Digital Health in the Circular Economy

WEBINAR

WHAT HAPPENS TO DIGITAL HEALTH DEVICES AT THE END OF THEIR LIFE?

A PRACTICAL GUIDE FOR OPERATIONAL WORKERS

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BEFORE WE START: A FEW HOUSEKEEPING NOTES

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🎤 Microphones & cameras

You're joining muted, and video is optional. Please keep your mic off unless you're invited to speak.

💬 Questions & Q&A

Use the Q&A panel for questions. At the end of the webinar, we will be discussing your questions during the discussion session.

📹 Recording

This session is being recorded. The recording will be shared with all registrants after the webinar.

📊 Live polls

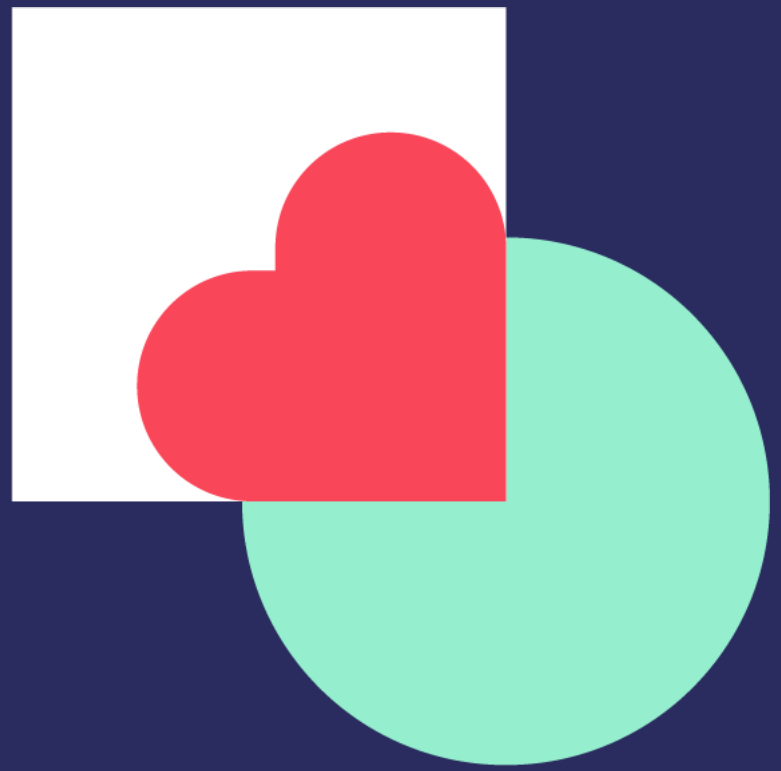
We'll pause a few times for quick Menti polls. A link or QR code will appear on screen.

📄 Slides & materials

Slides will be shared with all registrants after the session.

😊 Let's get started

Thanks so much for joining us today. Over to the agenda.



AGENDA

01. Welcome & what DiCE is

02. The problem: why this is harder than it looks

03. The manual: a guided walkthrough

04. Discussion & Q&A

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Horizon Europe project
2022 – 2026

20 partners
across Europe

circulardigitalhealth.eu

The challenge

Millions of digital health devices (e.g. glucose monitors, ECG leads, wearables, smart inhalers) reach the end of life every year. Most end up in the wrong stream or are incinerated.

What DiCE is doing

Developing training materials, and tools so that healthcare facilities, logistics operators, PROs, and treatment facilities have more practical guidance.

What we're sharing today

Practical guidance, tools, and decision frameworks for everyone handling digital health devices, developed with and for practitioners.

DIGITAL HEALTH DEVICES ARE NOT LIKE OTHER E-WASTE

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They look like electronics, but they're much more complicated to manage at the end of life.

Biological contamination

A used glucose strip reader or ECG lead may carry blood-borne pathogens. You can't just put it in the WEEE bin. But the standard WEEE rules don't tell you what to do instead.

Patient data inside

Most connected devices retain data (e.g. Bluetooth IDs, health readings, patient identifiers). GDPR applies. Some recyclers can carry out data wiping or destruction, but only under the sender's supervision; without this, it's a breach waiting to happen.

