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MANAGING MEDICAL DEVICES: IN VITRO DIAGNOSTICS

MT1 COLLABORATIVE

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MANAGING MEDICAL DEVICES

IN VITRO DIAGNOSTIC & POINT OF CARE TESTING DEVICES

DISCLAIMER

This information has been gathered from UK government guidance (August 2025). As such, this information may be subject to change.

This resources relates solely to In Vitro Diagnostic, specifically those that do not come into direct patient contact on a routine basis, (but that may cause patient harm if they do not function correctly), and Point of Care Testing devices.

You should use this guidance in conjunction with the main Managing Medical Devices resource, as there is overlap between the two guidances.

CONTENTS: IN VITRO DIAGNOSTIC DEVICES

CONTENTS: POINT OF CARE TESTING DEVICES

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INTRODUCTION

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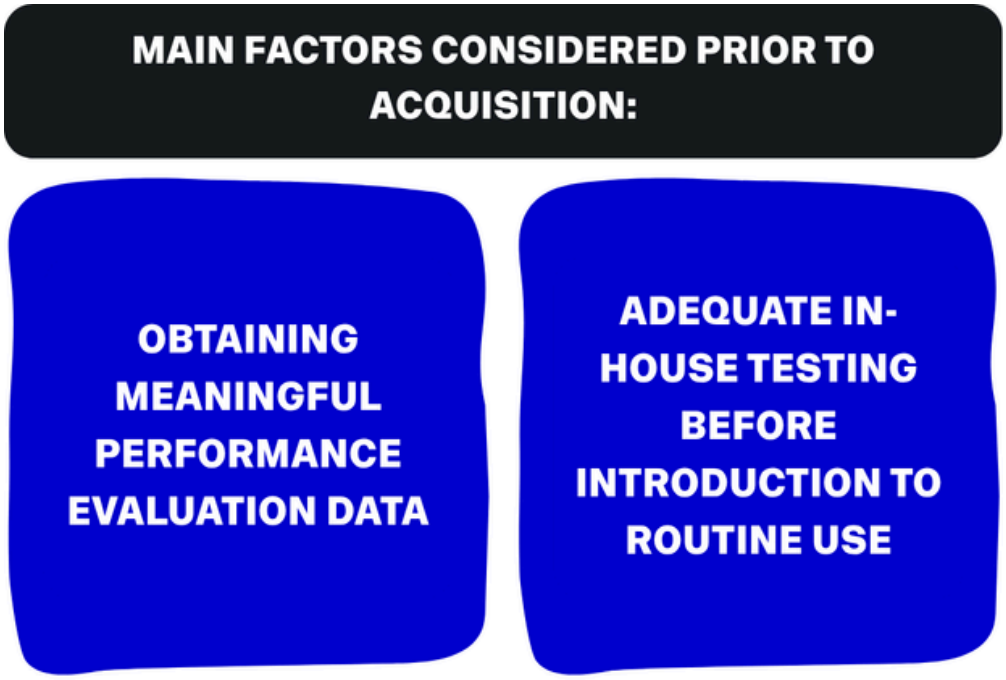
OVERVIEW: DEFINING IVDs

“IVDs [medical devices] are test kits and instrumentation used to test human samples to assist clinical diagnosis or decisions concerning clinical management.”

The term IVD includes individual reagents, and devices that contain reagents, instrumentation and software. This also includes items such as dedicated software and calibration materials.

IVDs should be considered as a “system” where changing a part of that system (e.g. a swab kit) requires consideration to the continued use of the rest of that system (e.g. does changing the swab kit require different reagents etc?)

ACQUISITION



The persons responsible for these devices, and for making decisions about these devices, include:

