), and so on. It may also accept lab values (like cholesterol or blood glucose levels) if those are part of the assessment – these might be manually input or possibly pulled from integrated lab systems. Ensure units are correct (e.g., mmol/L vs mg/dL if relevant; in the UK context, cholesterol in mmol/L, blood pressure in mmHg, etc.). The system may perform validations; for example, if you accidentally type an implausible value (like a heart rate of 600), it might reject it or warn you. Heed these warnings and correct any entry errors. If certain measurements aren't available or applicable, leave them blank or mark as not done if the software provides that option.
- **Decision Support Prompts:** As you enter data, *Interactive Consultations* may generate real-time prompts or alerts. For example, after entering smoking status and blood pressure, the system might prompt: "Patient is eligible for smoking cessation advice program – consider referral" or if you input a high blood pressure reading, it might alert: "BP above recommended threshold, follow hypertension protocol." Similarly, if the software includes a risk calculator (such as a cardiovascular risk score

like QRISK3), it will calculate that once all required inputs are provided and display the result. These decision support features are meant to aid your clinical decision making by drawing your attention to guidelines or risk estimations. Always interpret these suggestions in context. They are not commands – for instance, a prompt is not an automatic referral, it's reminding you to consider one. Continue to use your clinical judgment. If a prompt seems inappropriate (e.g., suggesting a test that was just done yesterday), you may acknowledge it and not follow it, based on the patient's actual needs. The software may allow you to dismiss or override alerts with a rationale.

- **Patient Engagement Features:** In some settings, you might have the option to share visualisations with the patient (e.g., the software might display a chart of their risk factors or a "heart age" graphic). If you are in a position to do so (like turning the screen to the patient or in a shared telehealth screen), these can be used as educational tools to enhance the consultation. This isn't mandatory for using the software but is a feature to improve communication.
- **Documentation (Notes):** Throughout or at the end, you will have the opportunity to enter free-text notes about the consultation. For example, documenting the patient's chief complaint in their own words, or summarising your assessment plan. There may be a text area labelled *Clinical Notes* or similar. Write your notes as you would in any medical record, capturing pertinent positives, negatives, and your plan. Since *Interactive Consultations* might be used alongside or integrated with formal medical record systems, clarity and completeness in documentation are important. If the software provides a structured format (like separate fields for *Diagnosis* or *Advice Given*), use them accordingly. Ensure that you also record any actions not prompted by the software (for instance, if you noticed an unrelated issue during the exam and addressed it, include that in notes).
- **Mandatory Fields:** The system may enforce completion of certain critical fields before finalising (for example, it might require at least one blood pressure value or a yes/no on smoking status). If you try to proceed without entering something essential, the software will alert you (e.g., "Blood pressure is required to calculate the risk score" or an asterisk indication). At minimum, provide a reason if something cannot be obtained (some systems allow an input like "unable to obtain" or skipping with justification). This helps maintain data quality.

5. Review & Confirmation

After entering all information, it's good practice to review the compiled results on the summary or review screen. Most systems will have a summary that collates the data you entered and presents any calculated outcomes (like risk percentages, recommended follow-ups). Take a moment to cross-check values with what you have on paper (if you jotted vitals down) or with the patient's answers. Verify spelling of any free-text entries (especially diagnoses or names of conditions). This is analogous to reviewing your written notes before signing off. If the software flags any inconsistencies (for example, it might say "Weight not entered, BMI not calculated"), either enter the missing data if available or acknowledge it if it had to be skipped. Ensure that any decision support output (like "10-year CVD risk = 15%") makes sense given the data – if something looks off (say it seems too high or low), double-check the inputs for errors. This review step helps catch mistakes and finalise an accurate record.

6. Finalise and Save

Once satisfied, save the consultation record. In a cloud-based system, data may be auto-saving continuously, but there is typically a formal step to finalise or sign off the encounter. This could be labelled "Complete Consultation", "Save & Finish", or similar. Activating this will lock in the data and timestamp the entry as complete. After finalisation, the record is stored in the system's database associated with that patient. Depending on your workflow, finalising might also trigger certain automated actions, such as sending a summary to the GP's electronic health record, notifying another service (if referrals are made within the system), or making the data available in reporting dashboards. Follow any on-screen instructions upon saving; for example, the system might confirm "Consultation saved successfully" or might present options to print the summary or schedule a recall.

7. Output and Handover

If needed, generate any outputs for the patient or other providers. *Interactive Consultations* may have a feature to produce a patient summary printout or a PDF report of the key findings and advice. If it's part of your practice to give the patient a "take home" summary or advice leaflet, use the software's print function to generate this (usually found on the summary page). Ensure any printed material is given to the correct patient and no sensitive data for others is inadvertently included. Also, if integration with other systems is enabled (for instance, sending a coded result to the patient's GP record via FHIR or similar), confirm that this process has occurred or trigger it as needed. Often, such transfers might be automatic upon finalisation or require clicking

an "Send to GP system" button. Follow your local procedures for sharing data.

8. Logout and Security

After finishing with one patient (especially if you have a gap before the next), log out or lock the session to prevent unauthorised access. Given that the system contains personal health information, you must ensure it is not left open on the screen for others to see. Use the logout function (often found under a user menu or simply by closing the browser if the system auto-logs out on close). If you are moving immediately to another patient, the software may allow quickly switching without full logout but be mindful of confidentiality in shared environments (always at least exit the patient's record). The software will usually auto logoff after a period of inactivity as a safety measure – you may need to log back in if that happens.