Lithium battery risk

Swollen or damaged lithium batteries in small wearables and monitors pose fire and chemical hazards. WEEE depollution should screen for these, but small devices carry a real risk of being missed in the stream.

Four different legal frameworks

WEEE, GDPR, the EU Medical Device Regulation, and health & safety legislation all apply, but none of them cross-references the others. No single document translates this into operational actions.

THE GAP: WHAT'S MISSING IN PRACTICE

DiCE reviewed existing guidance across Europe.

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> Very few operationally-focused guidelines currently exist that specifically address the collection, sorting, handling, transport, and treatment of digital health devices.

DiCE review of existing protocols and best practices

What this means on the ground:

- Nurses and cleaners don't know which bin a used glucose monitor goes in, so it goes in the general waste
- Logistics companies aren't sure which permits they need for health facility pickups
- PROs receive devices they can't treat properly because there's no decontamination declaration from the hospital
- Reusable, repairable devices go straight to incineration because no one has a reuse assessment process
- Lithium battery fires at sorting facilities because batteries weren't identified or removed at source

MANUAL OVERVIEW

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We'll move through the full lifecycle of a digital health device and pause at each stage to discuss what works, what doesn't, and what you need.

PART A

Prevention → Sorting → Handling → Storage

- Ch. 5 Manager's Guide (PRO / logistics selection)
- Ch. 6 Prevention & procurement
- Ch. 7 Reuse & refurbishment
- Ch. 8 Collection & sorting
- Ch. 9 Safe handling
- Ch. 10 Storage

For healthcare facilities

PART B

Transport → Treatment → Reprocessing

- Ch. 11 Transport & shipment
- Ch. 12 Treatment (WEEE vs medical waste)
- Ch. 13 Reprocessing (Article 17 EU MDR)

For logistics, PROs & treatment facilities

TOOLS

Decision trees & checklists

- 6 decision trees
- Sorting fact sheet & bin labels
- Leaflets for managers and staff
- PRO, logistics & procurement checklists
- Information leaflets for home use

Referenced throughout, walkthrough included

This manual is intended to complement existing legislation, standards, and internal procedures; it does not replace them.

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PREVENTION OF USED DIGITAL HEALTH DEVICES

Stop the waste before it happens

PREVENTION STARTS AT THE TOP OF THE WASTE HIERARCHY

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The goal: keep devices in use as long as possible. Every step down the hierarchy is more costly, both financially and environmentally.

Manual focus: Prevention (Ch.6) → Reuse (Ch.7) → Sorting for quality recycling (Ch.8)

WHAT TO ASK SUPPLIERS AT THE PROCUREMENT STAGE

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Build circularity into tenders. Score offers on these criteria, typically 15–30% of the total score, increasing over time.

Reusability & durability

Expected service life? Multi-patient use with cleaning/disinfection? Which components fail first, and how long do they last?

Repairability & maintenance

Non-destructive disassembly (standard fasteners, not glued)? Spare parts available for how many years? Repair manuals accessible?

Battery safety & replaceability

User- or technician-replaceable battery? Safe removal procedure at end of life? Battery chemistry & EU Battery Regulation compliance?

Software & obsolescence prevention

How long will security updates be provided? Does the device work offline? Do updates avoid forced obsolescence?

Data security by design

Secure reset/wipe accessible to operational staff? Where is data stored — device, server, cloud — and how is it deleted?

Circular services & take-back

Supplier take-back, refurbishment, or trade-in options? Established reuse/refurbishment routes through authorised partners?

DAILY PREVENTION PRACTICES

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Once devices are purchased, prevention continues through daily handling. Operators are the first line of defence.

1. **Use as intended**
   Follow manufacturer instructions. Report defects early to maintenance — a minor fault caught early can save a device from the waste stream.

2. **Protect reuse candidates**
   Keep a dedicated, clearly labelled container for "potentially reusable" devices. Never mix with WEEE or general waste streams.

3. **Handle with care**
   Do not stack, crush, or drop devices. Do not mix digital devices with other items in bins or boxes.