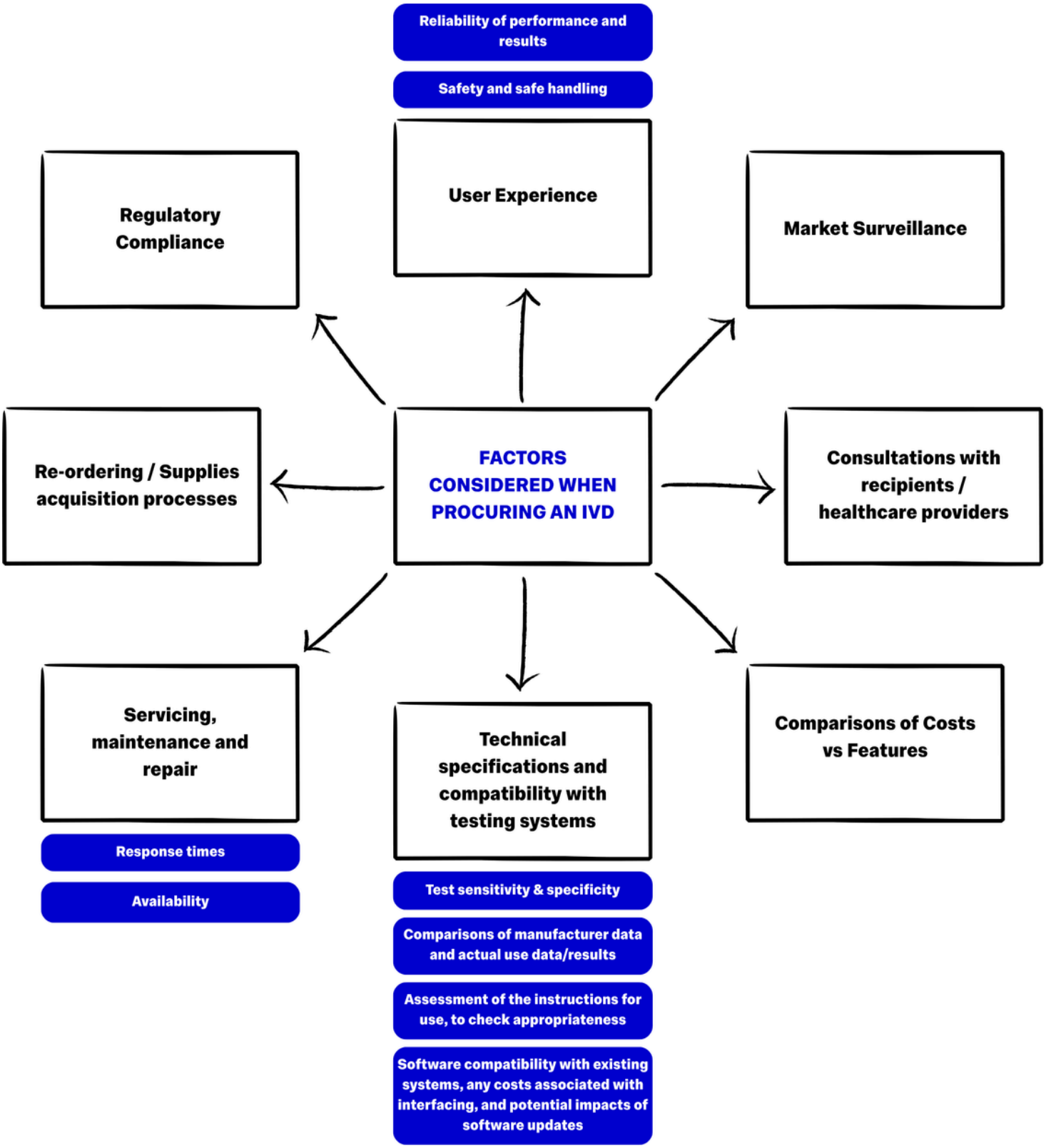
- Purchasers
- Pathology Managers
- Scientists, technicians, and other pathology lab staff
- Doctors, nurses, or other end users

All IVDs on the UK market **must** be CE/UKCA marked.

IVD manufacturers are required by law to state the performance characteristics of the IVD device when used within the instructions.

However, because there is no legal requirement (even for CE marked devices) to demonstrate clinical utility (not to be confused with clinical efficacy) as a condition of placement on the market, the onus is on the purchaser to check that the device is suitable for the required purpose.

ACQUISITION



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INSTRUCTIONS & TRAINING

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INSTRUCTIONS FOR USE

N.B. If the user reassigns the purpose of the IVD, or alters the instructions for use without manufacturer permission, the user is now liable for any performance issues/failures or patient harm (not the manufacturer).

Healthcare provider defined SOPs relating to IVDs must exactly reproduce the manufacturer's instructions. This is the responsibility of the hospital, but may be discussed when the manufacturer contract is defined. As such, **instructions from the manufacturer must be clear and complete.**

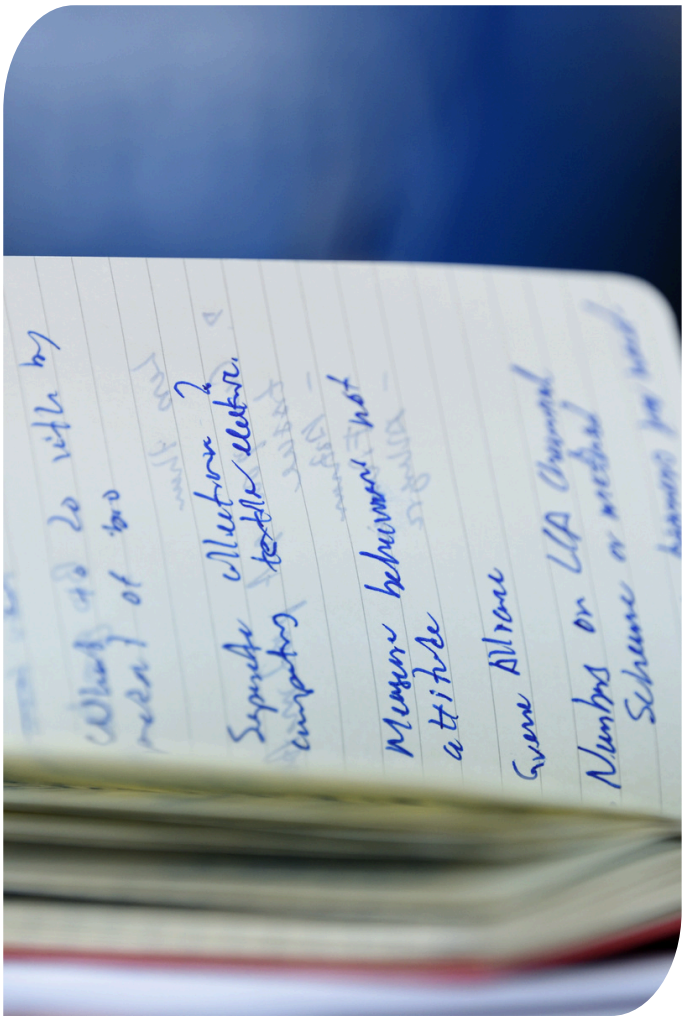
It should be noted that **users are entitled to instructions that are clear and comprehensible in their native language. It is unacceptable for instructions to be provided in poor translations that may obscure or alter meaning.**

