

Greener, Smarter Healthcare: Electronic Instructions for Near-Patient Tests



Executive summary

- Near-Patient Tests (otherwise known as Point-of-Care tests) are an essential part of healthcare. They are used by healthcare professionals to test patients and provide them with results right where they are, without the need to send the samples to the laboratory.
- The demand for near-patient testing diagnostics is accelerating due to the growing burden of chronic diseases, demand for faster diagnostics and advances in technology.
- Electronic instructions for use bring many benefits to healthcare professionals and society over paper-based instructions including: better availability, better utility, enhanced accessibility, reduced carbon footprint and up-to-date information.
- EU rules should be updated to allow electronic instructions for near-patient testing devices. This would help make Europe's healthcare safer, faster and greener.



What is near-patient testing?

Near-patient testing (NPT), also known as 'Point-of-Care' (POC) testing, is carried out outside of the centralised laboratory by a healthcare professional; they are not used by the patient themselves (not self-tests). Such tests are used in a variety of healthcare areas and settings, e.g. **at the patient bedside, in ambulances, emergency units, doctor offices, patient homes, community health centres and airports** (see info box below for NPT examples).

NPTs are critical to daily healthcare because they deliver **fast results** to the healthcare professionals right where their patient is, without waiting for samples to be tested in the laboratory. With NPT, healthcare professionals can **take decisions right away** and **patients get treatment sooner**. These tests are especially critical in places with limited laboratory facilities or where point of care decisions are needed.

In Germany alone, more than 10,000 POC testing analysers were installed in healthcare facilities by the end of 2023. Europe already represents around 30% of global POC testing by volume, which means tens of thousands of systems (likely 50,000 to 100,000 or more) are now supporting hospitals, clinics, and other care settingsⁱ.

Near-patient testing can be found in almost every area of medicine. For example:

- Rapid strep tests
- Bedside blood gas monitors
- Rapid flu tests
- Ambulance cardiac triage tests
- Rapid HIV tests
- Activated clotting time tests
- Dipstick urinalysis
- Fecal occult blood tests

The **demand for near-patient testing is rapidly growing in Europe** because of the rising need for fast diagnostics, the increasing prevalence of chronic diseases, advances in technologyⁱⁱ, and the shift toward more decentralised healthcare^{iii,iv}.

Digital and sustainable near-patient testing is the way forward

The expansion of the NPT sector highlights the **enormous potential of NPT to transform care delivery**. At the same time, it creates a valuable opportunity for digital transformation. The sector needs to move from paper to electronic instructions for use. Electronic instructions for NPTs can not only reduce environmental impact and streamline processes but also support the continued growth of this innovative and patient-catered field.

Benefits of eIFU



Better utility



Better availability



Reduced carbon footprint



Up-to-date information



Enhanced accessibility

The adoption of electronic instructions, otherwise known as electronic instructions for use (eIFU), **would make healthcare safer, faster, and greener**. eIFUs would reduce paper waste, speed up updates, cut costs, and they already are strongly preferred by healthcare professionals. Almost 90% of healthcare professionals say they would rather use electronic than paper instructions for use^{vi}. Yet, for near-patient testing (NPT) devices paper IFUs are still mandatory. Updating this rule would align with the European Union's goals on digitalisation, sustainability, and simplification, while ensuring professionals get clear, up-to-date information.

In this booklet, MedTech Europe highlights the many advantages eIFUs offer as compared to paper instructions for NPT, including **better availability, better utility, enhanced accessibility, reduced carbon footprint and up-to-date information**.

Better availability

eIFUs are accessible online at anytime, anywhere, allowing healthcare professionals to familiarise themselves and prepare for a given procedure

Because near-patient testing is performed at the side of a patient, quick and reliable access to clear information is essential to healthcare professionals using these devices. The possibility to use electronic instructions for use for near-patient testing devices can **enable easier access to information for doctors and nurses**, especially since the use and preference for digital tools have spiked in recent years.

The **uptake of digital tools has grown** since 2010, when the European regulation¹ mandated that paper instructions for use (IFUs) should accompany NPT devices. Europe currently has a coverage rate of over 90%^v in access to the internet. Recent surveys also show that most **doctors and nurses prefer electronic instructions** over paper ones. This preference acknowledges the safety, reliability, and convenience of eIFU in healthcare settings.



90% of healthcare professionals prefer eIFU

MedTech Europe eIFU survey for medical devices (2022)

In 2022, MedTech Europe surveyed healthcare professionals in the EU and hospital administrative staff/hospital pharmacists, and ~90% of them prefer eIFU due to better storage, easier navigation, faster updates, current information, and waste reduction^{vi}.