4. **Route quickly**
   Move devices to the assessment point promptly, delay risks battery leakage, corrosion, or contamination spreading.

5. **Inspect at point of removal**
   Apply a visual check the moment a device is taken out of service: contamination? Damage? Battery condition? This determines the stream.

Operational instruction summary	
WHO	Operators (clinical staff, biomedical technicians, cleaning staff), supervised by ward/department manager and biomedical service
WHEN	Continuously, every time a digital health device is taken out of service or moved between locations
TOOL	Apply the reuse decision tree (Annex 2) at the moment of removal to determine the correct stream

Key principle

Early and correct segregation is the single most important action for keeping devices in the circular economy. A device placed in the wrong bin at the moment of removal is almost impossible to recover afterwards.

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REUSE & RE-DEPLOYMENT PATHWAYS

Always assess reuse before considering waste treatment

THREE LIFE-EXTENSION PATHWAYS

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1 Reuse / Re-deployment

When to use

✓ Device is functionally intact and safe to handle

✓ Not contaminated (or appropriately decontaminated)

✓ Data can be securely removed or reset

✓ Reuse complies with EU MDR requirements

Examples

→ Internal re-deployment to another ward or department

→ Transfer to another healthcare or care institution

→ Use for training or education (non-clinical)

2 Refurbishment & Repair

When to use

✓ Not immediately reusable — but technically repairable

✓ Spare parts, tools, and expertise are available (OEM or service partner)

✓ Can be returned to a safe and compliant condition

✓ Data stored on the device can be securely removed or destroyed

Examples

→ Battery replacement

→ Sensor or cable replacement

→ Recalibration by authorised partner

3 Waste Treatment (last resort)

When to use

✓ Contaminated and cannot be safely decontaminated

✓ Physically beyond repair

✓ Data cannot be securely erased

✓ Reprocessing is not legally permitted in this jurisdiction

Examples

→ WEEE treatment (non-infectious)

→ Medical waste / incineration (infectious)

→ Reprocessing under Article 17 EU MDR (where authorised)

REUSE / RE-DEPLOYMENT PROCEDURES

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1 Identify at point of removal

Visual inspection at the moment device is taken out of service: no contamination, intact battery, no visible damage. If conditions are met, this device is a reuse candidate.

2 Place in dedicated container, immediately

Use a separate, clearly labelled "REUSE CANDIDATE" container. Never mix with WEEE or medical waste. Protect from damage, do not stack.

3 Apply "REUSE CANDIDATE" label

Label the device visibly. This signals to everyone downstream that this device must not be routed to recycling or waste without assessment.

4 Route to assessment point within 24 hours

Send to the biomedical service or designated reuse coordinator. Delay risks battery leakage, contamination, or the device being lost into a waste stream.

5 Data wipe / reset

Run the certified data erasure procedure. Use tools that generate an audit trail. Do not proceed if data cannot be confirmed deleted.

6 Functional and safety checks

Power on, battery condition, display, basic connectivity. If any check reveals a safety risk, stop, route to the appropriate stream.

7 Decide the reuse pathway

Internal re-deployment / transfer to another institution / use for training. Validated by the ward or department manager.

8 Record the decision

Log the device (UDI), the decision, and the receiving department or institution. This is your traceability record.

⚠ IMPORTANT: If visual inspection or any check reveals a safety risk, STOP. Do not attempt data wiping on a damaged device.

DATA & FUNCTIONAL CHECKS

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The ORDER matters. A device with a safety risk should not be reused regardless of data status; safety checks come first.

1 Visual inspection

Damage, cracks, corrosion, missing parts, burned marks, physical deformation

2 Power & battery check

Swelling, leakage, overheating, charging failure. Swollen battery = route to Stream 5 immediately

3 Basic operation test

Power on, display function, connectivity check where relevant. Device must behave normally

4 Data wipe / reset

Certified logical erasure per internal procedure or manufacturer guidance. Must generate an audit trail (GDPR)

5 Confirm no data remains

Verification step: confirm that no user data is accessible after the wipe. If uncertain, escalate to the Data Protection Officer.