The manufacturer must maintain appropriate contact details for all device users, to be able to communicate:

- Updates to instructions
- Product recalls
- Safety information updates
- Software updates and accompanying information

All users must automatically be sent any updates to usage instructions.

Instructions for use should also cover **storage requirements**, including any necessary conditions such as **temperature and humidity**, and **shelf-life of any consumables**, they should contain a **template/ideal servicing and maintenance schedule** and should also **clearly state any required training users must complete** prior to use.



TRAINING

The **manufacturer is responsible for providing appropriate training** covering the safety, quality, and performance of the device in question.

The healthcare provider receiving the IVD will decide on:

- Which personnel will receive training
- How, when and by whom the remaining personnel will be trained
- When re-training/refreshers are required
- Training for temporary/locum/on-call staff
- Future training needs (when those trained by the manufacturer leave their roles)
- Training updates when the IVD instrumentation/software is changed/updated
- Training records and documentation

Where samples for IVD analysis are collected by patients, clinical staff/ward staff etc, there must be adequate instructions to pass on to train those people on how to take samples properly.

If your device requires patients and end users to collect their own samples, **include a dedicated section in the "Instructions for Use" on proper sample collection,** as well as including a "how to train others" section in the training provision.

You should also **include instructions to clinical staff on how to check if a sample is good quality / acceptable**.

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RECEIVING A NEW DEVICE

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ACCEPTANCE CHECKS

when creating the manufacturer's pack, you should consider drafting a checklist of items that need to be verified on receipt of the device. The receiving hospital may choose to use their own checklist, but providing one ensures your device is received in the best possible condition.

ACCEPTANCE CHECKS	
☐	Electrical testing e.g. PAT
☐	Damage checks (for transport induced damage)
☐	First use calibration
☐	Checking the quality of the instructions for use
☐	Adequacy of training
☐	Checking that the device received is the same as what was ordered, including model numbers
☐	Compatibility with the rest of the testing / diagnostic system, and with existing infrastructure
☐	Completeness checks - Have all items and accessories been received as per the purchase order?

COMMISSIONING

Equipment and device commissioning is usually conducted by the manufacturer (or their supplier / representatives) for larger/more complex IVD instrumentation. For smaller IVD devices, the hospital and supplier will usually co-ordinate installation based on the manufacturer's instructions.

Commissioning may require the involvement of the hospital or healthcare provider's in-house technicians, medical engineers and pathology lab specialists. This process will include electrical testing e.g. PAT.

User Verification

The **userbase will verify the performance claimed by the manufacturer** with actual performance data. This will often compare the performance of the new device with that of the device it replaced to ensure the appropriateness and reliability of the results produced.

This will occur prior to the device being officially used for actual patient samples.

Software will be checked to ensure it behaves properly within the local systems, as intended by the manufacturer.

If any aspect of this testing suggests the device is not performing as expected/to the gold standard, the manufacturer and healthcare provider should co-operate on an investigation to determine why and to find an appropriate resolution.

The healthcare provider is responsible for keeping records of any actions taken, including introductions and local modifications of devices, training, and acceptance testing.

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MAINTENANCE & REPORTING

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MAINTENANCE & REPAIRS

The manufacturer is responsible for issuing guidance on planned preventative maintenance and for training selected staff on any maintenance and repairs that will be conducted in-house.

The hospital or end user are responsible for ensuring the device has been properly cleaned and decontaminated prior to any maintenance or repairs. This process should be stipulated in the manufacturer's instructions.

Instructions should also clarify if, where repairs and maintenance undertaken by third parties, the third party finds device faults or instrument failings, who is responsible for reporting to the manufacturer and/or MHRA e.g. the hospital or the third party.

The healthcare provider is responsible for ensuring contracts with third parties are in line with any relevant manufacturer's instructions.

Breakdowns & Emergencies

Wherever possible, the device should be temporarily replaced with an appropriate model (ideally the same as the broken device) that is compatible with existing systems and consumables.

Where that is not possible, the hospital should contract a reliable third party with 24hr call-out/servicing available. This may be a service offered by the manufacturer, in which case, will be covered by the hospital-manufacturer/supplier contract.

The hospital is responsible for ensuring testing services are as uninterrupted as possible.

ADVERSE EVENT REPORTING

IVDs are unusual in that it may not be immediately obvious that an abnormal test result is due to a device fault. The fault may only be found when consistent results become apparent from different labs using the same instrumentation.