Special Considerations for SaaS (Online) Operation

- **Internet Connectivity:** Because *Interactive Consultations* runs via the internet, an active network connection is crucial during use. If your clinic's Wi-Fi or network is unstable, consider using a wired connection for the workstation, if available. In the event of a temporary connection loss, the software might display a warning (e.g., "Reconnecting…"). Do not continue entering large amounts of data during a disconnection warning, as it may not be saved. Wait for the connection to resume (or switch to a backup network if possible). For critical clinics, ensure IT has contingency network plans.
- **Browser Compatibility:** Use one of the recommended browsers (e.g., Chrome, Edge) updated to a recent version. Avoid using deprecated browsers (like Internet Explorer) which may not be supported; if you do, functionality may be broken (e.g., buttons not responding). If the interface appears misaligned or some features don't work, try updating your browser or switching to another supported one. The software is tested on common configurations; contact support if you face compatibility issues.
- **Cloud Data Sync:** If multiple team members are working on the same patient at once (not typical, but possible in some workflows), be cautious – the system usually prevents simultaneous edits on the exact same record to avoid conflicts. If, for example, a nurse starts entering data and a doctor later opens the same in-progress session, follow the on-screen cues: the system might lock one out or require a refresh to see updated info. It's best to have one user complete the consultation record at a time to prevent data overlap.
- **During Consultation Patient Interaction:** You can choose how much to involve the patient in watching you use the software. Some users position the screen, so they maintain eye contact and only intermittently look at it, whereas

others openly share the screen content (especially if visual aids are shown). Use whatever style ensures you still engage the patient effectively and do not let data entry dominate the encounter to the detriment of communication. The goal is for the software to assist, not distract, in the patient interaction.

Error Handling and Troubleshooting

Despite robust design, you may occasionally encounter errors or technical issues:

- If a certain function isn't working (e.g., a button click does nothing), first check for any on screen message or highlighted field indicating what might be wrong (the software often highlights missing required fields in red). Complete any missing info, then try again.
- If the system appears to freeze or become unresponsive, you can try logging out and logging back in or refreshing the browser page. Note that unsaved data might be lost, so it's better to use any "Save Draft" feature (if available) before a refresh.
- If an error message appears (e.g., "Server error" or a code), follow any instruction given (it might say to contact support or try again later). Capture the error details or code to report to your IT support or to Health Diagnostics support.
- In case of a full system outage (cannot access the site at all), revert to paper forms or alternative means to conduct the consultation (as mentioned earlier) and ensure clinical care continues. Health Diagnostics systems are hosted with high availability in mind, so outages should be rare. They will also have support contact channels – keep those handy (e.g., an IT helpdesk number or email).
- The application may display a maintenance notice if it's undergoing scheduled updates ("System maintenance in progress, service will resume at 2:00 AM" etc.). These are typically off-hours. If for some reason maintenance overlaps with your use, follow the same protocol as outage: use offline documentation and input data later once the system is available.

By following these step-by-step instructions, health professionals can effectively incorporate *Interactive Consultations* into their workflow, ensuring that patient consultations are documented comprehensively and that the clinical decision support features of the software are utilised appropriately. Always remember to keep patient safety and data security at the forefront – when in doubt, pause and seek help (either from a colleague, an IT support person, or the software's support resources) rather than proceeding in uncertainty. With practice, using *Interactive Consultations* will become a seamless part of your consultation routine, much like using any electronic health record system or medical device in your practice.

4. Warnings and Precautions

Using *Interactive Consultations* safely requires adherence to certain warnings and precautions. These have been derived from the manufacturer's risk analysis and experience to mitigate potential hazards. Please read and observe all the points below before and during use of the software. "*Warnings*" indicate risks that could result in serious harm to patient or user if ignored, while "*Precautions*" *(Cautions)* indicate measures to prevent misuse or minor harm. In a software context, harm could mean incorrect clinical decisions, data breaches, or loss of important information. All users are responsible for operating the software in compliance with these instructions to maintain safety, effectiveness, and data security.

General Warnings:

- **Supplement to Clinical Judgment – Not a Replacement:** The software is intended to aid clinical decision-making, not replace it. Do not rely solely on the software's outputs for critical decisions or diagnoses. Always verify the software's suggestions against your own clinical assessment and other diagnostic inputs. For example, if *Interactive Consultations* calculates a low cardiovascular risk score but you see concerning signs in the patient (perhaps not captured by the algorithm), do not be falsely reassured by the software – pursue further evaluation as needed. Conversely, if the software flags a high risk or an alert that seems inconsistent with the patient's overall picture, double-check and use professional judgment before acting. Over-reliance could lead to misdiagnosis or delayed treatment, which can seriously harm the patient.
- **Data Entry Accuracy:** The output quality is only as good as the input quality. Entering incorrect or incomplete patient data can lead the software to provide wrong recommendations or calculations. *Warning:* Always double check key entered values. A typo in entering patient weight (e.g., 7 kg instead of 70 kg) could drastically alter a risk score. The software does have validation checks and may warn for improbable values, but it cannot catch all mistakes (especially those that are plausible but incorrect, like swapping systolic and diastolic blood pressure). Thus, the user must ensure accuracy. If you realise an error after finalising, correct the official record according to your clinical governance (which may involve adding an addendum or correcting entry as per system capability).
- **Use by Trained Professionals Only:** *Interactive Consultations* is for use by qualified healthcare professionals. It is not to be used by patients or untrained staff. *Warning:* Under no circumstances should a patient be allowed to self-assess using this software unsupervised, nor should administrative personnel use it to triage patients without clinical oversight. Unauthorised or untrained use could result in misinterpretation of the information and subsequent harm (e.g., a patient seeing an unfiltered risk result might panic or misjudge their

condition). Always restrict access to those with appropriate clinical training and ensure each user has unique login credentials that are kept secure.

- **Initial Training and Ongoing Competence:** *Precaution:* Users must be adequately trained on the software before using it clinically. Even though the interface is designed to be intuitive, training covers things like how to properly enter data, interpret risk outputs, handle alerts, and what to do during technical issues. Skipping training increases the chance of user error – e.g., a user might misread an on screen value or skip a section inadvertently. Health Diagnostics typically provides user guides or training sessions; new users should utilise these. If you are unsure about any feature, consult the user manual or seek additional training rather than proceeding incorrectly. Periodic refreshers are advisable, especially when the software is updated or new features are introduced.
- **No Modification or Unauthorised Integration:** *Warning:* Use the software as provided by the manufacturer, without attempting to modify, reconfigure beyond intended settings, or extend it with unofficial add-ons. This includes not trying to tamper with the browser console, injecting scripts, or using the software's API (if any) in unintended ways. Any software changes could bypass safety features or introduce errors. For instance, using browser plugins to auto-fill fields might seem to save time but could input wrong data in wrong places. Only use plugins or modules that are explicitly approved by Health Diagnostics. If an integration with another system is needed (say to fetch lab results), it should be done via official channels (approved interfaces) rather than custom hacks. Unauthorised modifications not only violate the software licence but can create unpredictable hazards.
- **Cybersecurity and Access Control:** *Precaution:* Because this is a networked software handling sensitive personal health data, maintaining cybersecurity is paramount. Your organisation's IT department and Health Diagnostics will handle server security, but end users must also follow security best practices. This includes:
    - Never sharing your login credentials. If you suspect your password is compromised, change it immediately.
    - Use strong passwords that are hard to guess (the system may enforce some complexity). Do not write passwords where others can find them.
    - Log out after use, as mentioned, and lock your workstation when stepping away (even briefly).
    - Only access the system from secure networks. Avoid using public Wi-Fi with this system unless you're on a VPN. In hospital/clinic, ensure your device has up-to-date antivirus and firewall as maintained by IT.
    - Be wary of phishing – any unexpected emails asking for your login info or offering software "patches" should be treated suspiciously and verified through official channels.