1) In Vitro Diagnostic Medical Devices Regulation 2017/746/EU currently allows IFU in electronic format to accompany all professional-use devices except for near-patient testing devices.

The European Commission has recently allowed the use of eIFUs for healthcare professionals using medical devices², since providing instructions for use in electronic form will help the health sector deliver better and faster solutions. This expansion only covered the Medical Devices Regulation³; as such it does not affect near-patient testing. Given that NPT devices are used by healthcare professionals in the same or similar setting as medical devices, eIFUs should be supported also for near-patient testing.

Better utility

eIFUs are searchable, can embed user specific views in different formats, they are easier to handle and store

eIFUs simplify the use of near-patient testing devices. Unlike bulky paper booklets that can be lost, thrown away, or quickly become outdated, **eIFUs are always accessible and up-to-date**. They can be searched in seconds, and they can offer information in more user-friendly ways, such as step-by-step illustrations, videos, or tailored views for different users. This makes them **simpler to handle, easier to store, and more convenient** for both healthcare professionals and patients.

Enhanced accessibility

eIFU can be customised with e.g., text resizing, text-to-speech functions, improving usability for healthcare professionals with impairments

eIFUs make it easier for healthcare providers to **quickly access the information** they need when using near-patient testing devices, such as rapid diagnostic tools used at the bedside or in clinics. Instead of relying only on printed manuals, **eIFUs can be accessed online or through digital devices**, ensuring the most up-to-date instructions are always available. This helps to reduce errors, supports safe and effective use, and improves convenience, especially in fast-paced care settings where having timely and accurate results are critical.

2) Commission Implementing Regulation (EU) 2025/1234 of 25 June 2025 amending Implementing Regulation (EU) 2021/2226 as regards the medical devices for which the instructions for use may be provided in electronic form.

3) Medical Devices Regulation 2017/745/EU. Near-patient testing however falls under a different law: *In Vitro* Diagnostic Medical Devices Regulation 2017/746/EU.

Reduced carbon footprint

eIFU significantly reduces paper waste, the shipping weight of products, and contributes to lower overall greenhouse emissions

eIFUs reduce costs and unnecessary paper waste. Moving from paper to eIFUs in near-patient testing offers an opportunity to **make healthcare 'greener' and more efficient**. Unlike booklets that can be hundreds of pages long that are often left unused^{vi}, electronic instructions are not only 'greener' but also lighter, faster to update and much easier to navigate.

According to MedTech Europe's estimation, to make paper IFU for just 10 medical technology companies requires **cutting down approximately 6 billion trees each year**. This roughly accounts for trees spread over the size of Belgium or Costa Rica^{vii}.

The shift to electronic instructions also supports Europe's vision for a more sustainable economy. By reducing paper use, we **help protect forests, cut down on packaging waste, and lower the carbon footprint** linked to paper production and transport. With more than 5,000 NPT devices and more than 200 manufacturers registered in Italy alone^{viii}, adopting eIFUs can save resources across whole Europe, support EU climate goals, and ensure that vital information is always just a click away.

Up to date information

eIFU – always the most current validated version. The paper IFU originally received with the device may be superseded by a new version which may take longer to reach healthcare professionals

eIFUs ensure that users always have easy access to the most current information. While paper manuals are a reliable source of reference, eIFUs provide the added benefit of delivering updates quicker, ensuring healthcare professionals can always work with the very latest manual. **By providing immediate access to the latest instructions**, eIFUs support accuracy, safety, and efficiency in everyday use.

eIFUs can not only improve access to the most up-to-date guidance for healthcare professionals performing testing but also reduce paperwork, allowing doctors and nurses to **focus more on patients rather than administration**.

Conclusion

Making eIFUs available for near-patient testing devices would make healthcare simpler, 'greener', and more in line with Europe's digital and sustainability goals. Today, healthcare professionals using these devices, who are trained and qualified, still receive paper manuals by default, even if they prefer electronic versions.

eIFUs are easier to search, update, and store, and data from MedTech Europe show that professionals increasingly want to use them. Paper copies should remain available free of charge for anyone who requests them, but there is no need to provide them automatically when they are not required.

Shifting from paper to electronic instructions for NPTs is the next step forward in the *in vitro* diagnostics sector. Electronic instructions reduce unnecessary costs and packaging waste, while ensuring healthcare professionals have quick, convenient access to the most up-to-date information. Updating the current EU rules to enable eIFUs for near-patient testing would better serve users and help Europe move toward its vision of a more sustainable, digital future.

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

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- vii) Based on data from Italian Registry Elenco database