Prompt reporting is required to contain larger-scale faults or issues with equipment.

The MHRA encourages users to report any faults immediately, even where the cause is not yet known. This onus is primarily on the users, **but the manufacturer is legally required immediately report any known faults to both the MHRA and to all device users** – Known as the "Vigilance Reporting System for Manufacturers".

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POINT OF CARE TESTING DEVICES (POCTs)

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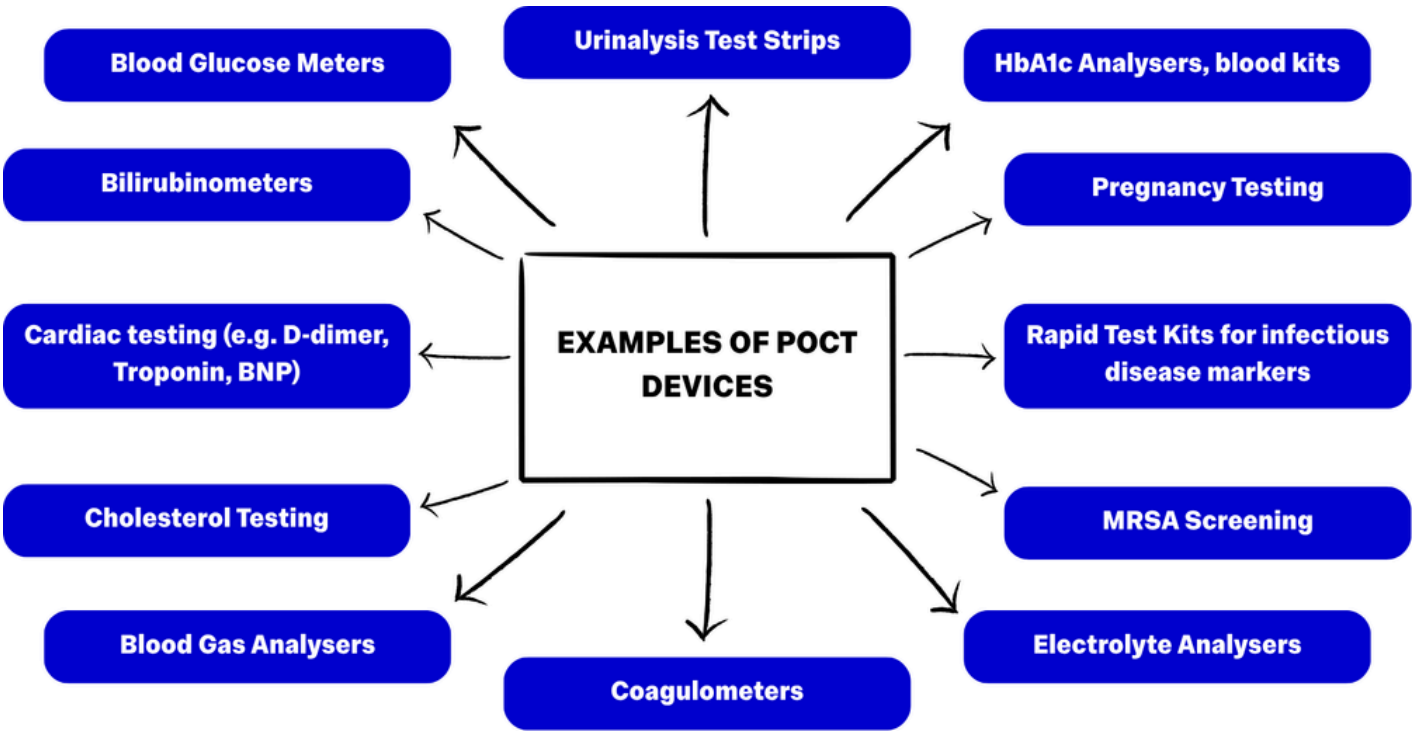
WHAT ARE POCTs?



This graphic shows some examples of IVD POCT devices - Can you think of any others?

POCT devices can be classed as:

Non-instrumental systems

Disposable systems and devices

Small analysers, palm or handheld devices

Desktop or benchtop analysers

Systems designed for use in clinics or labs

ACQUIRING A POCT DEVICE

The steps taken for the acquisition of POCT devices are very similar to the steps for other medical devices. In addition, the hospital will:

- Identify the clinical need – what benefit does this system have over standard laboratory testing?
- Consideration of the benefits of POCT to patients
  - How is the service currently provided, will POCT improve the service?
  - Which patients and which tests?
  - Is lab service access difficult for patients with conditions that require regular monitoring?
  - Will the POCT improve diagnostic/treatment timelines?
  - Can you provide evidence that introducing POCT will be a measurable clinical improvement?
  - Is POCT cost-effective compared to lab testing?
  - Does the POCT match lab testing in terms of results quality?
  - Any other patient benefits to providing the service in a different way?
- Consider any disadvantages, including costs.