- Health Diagnostics implements robust encryption and data protection (compliant with UK GDPR and NHS Digital standards), but a careless user (like leaving a session open on a public computer) can still cause a breach. A data breach could lead to patient confidentiality being compromised or even identity theft. It's part of your professional duty to handle patient data responsibly.
- **Recognise and Report Malfunctions:** *Warning:* If the software behaves abnormally, stop using it for clinical decisions and seek support. Examples of malfunctions include:
    - Calculations that are obviously incorrect (e.g., a 30-year-old with modest risk factors showing a 90% 10-year risk of heart disease – clearly an outlier).
    - The interface freezing or not responding to inputs in the middle of a consultation.
    - Data not saving or loading incorrectly (e.g., you enter notes, but they disappear).
    - An error message like "Application Exception" popping up.
- Continuing to use the software in such a state might result in wrong data being recorded or crucial information not being available. Instead, switch to an alternative method (paper notes, etc.) to continue the patient's consultation safely. Immediately after, document what happened with the system and contact technical support. Health Diagnostics provides a helpdesk for issues; have details like the time of incident, what you were doing, and any error codes ready. Do not attempt to troubleshoot beyond basic steps (refresh, reboot) unless guided by IT – for instance, don't try to fix the database or code yourself. Using the device while knowingly malfunctioning is dangerous and could also void liabilities. Once resolved, double-check any data entered around the time of the glitch for accuracy.
- **Follow On-Screen Warnings:** The software itself will present on-screen warnings or advisories which are part of its safety features (for example, a pop-up might warn "Unsaved data will be lost if you navigate away" or "Patient age out of expected range for this module"). *Precaution:* Always read and act on these. They are not mere suggestions; they often indicate a potential safety issue or workflow requirement. If you bypass or ignore them, you may inadvertently cause harm or data loss. For example, if you ignore a warning about unsaved data and go back, you could lose that data permanently and have to re-gather information from the patient (which might be impossible if the patient has left). If a warning says a certain module is not intended for patients under 18, do not attempt to force the software to use it for a younger patient – the content may not be valid for them. The warnings are part of the information for safety provided by the software design (akin to label warnings on a pill bottle) and should be treated with equal seriousness.

In addition to the above general points, refer to the quick-reference table below summarising key safety warnings and precautions:

Safety Warning or Precaution	Description and Rationale
Professional Use Only – No Self-Use by Patients.	**Warning:** Only qualified healthcare professionals should use *Interactive Consultations*. Patients or untrained individuals **must not operate the software or act on its outputs alone**. The medical information presented requires clinical interpretation; without proper training, a user could misunderstand risk scores or prompts, potentially leading to anxiety or harmful actions. Access is controlled via logins to enforce this. Always ensure you have logged out to prevent an unauthorised person from viewing or using the system under your session.
Training Required Before First Use.	**Precaution:** All users should undergo training or read the full user guidance before using the software in practice. Training ensures familiarity with the interface, how to properly enter data, and what the various outputs mean. Using the device without training could result in misuse – e.g., skipping a section unknowingly or misinterpreting a risk percentage. If you are unsure about something during use, stop and consult the training materials or seek help rather than guessing.
Do Not Use as Sole Basis for Care Decisions.	**Warning:** *Interactive Consultations* is **not a standalone diagnostic tool**. Never make a clinical decision (diagnosis, treatment change, etc.) based only on what the software tells you. For example, if the software doesn't flag any issues, but you clinically suspect something, you must investigate further despite the software. Conversely, if it flags a high risk but you have contrary evidence, validate the situation rather than acting blindly. Always corroborate findings with physical exams, patient history, and possibly additional tests. This redundancy ensures that an error or limitation in the software doesn't directly translate into patient harm.
Ensure Accuracy & Completeness of Data Entered.	**Precaution:** Double-check all entries, especially critical values (like identification, allergies, test results). The phrase "garbage in, garbage out" applies: **wrong input = wrong output**. The software will warn for obviously missing or out of range data, but it cannot tell if you selected the wrong patient or mistyped a number that is still plausible. Make sure each patient's data is in their own record. If you paste or import data, verify it's correctly placed. When possible, use the software's integration features (like pulling demographics from the NHS Spine (PDS service) or GP system) to minimise manual entry errors. The user carries responsibility for final data correctness.
Use Only Manufacturer-	**Warning:** Do not attempt to alter the software's code or use unofficial patches/extensions. For instance, do not install any