6 Label the outcome

Apply outcome label: REUSE / REPAIR / RECYCLE / MEDICAL WASTE. Update the device record

📋 Responsible: Biomedical service / IT for data wipe · Operators for battery check · Waste management lead retains Data Destruction Certificate (linked to UDI).

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COLLECTION & SORTING AT HEALTHCARE CENTRES

The right stream, from the first moment

SORTING STREAMS

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Sort on four criteria: intended pathway · contamination status · battery/physical risks · data sensitivity.

1	**Reuse / Re-deployment Candidates** Criteria: Functionally intact, clean, data removable	Action: Protect from damage · Label "REUSE CANDIDATE" · Route to assessment within 24h	GREEN bin label: REUSE
2	**Repair / Refurbishment Candidates** Criteria: Faulty but potentially repairable, no contamination	Action: Avoid destructive handling · Label "REPAIR CANDIDATE" · Route to authorised repair partner	LIGHT GREEN bin label: REPAIR
3	**WEEE Recycling (non-contaminated)** Criteria: End-of-life, non-contaminated, not reusable or repairable	Action: Place in WEEE container · Apply WEEE label · Hand to authorised PRO or logistics provider	BLUE bin label: WEEE
4	**Medical Waste (infected / potentially infected)** Criteria: Infected, potentially infected, OR uncertain status	Action: Handle with full PPE · Leak-proof packaging · Label "INFECTIOUS" · Medical waste route	RED bin label: MEDICAL
5	**Damaged Battery / High-Risk Devices** Criteria: Swollen, leaking, or overheating batteries; fire risk	Action: Do NOT further handle · Place entire device in non-combustible container · No battery removal	BLACK/GREY bin · Class-D extinguisher nearby

📌 PPE: Personal Protective Equipment, **PRO:** Producer responsibility Organization, **WEEE:** Waste Electrical and Electronic Equipment

SORTING & COLLECTION POINTS

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Sorting a device — step by step

1. Apply the sorting decision tree available to the device
2. Place the device in the correct labelled stream (1–5)
3. Apply the corresponding tag: REUSE / REPAIR / WEEE / MEDICAL / BATTERY
4. Batteries: if intact and authorised → dedicated battery container
5. Swollen or leaking battery → route entire device to Stream 5, NO further handling
6. Record the device in the collection log

WHO Operators in the department · High-risk items: waste management lead + infection-control officer

Setting up collection points

Segregation at source

Collection points should be as close as possible to where devices are taken out of service. The earlier the sort, the better.

Clear labelling & signage

Colour-coded bins. Room-level signage at entrance: stream identification, hazards, restricted access, contact person.

Restricted access for data devices

A separate, lockable container or cabinet for devices likely to carry patient data. Restricted to authorised staff only.

Dedicated procedures for high-risk

Stream 4 (infected) and Stream 5 (hazardous - damaged battery) must have separate procedures displayed at the collection point, and staff must be trained on them.

Regular emptying & maintenance

Empty per agreed schedule with PRO or logistics provider. Inspect weekly. Replace damaged or faded labels within 7 days.

WHEN Every time a device is taken out of service or arrives at a collection point

IDENTIFYING HIGH-RISK DEVICES & TRACEABILITY

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High-risk or sensitive devices

Potentially infected or contaminated

Any device from clinical contact where infection cannot be excluded → treat as infectious.

Physically damaged

Cracked housings, exposed components, visible leakage → immediate isolation, no further handling until assessed.

Battery risk

Swollen, overheating, or leaking battery → Stream 5, no battery removal, call waste management lead.

Data-sensitive

Devices likely to contain patient or health-related data → restricted handling, locked container, DPO involved before routing.

📌 **DPO**: Data Protection Officer, **UDI:** Unique Device Identifier

Documentation & traceability

Every device should be traceable from collection to its final destination.