POCTs: ADVANTAGES

Advantageous **in remote locales** where lab access may otherwise be limited

Greater patient involvement in their own care

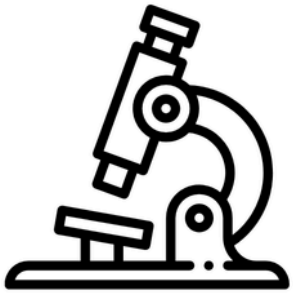
May offer **easier access to services** for elderly and disabled patients

Financial - Can reduce the number of clinic visits, reduce hospital stays, and use fewer consumables

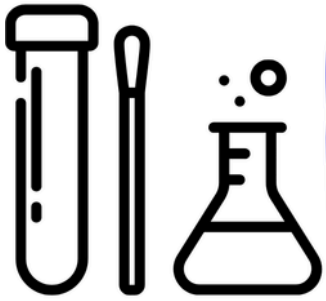
Improved turnaround time by shortening the pre- and post-analytical processes

Improved patient experience

Improved monitoring for conditions requiring regular testing



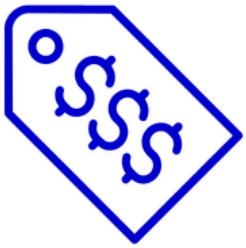
Available outside of lab hours



Smaller sample and reagent volumes required, can be less clinically invasive

POCTs: DISADVANTAGES

Data recording may be **complex and less robust** with poor interfacing with patient records



Can be expensive

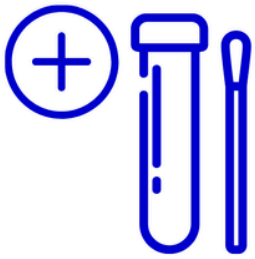
Incompatibility with lab results - including differing reference ranges

Unnecessary duplication of equipment - Multiple units running simultaneously

Risk of **poor analysis** or **result quality**

Failure to detect **false or incorrect results**

Poor record keeping capabilities



Inappropriate testing - The availability of testing arrays (over single tests)

Lack of **result interpretation**

POCT ACQUISITION CONSIDERATIONS

Hospitals will also consider the financial costs of implementing a POCT system, usually in comparison with existing processes, labs, and infrastructure. There may also be a consideration for costs associated with changing testing processes e.g. will there be a cost associated with removing old equipment or changing lab facilities.

- **Capital costs**
  - Initial purchase
  - Required accessories e.g. centrifuges, incubators, racks etc.
  - Provisions for safe environments, storage etc.
  - Site alterations required to accommodate POCT facilities
  - Depreciation of value e.g. costs won't be recouped at the end of the life cycle
  - Interfacing with information capture and record keeping systems
- **Other fixed costs**
  - Routine and preventative maintenance
  - Internal quality control materials, participation in external quality control measures
  - Any required accreditation scheme compliance
- **Variable costs**
  - Consumables
  - Record-keeping systems that interface with existing systems
  - Waste disposal
  - Cleaning and decontamination
  - Demand
- **Professional costs**
  - Indemnity insurance, legal liabilities
  - Laboratory support
  - Management of the POCT programme
  - Operator time
  - Staff training
  - Specialist staff requirements

Other factors considered prior to acquisition include:

- **Accuracy, reliability and precision** of results
- **Robustness of the device** itself – fragile devices may not have a good lifespan
- Results **record keeping** capabilities

POCT ACQUISITION CONSIDERATIONS

Acquisition will usually be supported by consultation with an accredited laboratory. **A local evaluation may take place to ensure compatibility with local reference ranges and clinical practice guidelines.**

N.B. A system that uses different reference ranges for results compared to standardised laboratory practices is unlikely to be selected for acquisition, as there is significant risk of worse patient outcomes.

Part of the acquisition assessment will cover whether or not the device will meet the defined clinical need. This will include assessments of how well the new device or system will fit within the existing hospital infrastructure.

- What is the **expected workload?**
- **Who is using the equipment?** Primary user base?
- **What evaluations of the equipment are available?** E.g. manufacturer's, external, clinical trials, other hospitals etc.
    - Are the evaluation results comparable with the existing lab service in use?
- Comparison of the **manufacturer's performance claims vs the performance requirements** for the service
    - Sensitivity
    - Specificity
    - Accuracy
    - Repeatability
    - Reproducibility
    - Measurement ranges
- **Where will both the equipment and its required consumables be sited?**
    - Adequate space?
    - Adequate services? (Electricity, water connection, ventilation, temperature and humidity control?)
- Will the new POCT device interface well with existing IT infrastructure and record keeping databases?
- **Are there any health and safety issues** that will need to be maintained e.g. sharps, water, biohazards etc?
- Consideration will be given to standardisation of equipment:
    - Minimising results variations
    - Cost-effectiveness of primary purchases, consumables, and equipment life cycles
    - Benefits around staff training
    - Implications for support staff who will maintain the device

CLINICAL GOVERNANCE

Clinical Governance covers the hospital's procedures for monitoring and improving services, assessments and scrutiny for clinical effectiveness, and auditing processes.