Provided Software Versions.	browser plugin specifically meant to manipulate *Interactive Consultations* unless approved by Health Diagnostics. Tampering can disable safety mechanisms or cause calculation errors that are not immediately visible. Health Diagnostics validates each release version for safety – a modified version is unvalidated and could be dangerous. If you think the software lacks a needed feature, request it through proper channels rather than trying to build it yourself.
Maintain Cybersecurity (Device & Network).	**Precaution:** Protect patient data by following IT security best practices. This means use strong, confidential passwords and change them periodically, keep your computer's security software up to date, and only use the system on secure networks. If you suspect malware on your workstation, refrain from accessing patient records until it's resolved, as keyloggers or similar malware could steal information. Avoid saving patient data to unencrypted local files (e.g., don't copy and paste data to personal notes outside the secure system). All data within *Interactive Consultations* is stored on secure servers (e.g., in UK data centres with NHS Digital DSPT compliance), but if you export data, its security becomes your responsibility. Always log out to prevent unauthorised access — an unattended logged-in session could be exploited by others.
If Software Malfunction, Cease Use & Report.	**Warning:** If you encounter a software bug or malfunction that could affect patient data or recommendations, **stop using the software for clinical purposes immediately**. Switch to a backup method (like paper charts; and/or supplied offline templates) to continue the consultation. Do not continue entering new data, as it might not save correctly or may propagate the error. **Inform technical support** as soon as possible with details (time, what you were doing, patient ID if relevant, screenshots if safe to capture without patient info). The sooner issues are reported, the quicker they can be addressed. Continuing to use a malfunctioning system could lead to documentation loss or incorrect outputs that might mislead care.
Adhere to On-Screen Alerts & Guidance.	**Precaution:** Pay attention to any alert boxes, coloured highlights, or advisory text the software shows. These are built-in safety prompts. For example, if a pop-up warns that "This patient is under 18 – paediatric norms may not apply," it is cautioning you that certain automated guidance might be invalid for that patient's age. Likewise, a yellow highlight on a field may indicate an abnormal value – prompting you to double-check it. Follow any suggested actions (fill in missing data, confirm an override, etc.). These messages are part of the risk control measures by design; ignoring them

	may reintroduce risk (like incomplete data leading to false conclusions).

Additional Notes on Safe Use:

- **Audit Trail:** Be aware that all user actions in the software are logged (each entry is tagged with user and time). This is important for patient safety and accountability. If an incident occurs, the logs can be reviewed. Users should never attempt to falsify or hide entries – not only is this unethical, but the system will have an audit trail.
- **Concurrent Sessions:** Avoid having the same user account open in two places at once (say, your PC and a tablet simultaneously). This could potentially cause save conflicts or audit confusion. If you need to switch devices, log out from the first before continuing the second.
- **Clinical Validation of Updates:** When the software is updated (new version), take note of any changes in behaviour of calculations or protocols. Health Diagnostics will usually highlight these in release notes. If new warnings or options appear, incorporate them into your practice. Essentially, stay informed about the tool you are using – treat it as you would a piece of medical equipment that could be updated or recalibrated.
- **Risk of Data Loss with Improper Shutdown:** Because *Interactive Consultations* is an online tool, closing the browser or turning off your computer too quickly could risk losing the last-entered data if it hadn't saved. Always use the provided interface buttons to navigate and save, rather than relying on the browser's close or back button. If you accidentally close the session, log back in promptly – the system may or may not have saved your progress. Re-enter anything missing.
- **Contingency for Downtime:** Users should be prepared (and trained) on what to do if the software is unavailable. This might involve using paper forms that mirror the electronic workflow, which can later be transcribed into the system. In some cases, Health Diagnostics provides an "offline template" (for example, a printable consultation form to use when the system is down). Familiarise yourself with these procedures as part of safe practice – it ensures continuity of care.
- **Patient Identification***:* When printing or exporting data from the system, ensure it is labelled correctly and handed or sent to the correct patient/destination. Misdirected communication is a safety/privacy issue. The system might auto-fill identifiers on printouts; verify them.
- **Integration Points: If** *Interactive Consultations* sends data to other systems (like GP electronic health records), monitor those transfers periodically. Make sure, for example, that referrals you mark in the system actually get received by the target system. While the software automates such tasks, a precaution is to

periodically confirm the backend processes (especially early in adoption). Any integration failure could mean information isn't reaching where it should, affecting patient follow-up.

By following all these warnings and precautions, users will greatly minimise the risk of errors or harm associated with using *Interactive Consultations*. The manufacturer has implemented these in line with regulatory expectations (in the UK, meeting requirements akin to MDD Essential Requirements on information for safety). Users should consider these not as optional advice but as integral to the correct use of the medical device.

Incident Reporting: If any serious incident occurs in relation to the software – for example, if a patient is harmed or nearly harmed because of something to do with the software (malfunction or misuse) – you must follow your organisation's incident reporting procedures and also report it to the manufacturer (Health Diagnostics). In the UK, healthcare professionals are encouraged (and for manufacturers, required) to report adverse incidents involving medical devices to the MHRA (Medicines and Healthcare products Regulatory Agency) via the Yellow Card scheme or other designated pathway. Timely reporting allows the manufacturer and regulators to investigate and take action (like issuing warnings or software fixes) to prevent future occurrences. Health Diagnostics, as the manufacturer, will also carry out vigilance activities and feedback any findings to users (see Section 7 on Post-market surveillance). Remember, maintaining patient safety is a collaborative effort – your vigilance in using the device and reporting problems is a critical component.

5. Maintenance and Storage

System Requirements and Configuration (Client Side)

- **Hardware (Client Devices):** The software can run on any reasonably modern computer or tablet that supports a web browser. It does not require heavy processing on the client (most processing is server-side), but a recommended baseline might be: a device with at least 4 GB of RAM (8 GB preferred), a dual-core processor, and a screen with ≥1280x800 resolution so you can see all interface elements clearly. In practice, any standard GP surgery desktop or a modern tablet like an iPad or Surface Pro should suffice. If your device is extremely old and slow, you might experience lag in the browser – if so, consider an upgrade as per your organisation's IT renewal cycle. There is no specialised hardware needed (no dongles or specialised monitors).
- **Operating System & Browser:** *Interactive Consultations* is OS-agnostic to a large extent; it works on Windows, macOS, iOS, etc., as long as a supported browser is used. Officially supported browsers include Google Chrome, Microsoft Edge, Mozilla Firefox, and Safari (for iPad or Mac), in their latest versions. Microsoft Internet Explorer is not supported (and is obsolete). Google Chrome or Edge on Windows 10/11 are common choices. Using the latest OS

security updates is important too (e.g., ensure Windows updates are applied) to protect the environment. The client system should be configured to allow the *Interactive Consultations* site through any local firewalls or proxy filters (some NHS networks have strict web filtering; your IT should whitelist the service's URL).