Clinical governance gives hospitals the oversight to consistently improve monitoring and service delivery across their scope of practice. This process includes:

- Consultation and patient involvement where applicable
- Clinical risk management
- Clinical audit
- Research and effectiveness
- Staffing and staff management
- Education, training, continued personal and professional development
- Use of information to support clinical governance and service improvement

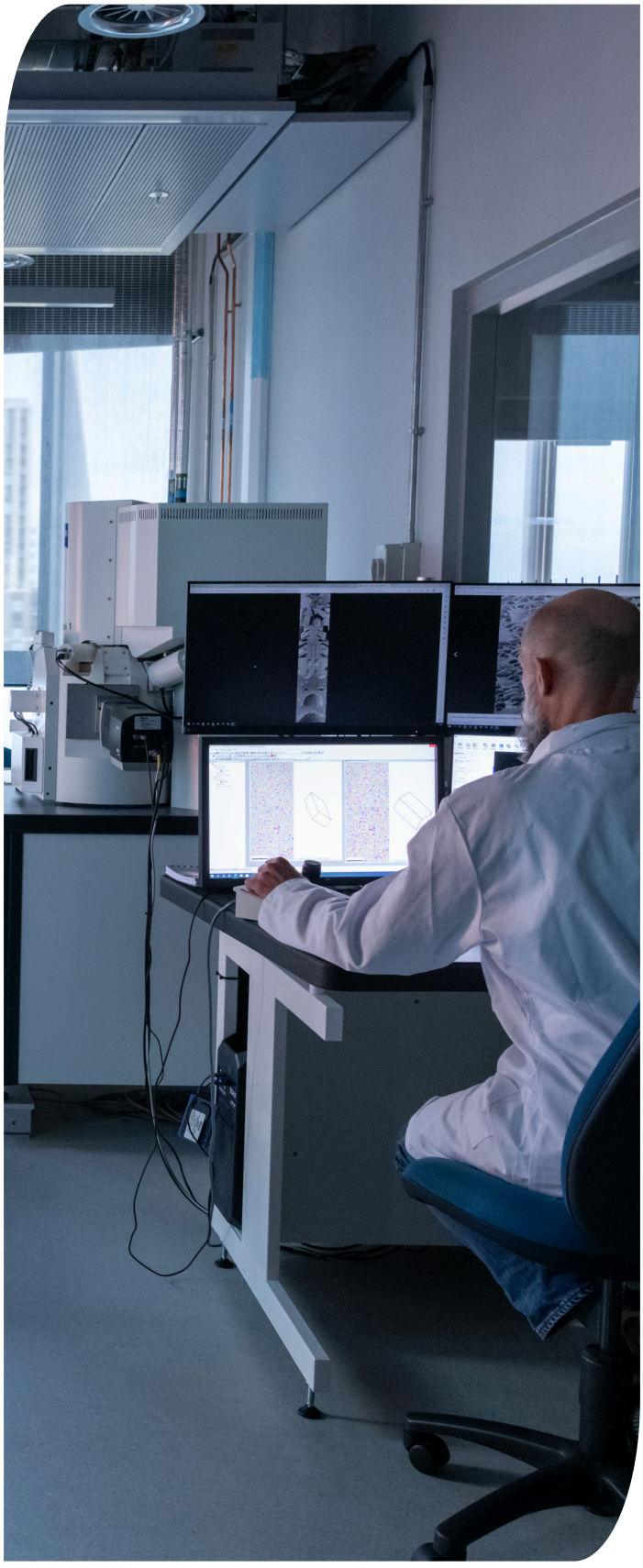
Using **a POCT system instead of laboratory testing is classed as a clinical governance issue**, and as such is subject to careful scrutiny. Some hospitals will set up a dedicated POCT Committee to undertake the necessary clinical governance tasks.

Whilst this process is usually kept in house within the hospital, **as a manufacturer or supplier of a POCT device, you may be asked to provide information to the hospital or the delegated committee, to support the process.**

MANAGEMENT & ORGANISATION

The hospital will appoint a designated POCT Co-Ordinator at the outset of the development of a POCT service. They will be a senior clinician or senior professional in a relevant field. They are responsible for:

- Results that are generated by the POCT
- The correct usage and handling of the device – Defined in partnership with the manufacturer, based largely on the manufacturer's instructions for use.
- Clinical governance
- The medico-legal liabilities around erroneous results – **N.B. if the hospital can demonstrate that the device has been used strictly in line with the manufacturer's instructions, the legal liability will rest with the manufacturer** (under the Consumer Protection Act 1987).



TRAINING

As with other medical devices, training is usually provided in the first instance by the manufacturer or their supplier representatives.
When designing the training package for IVD POCT devices and systems, you should consider:

TRAINING (POCT Devices)
DELIVERY
Who is able to provide the support for staff training?
Are core competencies assessed by a qualified person? Are learning packages accredited?
Who is responsible for creating the training package certification for staff competence?
How long is training and what materials are needed?
Can the training be offered by the hospital / lab, or is it only available from the device manufacturer / supplier?
USERS & USAGE
Is there a Continuing Professional Development (CPD) programme for staff delivering the POCT service?
Does the training manual identify operator dependent steps of the POCT process?
Can staff be released from their daily duties to undertake training?
UPDATES & RECORDS
How will training updates and refreshers be undertaken and assessed?
How are training records created and updated? Who is responsible for storing certificates?

INSTRUCTIONS FOR USE

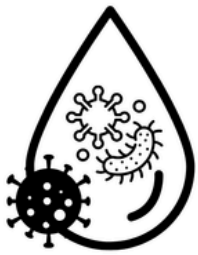
Consider these specific instructions for POCT devices in tandem with the advice in the Medical Devices resource here[SM1] .
As is standard, instructions for use must be clear and complete, including every detail of the device and its function, including:

- The intended purpose of the device
- Performance characteristics
- Interpretation of results
- Limitations of use
- Sampling requirements including sample type
- Storage of reagents and samples, storage requirements
- Expiry dates
- Quality assurance procedures
- Health and safety issues and recommended mitigations
- Contraindications for use e.g. samples from patients taking X medication should not be tested on the device etc.

As POCT devices are commonly used to test for infectious diseases, and even in other use cases will often require biological samples (e.g. saliva swabs, blood samples etc.), **the Instructions for Use must also include information on Infection Control.** The Manufacturer Information, and the Instructions for Use should include information on how the device incorporates the following, to support local infection control policy:

Standard (universal) **infection control** precautions

Prevention of exposure to blood-borne viruses or other diseases



Prevention of sharps injuries

Prevention of cross-infection between patients e.g. not using single-use sharps for multiple patients

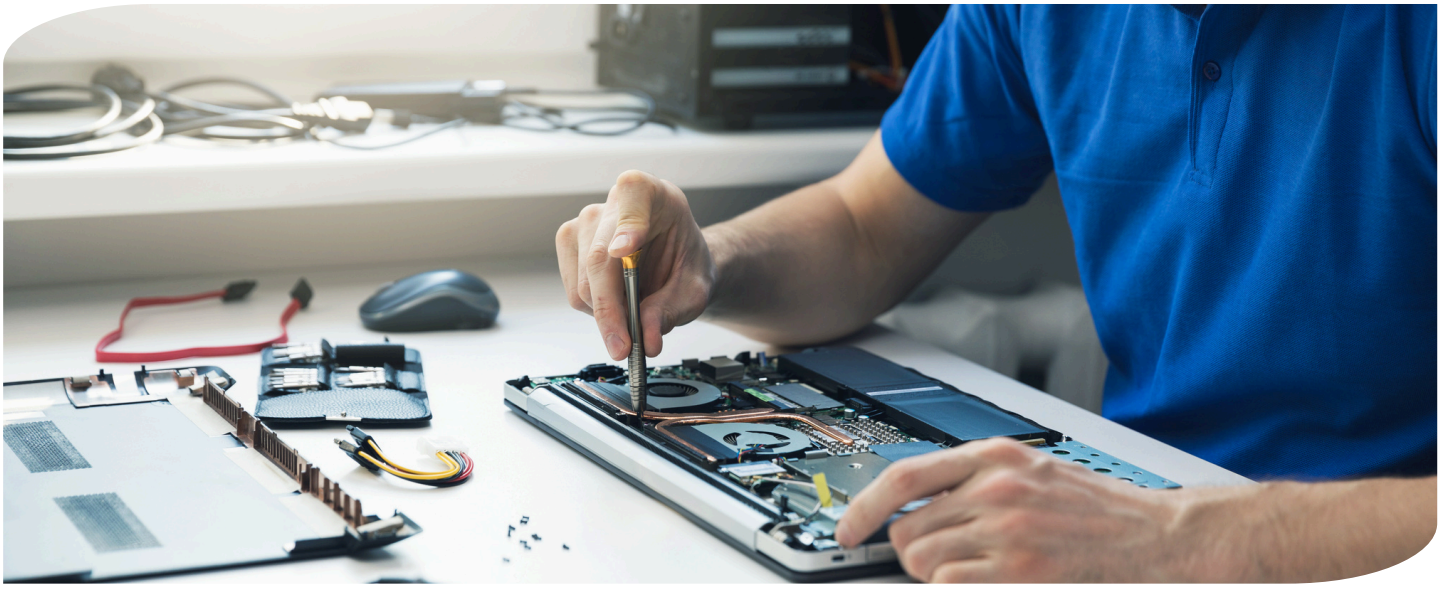
Safe handling and **disposal of waste**, including sharps

Safe medical device use including decontamination for reusable items and waste disposal procedures