- **Network and Connectivity:** Since it's cloud-based, you need a reliable internet connection. Within NHS or clinic environments, this might mean a secured broadband or N3/HSCN network connection. Bandwidth: the software exchanges relatively lightweight data (text and some images) so it doesn't require massive bandwidth, but a stable connection with at least a few Mbps is recommended. Latency should be low for best experience (if using over a satellite link with high latency, you might notice slowness). If using over Wi-Fi, ensure good signal in consultation rooms. If using via mobile hotspots or 4G/5G (for example, in community outreach settings), verify the signal and data plan are adequate. All communications are encrypted (HTTPS); make sure your network allows HTTPS traffic to the service domain.
- **Server-Side (Manufacturer) Configuration:** While users do not manage the servers, it's worth noting that Health Diagnostics hosts the service in ISO 27001-certified data centres within the UK, with redundancy (primary and backup servers, failover plans). This means downtime should be minimal and data is regularly backed up by the provider. The user's role is mainly to report any performance issues that might indicate something is off on the server (e.g., the system consistently slow at certain times).
- **Integration Setup:** If *Interactive Consultations* is integrated with other systems (EHRs, lab systems, etc.), some configuration is needed during initial deployment. This is generally handled by Health Diagnostics' implementation team in collaboration with your IT department. Once set, it usually doesn't require user intervention. However, if you notice an integration isn't working (e.g., data not flowing to GP system), that might require maintenance attention – inform support.

Data Management and Backup

In a cloud service, data is stored on the central server/database maintained by the provider. Health Diagnostics will have backup routines (e.g., nightly backups of the database, possibly real-time replication to a secondary data centre) to prevent data loss. This means that the burden of backup is not on the end-user – you don't need to manually back up patient consultation records locally (and indeed, for data protection reasons, you shouldn't download and store bulk patient data on local drives unless absolutely necessary). However, ensure that any explicit data export you perform (like downloading a set of reports for local analysis) is stored securely by your organisation and also backed up in your context if needed.

In the event of a catastrophic system failure at the provider side, Health Diagnostics' disaster recovery plans would be executed to restore data from backups (with potential minimal data loss in the last minutes/hours, depending on replication). As a user, it's wise to keep your own small notes if you feel concerned – for instance, if you entered a very critical piece of information right before an outage, note it down somewhere safe just in case. But routine manual backups by users are not required.

That said, local data caching: The application might cache some data on your device for performance (e.g., elements of the user interface, possibly last accessed patient info). This is usually ephemeral and not something you directly manage. Clearing your browser cache occasionally can help if you experience odd behaviour but note it will also log you out and remove any local storage – do this only if advised in troubleshooting.

User Management and Access Maintenance

Part of maintenance is keeping the user list up to date:

- When staff join, have a process to create their accounts (maybe through an admin portal if your site admin has one, or by requesting account creation from Health Diagnostics).
- When staff leave or no longer require access, promptly deactivate or delete their accounts to prevent unauthorised use. This is important for license management and security.
- Periodically review user roles and permissions. The software might allow assigning roles (e.g., Administrator, health professional, Read-only, etc.). Ensure people have the correct level of access. For example, only certain users should be allowed to bulk export data or configure settings.

Monitoring and Performance

While Health Diagnostics will monitor the health of their service (server performance, error logs), your local IT can monitor things like network connectivity and device performance. If multiple users report slowness, your IT should check if the network is congested or if there's a local issue. As an end user, report performance issues so they can be investigated – don't just tolerate a chronically slow system, as it may be fixable (perhaps a network equipment upgrade or a call to the provider if it's on their end).

Security Maintenance

Ensure your organisation's antivirus software is maintained on client machines that use the software. The risk of malware on a client machine includes potential unauthorised screen access or keystroke logging of sensitive data. So keep those defences up (IT typically manages this). Similarly, operating system updates (which often patch security holes) should be applied regularly on client PCs. The software

will work on updated systems; don't avoid OS updates for fear of breaking it (if any incompatibility were to arise from a major OS upgrade, the provider will communicate, but that's rare for web apps).

Configuration Management (for Customisable Elements)

Some aspects of *Interactive Consultations* might be configurable to your setting – for instance, custom question sets, local referral options, thresholds for certain alerts. These are usually set during implementation. Over time, your clinic's needs might change (e.g., adding a new module for a new local program, or changing a threshold for an alert according to new guidelines). Managing these changes would likely involve the software's admin interface or contacting the provider. If you have access, document any changes you make and inform users (e.g., "We updated the smoking cessation referral option to the new provider, which now appears in the advice section"). Periodically review these configurations to ensure they are up to date with current clinical practice. For example, if a risk calculator in the software receives an update, check that any local risk thresholds for action are still appropriate.

Scheduled Maintenance by Provider

As mentioned, the provider may have scheduled maintenance (which could involve downtime). They usually give notice. Make sure such notices reach the end users – sometimes an email might be sent to an admin who needs to forward it. If your organisation has a lot of users, designate someone to disseminate maintenance notices so no one is caught off guard.

Storage Conditions for Hardware: Even though the "device" here is software, the hardware you use (computers/tablets) should be cared for:

- When not in use, keep devices in a secure, indoor environment with standard conditions. Avoid extreme temperatures, moisture, or dust exposure for the client devices. For example, don't leave the clinic laptop in a car on a freezing night or a hot day. Not only can hardware be damaged, but patient data security could be at risk if a device is stolen from an insecure location.
- **Physical Security:** Lock portable devices away after hours. Use Kensington locks for desktops if in semi-public spaces. This prevents theft of devices that can contain cached access to patient info. Also ensure screens are positioned to avoid shoulder-surfing by unauthorised people, especially in reception or public clinic areas. Use privacy screens if needed.
- **Power Supply:** Ensure devices are powered reliably. For desktop PCs, use surge protectors to protect against electrical spikes. In critical scenarios (like a clinic where power outages happen), consider having a UPS (Uninterruptible Power Supply) so that you can gracefully save work and log out if power fails unexpectedly. For tablets, keep them charged; an unexpected shutdown mid-consultation could lead to data loss if input wasn't saved yet.

- **Cleaning:** If devices are shared and need cleaning (especially relevant in healthcare settings with infection control), follow proper cleaning procedures that won't damage them. E.g., use appropriate wipes for keyboards and touchscreens. The software itself doesn't need "cleaning", but the hardware does.

Maintenance of Related Systems

If *Interactive Consultations* connects to other systems (like pulling data from an EHR or sending letters to a printer), maintain those connections. For instance, keep printer drivers updated if the software prints directly, or ensure the EHR integration token is renewed before expiration. Health Diagnostics support can help if an integration stops working due to a configuration change (like an API key rotation).

Expected Service Life

With software, the concept of a "lifetime" is a bit different than a physical device. However, Health Diagnostics might consider a version of the software supported for a certain number of years. They will provide updates throughout, and likely transition users to newer versions or platforms as technology evolves. Typically, the service is ongoing, but if at some point the product will be retired or replaced by a new platform, the manufacturer will inform clients well in advance and assist with migration. As a user, you should remain engaged with these communications to plan training or data migration if a big upgrade is on the horizon. Based on industry practice, major overhauls might happen every several years, but incremental updates are frequent.

Responsibility Split in SaaS

It's worth clarifying:

- **Health Diagnostics (Provider) responsibilities:** server infrastructure, software functionality, security of data on the server, regular backups, regulatory compliance of the software, fixing bugs, providing updates, availability of support.
- **Customer (Clinic/Organisation) responsibilities:** providing suitable client devices and network, maintaining user access control, ensuring staff are trained, using the software according to instructions (including updating any local content configuration), reporting issues, and ensuring data outputs are handled appropriately (e.g., integrating with local workflows).

Support and Contact Information

Keep a record of how to contact Health Diagnostics support (e.g., email support@healthdiagnostics.co.uk or a phone number). Also know your internal IT support contact. Many issues can be resolved quickly with their help, so don't

hesitate to reach out for maintenance questions (like "How do I add a new user?" or "We have a new clinic starting to use it, what to configure?").

By adhering to these maintenance and storage guidelines, the software should function optimally over its service life, and the risk of downtime or data issues will be minimised. In summary: stay updated, stay secure, and communicate with the support teams when needed. This proactive approach to maintenance is part of the device's safe use.

6. Disposal

"Disposal" for a software-based medical device primarily concerns termination of use and data handling when the software (or the hardware it runs on) is no longer needed. Even though software isn't a physical object to throw away, there are important steps to ensure that when you stop using *Interactive Consultations*, no sensitive data is left accessible and any hardware used is properly managed. Below we address disposal in terms of: discontinuing the service (software decommissioning), and disposing of any hardware or media that may contain patient data (like computers or backup drives).

Discontinuing the Software Service (End of Contract or Use)

If your organisation decides to stop using *Interactive Consultations* – for example, switching to a different system or if a project ends – you should:

- **Export Needed Data:** Before termination, review what data needs to be retained for legal or clinical reasons. The service likely hosted all consultation records. Healthcare regulations (and good practice) often require patient records to be kept for a number of years (in the UK, adult records typically at least 8 years, and longer for certain types like paediatric or occupational health records). You may have an EHR into which information was already transferred after each consult. If not, you should export the records from *Interactive Consultations* in a readable format (like PDF or CSV) to store in your official record archive. Health Diagnostics can assist with a full data export if needed (especially if there's a lot of data). Ensure this export is done securely – e.g., encrypted files if stored on physical media for transfer. Once transferred to your custody, protect it under your data protection protocols.
- **User Accounts Deactivation:** As part of decommissioning, all user accounts on the system should be deactivated to prevent any further login. Health Diagnostics can do a bulk deactivation once the service period ends, or your admin can do it if you have that capability. This ensures nobody can log in after your organisation's use is supposed to cease.
- **Request Data Deletion from Provider:** Under UK GDPR and likely your contract, once you leave the service you can instruct the provider to delete or pseudonymise the personal data that was hosted, unless retention is required

for legal obligations. Health Diagnostics would then securely erase patient-identifiable data from their servers after confirming you have what you need. Typically, they might keep a backup for a short period in case you realise you need something, but they'll adhere to data protection law, meaning they won't keep your patient data indefinitely without purpose. They should provide confirmation when data deletion is completed, if you request it.

- **Obtain Documentation:** It's prudent to get a formal statement or certificate from Health Diagnostics confirming that the service has been terminated and data handled appropriately (e.g., "All data for Client X was securely deleted on date Y"). This can be useful for compliance audits.
- **Inform Users:** Let all staff know the date after which they should not use the system, to avoid anyone trying to log in and potentially being confused or entering data that isn't captured elsewhere.

Uninstallation (if any local components)

In most cases, *Interactive Consultations* is accessed via browser, so there is no application to uninstall on each PC (beyond perhaps a desktop shortcut or link). If any local software was installed (for example, sometimes optional components like a device integration plugin), those should be uninstalled via your OS (Control Panel on Windows, etc.). Removing such components ensures no orphan processes remain. It's minor since a browser-based system often just leaves cached files which can be cleared.

Secure Data Deletion on Local Devices

One often overlooked aspect is that local devices might cache or store some data:

- Web browsers might have cached pages or data (though sensitive data is usually not cached or is cached encrypted).
- If any data was exported or saved locally (e.g., PDFs of consultation summaries saved to a local drive), ensure those are either moved to secure storage or deleted from the local machine.
- If users downloaded any reports onto their Downloads folder, those should be cleared.
- If any temporary files were created (some software might create temp files), use a secure deletion tool as per your IT policy to remove them.
- Basically, treat the local PC as you would when decommissioning any system that handled patient data: do not just delete files normally (as that can be undeleted); instead, use tools that overwrite data or physically destroy drives if appropriate.

An easy approach if the device itself is to be repurposed or disposed: wipe the entire device to factory settings or per IT standards. This ensures no residual data in caches, etc. Of course, backup anything else the device needs first.

Hardware Disposal

If the computers or tablets used for *Interactive Consultations* are at the end of their life:

- Follow your organisation's IT asset disposal procedure, which likely aligns with standards like the UK's WEEE Regulations (Waste Electrical and Electronic Equipment) for environmental disposal, and with NHS information governance for data. Typically, this means either the device's storage (hard drive or SSD) is removed and destroyed, or the device is encrypted and then sent to certified recycling where destruction is verified.
- **Important:** Even if the software is cloud-based, those computers might have had patient data on them (in caches, or in other apps). So they should be treated as containing personal data. Before disposing of any device, ensure all patient data on it is securely erased or the storage destroyed. For PCs, a 3-pass overwrite or degaussing or physical shredding of the drive are common methods. For encrypted drives, if the encryption keys are securely destroyed, that can suffice.
- Remove any removable media or smartcards that were used specifically for the software (though unlikely for a web system). Ensure no USB sticks with exported data are lying around – if they were used, they should be securely wiped or destroyed.
- **Environmental:** The devices should be handed to an e-waste recycler or IT disposal service that certifies wiping and recycling. Don't just toss them in the bin. They contain materials (like lithium, lead, etc.) that require proper handling. In the UK, many organisations have contracts with IT disposal firms that provide certificates of destruction for drives and environmentally recycle the rest.