MAINTENANCE, REPAIRS & BREAKDOWNS

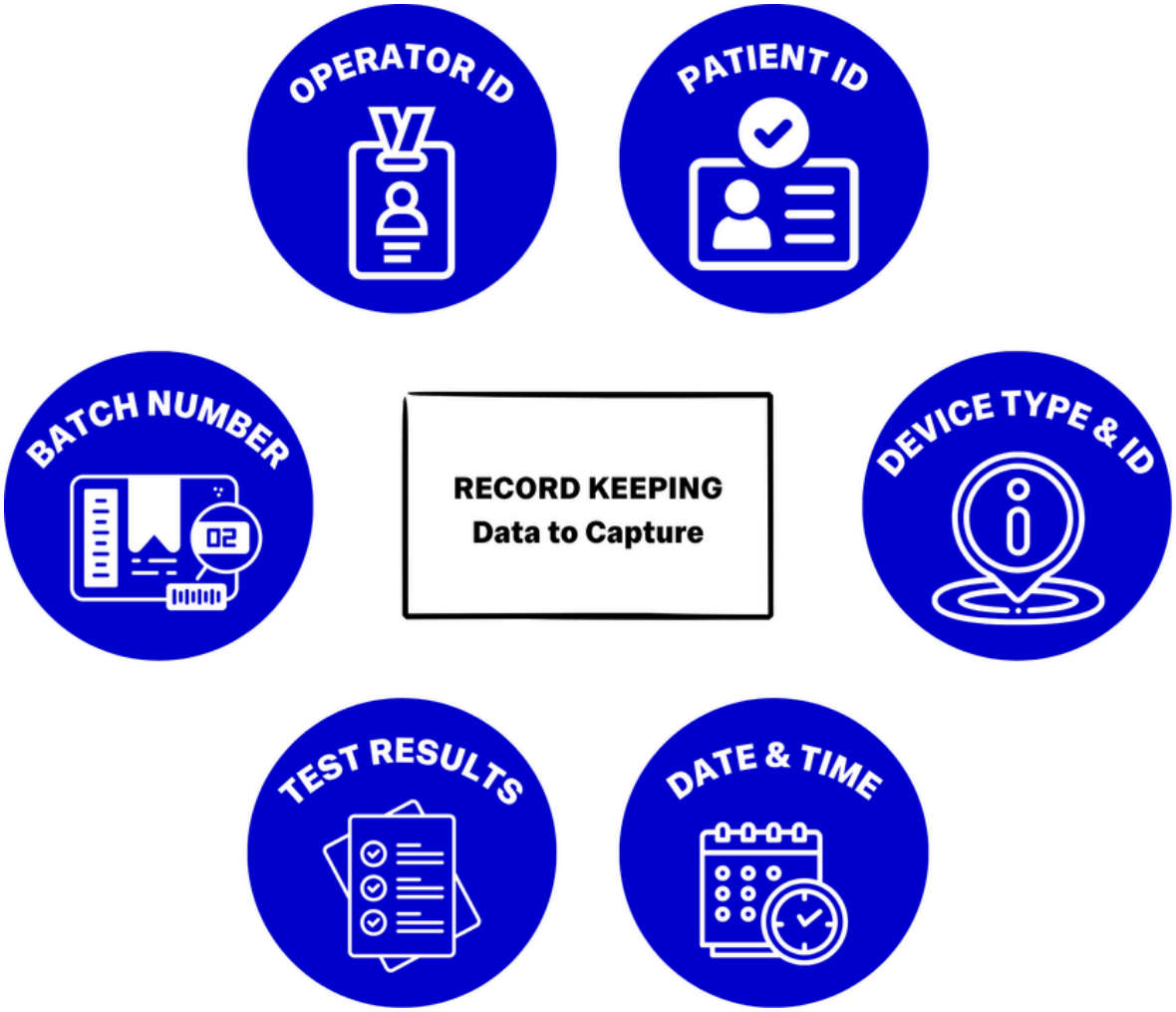
The advice for IVD POCT devices is very similar to the medical devices advise, found here. There, however, some specific questions you should be thinking about for POCT devices:

- **Who provides preventative maintenance and troubleshooting?** Is this regularly scheduled via the supplier, or can an in-house technician or team complete maintenance activities?
- Is a maintenance record maintained for each device in the service, and does it record all faults and repairs? **Who is responsible for keeping the record updated?**
- **Is a maintenance contract required for call-outs** and engineering support?
- Manufacturer instructions should include information on reagent record keeping and **weekly-monthly maintenance checks.**
- Procedures should be instated to cover how and when the manufacturer/supplier is contacted about repairs or breakdowns – This will happen at the local level, but it is prudent to provide suggestions in the manufacturer's instructions.
- Advice on the importance of reporting device defects, and who to report them to (either to the hospital who pass it on to the MHRA, or directly to the MHRA). The manufacturer is always responsible for reporting any faults or defects as soon as they become aware of them, and for notifying all device users.



RECORD-KEEPING

As a baseline, it's encouraged to consider including facility to capture record-keeping data within the standard issue device. Where this isn't possible, you should working towards smooth interfacing with hospital IT infrastructure.



IT Capabilities

Where possible devices should be able to interface with Laboratory Information Management Systems (LIMS) and Hospital Information Management Systems (HIMS).

FURTHER READING & RESOURCES

Guidance Policy (UK GOV) 2021
https://assets.publishing.service.gov.uk/media/6089dc938fa8f51b91f3d82f/Managing_medical_devices.pdf

IVD Policy 2021
https://assets.publishing.service.gov.uk/media/60118464e90e0714311c38ce/Management_of_in_vitro_diagnostic_medical_devices.pdf

Management & Use of IVD POC Testing 2021
https://assets.publishing.service.gov.uk/media/601a8c988fa8f53fbdc27dcc/Management_and_use_of_IVD_point_of_care_test_devices.pdf

GLOSSARY

MDMG – Medical Device Management Group
MDSO – Medical Device Safety Officer

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CONTACTS

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