End of Life of Software (if still continuing use of hardware)

If the hardware remains but *Interactive Consultations* is simply not to be used anymore (say you keep the PCs for other tasks):

- Remove any bookmarks or shortcuts to the software to avoid accidental attempts to use it.
- Clear saved passwords in browsers for that site, so there's no auto-login lingering.
- Essentially "delink" the hardware from the service entirely.

Documentation and Record-keeping

Maintain a record of when the system was decommissioned and by whom. Note that as a medical device, your organisation's clinical governance might require you to log the decommissioning date of the device in an asset register. Also, keep evidence of data migration and deletion. For instance, store the certificate of data

destruction from the provider (if provided), and list of files you archived to, say, your EHR or a secure drive. This protects you in case later there are questions like "where is the data from that service?" – you can show it was properly transferred or disposed. It's also useful if in the future a patient makes a data subject access request; you know which system (active or archive) their data is in, even if the live system is gone.

Legal Considerations

Under UK data protection law, once you no longer have a need to retain personal data, you shouldn't keep it indefinitely. So if *Interactive Consultations* held some data not needed elsewhere, make sure it's deleted. However, as mentioned, patient medical data often has an ongoing purpose (continuity of care, medico-legal record keeping). Align the disposal plan with advice from your Data Protection Officer or Caldicott Guardian on what data must be kept and what can be purged.

Continued Obligations

If the device was registered with MHRA, deregistration isn't typically needed just because one user stops using it – the manufacturer keeps it registered as long as it's on the market. However, if you were participating in any post-market surveillance (like surveys or reporting agreements), kindly inform the manufacturer that you are no longer using the device, so they can update their user base records and possibly learn why you stopped (manufacturers appreciate feedback).

Transferring to Another User (if applicable)

If, instead of full disposal, the responsibility of the service is being transferred (say one clinic to another, or one region to another provider):

- Ensure a clear handover of data and responsibilities. Perhaps both parties and the manufacturer coordinate to migrate data or accounts.
- Update any data processor agreements accordingly (if a new entity becomes data controller).

Final Device Cleanup Checklist (for local IT)

- All user accounts on *Interactive Consultations* deactivated.
- Data exported and saved to [location], verified readability.
- Provider confirmed deletion of cloud data (or scheduled as per contract).
- Browser caches cleared on all devices.
- Any local installation components uninstalled.
- All hardware drives securely wiped or destroyed (if hardware also being disposed).
- Documentation of the above steps filed (with dates and responsible persons).

Following these steps ensures that when *Interactive Consultations* is phased out, it does not leave behind any stray data or access that could pose a risk, and that you

continue to meet your obligations for patient record retention and confidentiality. In essence, "disposal" here is mainly about data disposition and access termination. Always handle this phase as diligently as you would the initial deployment – it's the last step of the device's lifecycle in your practice and just as important for safety and compliance.

7. Regulatory Compliance and Updates

This section details how *Interactive Consultations* complies with the relevant UK regulatory framework and outlines how ongoing regulatory updates are managed. In the UK, medical devices (including software) are governed by the **UK Medical Devices Regulations 2002 (SI 2002 No. 618, as amended)**, often referred to as UK MDR 2002. These regulations essentially incorporate the requirements of the EU Medical Device Directive (MDD 93/42/EEC) into UK law, with some adjustments for the UK market (post-Brexit). They require that devices are safe, perform as intended, and have appropriate evidence of compliance (technical documentation, conformity assessment, etc.). They also mandate that devices be accompanied by sufficient information for use (like this IFU) in the local language.

UKCA Marking and Conformity

Interactive Consultations is UKCA marked, indicating that it conforms to the UK MDR 2002 requirements for medical devices when placed on the market in Great Britain . As a software medical device, it has been classified by the manufacturer under the classification rules in those regulations. The device is classified as Class I (General Medical Device), which is the lowest risk class, typically applicable because the software provides support for decisions but is not directly controlling a high-risk therapy or making irreversible diagnoses on its own. Under UK rules, Class I devices (that are non-sterile, non-measuring) do not require a conformity assessment by an external Approved Body; the manufacturer can self-declare conformity. Health Diagnostics has done so by drawing up a UK Declaration of Conformity, and by registering the device with the MHRA (which is required for all classes of devices in the UK). The UKCA mark on the device's documentation signifies that these steps have been completed and the device meets the Essential Requirements of the regulations (schedule 2A of UK MDR 2002, which mirrors Annex I of the MDD).

For the user, this means the device has been subjected to risk management, usability engineering, and technical verification processes to ensure it is safe and performs as claimed. The device identification, intended purpose, and safety warnings in this IFU are all part of fulfilling those Essential Requirements (ER 13 of the MDD/UK MDR pertains to information to be supplied).

The EU's newer Medical Device Regulation (EU MDR 2017/745) does not apply in Great Britain, but Health Diagnostics has taken into account its principles to future-proof the product.

Post-market Surveillance and Vigilance

Health Diagnostics, as the manufacturer, maintains a post-market surveillance (PMS) system as required by the regulations. This means they systematically gather feedback on device performance, track any complaints or adverse incidents, and update the device or IFU accordingly. For example, if multiple users reported confusion about a certain prompt leading to potential misuse, the company would investigate and possibly update the software interface or clarify the IFU. The vigilance system includes reporting of serious adverse incidents to the MHRA. As a user, if you report an incident to them, they will document it and take necessary action (and you should also report to MHRA as noted in Section 4). The MHRA may also issue safety communications (Field Safety Notices) if any serious issue is identified. Health Diagnostics is committed to addressing any such safety issues immediately – for instance, by a software patch or an interim advisory to users. In short, the device is under continuous monitoring even after deployment, in line with regulatory obligations to ensure ongoing safety.

UKCA Labelling

On the software's splash screen or accompanying info (perhaps within the "Help -> About" section or on the packaging of any printed manual), you'll find the UKCA symbol. For Class I devices, no Approved Body number is attached to it (since none was involved). You will also see the manufacturer's name and address (Health Diagnostics Ltd, Chester, UK) clearly given (which we have also listed in this IFU in Section 1). If this software were to be marketed in Northern Ireland or the EU, appropriate CE marking and possibly UK(NI) marking would be used under those jurisdictions, but for Great Britain, UKCA is the mark of conformity.

Registration with MHRA

As per current UK rules, Health Diagnostics has registered *Interactive Consultations* with the MHRA's device registration system (every Class I device and above must be registered before being put on the market in GB). This means the MHRA has on file details of the device, its risk class, and the Responsible Person (not applicable since the manufacturer is UK-based). For users, this doesn't directly affect day-to-day use, but it's part of the regulatory compliance picture ensuring the device is known to regulators.

Standards and Quality Systems

Health Diagnostics asserts that the development and maintenance of *Interactive Consultations* comply with relevant standards:

- Risk management is performed according to **ISO 14971:2019**, which means all foreseeable risks have been identified, evaluated, and mitigated or accepted, and many of the warnings in this IFU serve as risk control measures for residual risks.

- The usability has been engineered following **IEC 62366-1:2015**, ensuring that the user interface design has considered potential use errors and is user-friendly. This was evidenced by formative and summative testing with real users during design.
- The software was developed within a quality management system certified to **ISO 13485:2016** (medical device quality management) – this ensures controlled design, verification, and validation processes. (While not explicitly in the IFU, most manufacturers will operate under ISO 13485 for regulatory compliance).
- Information provided here follows standards like **ISO 20417:2026 and ISO 15223-1:2021** for medical device information and symbols. For example, if any symbols are used (like the warning triangle ⚠ or the "authorised representative" symbol), they conform to those standards.
- Security considerations align with guidelines (e.g., **MDCG 2019-16** for cybersecurity for MDR, which we voluntarily follow for GB). This means the software has features and instructions (as we described) to ensure cybersecurity hygiene.
- The Company is also ISO 27001 certified for information security adding another layer of assurance for data protection.

Future UK Regulatory Changes

The UK government has signalled an intention to strengthen and update the medical device regulations (potentially aligning more with MDR requirements) in the coming years. As of the last update of this IFU (December 2025), the UK MDR 2002 remains in force, with acceptance of CE-marked devices extended until at least 2028 for MDD-compliant and 2030 for MDR-compliant devices on the GB market. Health Diagnostics is tracking these developments. When the UK introduces a new regulatory framework (often referred to as "UK MDR Plus" informally), we will ensure the device conforms to any new requirements by the applicable deadlines. This could involve, for instance, implementing a Unique Device Identification (UDI) system in the UK. If so, a UDI code will be assigned to *Interactive Consultations* and made available on labelling and documentation (a UDI is basically a barcode that uniquely identifies the software version and manufacturer). For now, UDI isn't mandatory in GB, but we already have identification mechanisms in place so that adding UDI when required will be straightforward.

MDR (EU) Considerations

Although MDR 2017/745 is not law in GB, we appreciate that it represents the state-of-the-art expectations. Therefore, we have voluntarily incorporated MDR-style content in our documentation, such as clearly stating intended purpose, detailed warnings, information on residual risks (Section 4), and including cybersecurity info (Section 4 and 5). This ensures *Interactive Consultations* would also meet the EU

requirements should it be marketed under MDR in the future or in Northern Ireland where MDR applies. Essentially, the device is built to be compliant with both UK and EU frameworks, and any differences (like labelling nuances or registration) are managed accordingly. For the user, this mainly means you have a high quality, thoroughly documented product that stands up to international scrutiny.

Responsibility and Support

Under UK regulations, the manufacturer (Health Diagnostics) has a responsibility to provide customer support and incident handling. We have a Person Responsible for Regulatory Compliance (if needed for MDR jurisdictions) internally and a point of contact for users, which is given in this IFU and on our website. If regulators or users raise issues, we act on them. For example, if MHRA issues guidance that affects software devices (like new alert wording requirements), we implement those. If any field safety corrective action were needed (like issuing an updated IFU or software patch to fix a safety issue), we would communicate this to all our customers and give clear instructions (for instance, "update will be applied on X date, please ensure all users are aware of the change Y that addresses risk Z"). Thus, you can be confident that the software isn't static – it's supported throughout its life.

Health Diagnostics also encourages users to be part of this compliance ecosystem by providing feedback. We might periodically send out user surveys or usage data (anonymised) analysis to see if the device is performing as expected. All of that feeds into continuous improvement, which is both a regulatory expectation and a quality goal.

Conclusion of Compliance

In summary, *Interactive Consultations* meets the current UK regulatory requirements for a medical device. It has been designed, tested, and documented in line with those laws and relevant standards, and carries the UKCA mark to attest its conformity. Users have been provided with this comprehensive IFU to fulfill the requirement that they have the information necessary to use the device safely and effectively. The IFU and the device itself will be kept up-to-date as regulations evolve (e.g., if UK introduces new labelling requirements or PMS requirements, we will update our practices and inform you).

By using a UKCA-marked device from an MHRA-registered manufacturer, you (and your patients) have the assurance that the product is under proper oversight. Should you ever require further information about the regulatory status – such as a copy of the Declaration of Conformity or information about the device's classification rationale – you can contact Health Diagnostics and we will provide those details.

Finally, please keep this IFU accessible (electronically or printed) for reference. It may be audited in clinical governance checks or CQC inspections to show that staff have appropriate instructions for medical devices they use. And if anything in this IFU appears unclear or if you have suggestions to improve it, we welcome your

input as part of our commitment to clear communication (which is, in itself, a part of compliance – ensuring the IFU is adequate and understandable).

Note: This IFU is written in clear British English as per the target user group. Should it need to be translated for use in other locales (e.g., Welsh for use in Wales if required, etc.), we would ensure the content is equivalently conveyed. The authoritative version, however, is this English text, version 1.0 as of the date below.