Minimum records must enable:

- Tracking from collection → reuse, treatment, or recycling
- Verification of correct routing (especially infected vs. non-infected)
- Proof of data destruction before any device leaves the facility
- Identification of which staff handled which device (incident management)

Minimum collection log fields

- Device identifier (UDI or serial number)
- Date and location of collection
- Stream assigned (1–5) and reason
- Name of operator who handled the device
- Destination (partner name, date of handover)
- Data destruction certificate reference (where applicable)

MENTI-PREVENTION & REUSE, SORTING IN PRACTICE

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1 **Do you currently separate potentially reusable devices from waste at the point of removal?**

Yes, no

2 **How does your team currently decide which bin or container a used digital health device goes into?**

Is there a written procedure? A training? Informal knowledge passed between staff? Or is it just... a guess?

Participation link:

https://www.menti.com/ale5it3pprjq

SAFE HANDLING AT HEALTHCARE CENTRES

PPE · data · damaged devices · emergencies

SAFE HANDLING PROCEDURES & PPE REQUIREMENTS

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Safe handling

1. Handle devices only in designated collection or sorting zones
2. Restrict access to unauthorised staff, lock the zone outside working hours
3. Do not stack, crush, or drop devices at any time
4. Replace inner bin liners without tilting or shaking the container
5. Use trolleys or carts, never carry heavy/unstable containers manually
6. Report any damage, leakage, or unauthorised access immediately

PPE requirements (per risk assessment)

Nitrile gloves
📍 All handling of used digital health devices, always

Safety goggles
📍 Broken devices, visible leaks, or risk of splatter

Apron or gown
📍 Suspected contamination or handling of infected devices

FFP2/FFP3 mask
📍 Aerosol risk — damaged batteries, dusty components

Protective footwear
📍 Heavy devices, risk of drops, or unstable loads

👤 **WHO** Operators in the collection/sorting zone · Supervised by: Waste Management Lead

⏱️ **WHEN** During every handling operation · Access control: continuous

🚨 RULE: No PPE = No handling. Operators must feel empowered to stop work and request equipment if it has not been provided.

HANDLING DAMAGED AND CONTAMINATED DEVICES

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Damaged devices

Risk: may release hazardous substances (gases, coolants, chemicals) or pose electrical hazards.

1. Do NOT open, break, or dismantle the device yourself
2. Handle with caution, especially devices with cooling circuits, screens, batteries, or internal modules
3. Place in intact, secure transport packaging to prevent further breakage or leakage
4. Deliver to an authorised collection centre or WEEE scheme
5. Battery removal: only if it can be done safely, otherwise let the treatment facility do it
6. Route to authorised treatment, do not mix with general WEEE without flagging the damage

Contaminated devices

Risk: infectious waste, may contain pathogens in quantities sufficient to cause disease (WHO).

1. Do NOT attempt to clean the device yourself if doing so poses a risk to staff
2. Label clearly and immediately: "INFECTIOUS / CONTAMINATED"
3. Use full PPE: gloves, eye protection, mask, protective clothing
4. Place in leak-proof packaging that prevents spills during transport
5. Separate any sharp components, treat as sharps waste
6. Handle per the facility's internal infectious waste protocol, not WEEE route

⚠ Contaminated devices do NOT go directly to WEEE processing until decontaminated.

EMERGENCY PROCEDURES

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Display at every collection point alongside sorting decision trees

Lithium battery fire / thermal runaway

› Do NOT use water or foam, reacts with lithium, intensifies the fire
› Use dry-powder or class-D / lithium-specific extinguisher if available
› If fire cannot be controlled within seconds → evacuate immediately, call fire brigade
› Close doors to contain smoke; do not block corridors
› After fire: do NOT touch device for 24h (re-ignition risk) · Document incident.

⏱ Immediately on first sign of smoke, hissing, swelling, or unusual heat

Sharps injury / needle-stick exposure

› Stop the activity immediately; do not put the device back in the bin
› Allow wound to bleed gently; wash with soap and running water for 5 minutes, **do NOT** scrub or squeeze
› Cover with a waterproof dressing
› Report immediately to occupational health or emergency department
› Identify and isolate the source device · Document incident

⏱ Immediately — report within 1 hour

Suspected contamination event

› Isolate the device, place in a sealed, labelled bag
› Remove contaminated PPE; wash hands and exposed skin immediately
› Alert infection-control officer and waste management lead
› Notify any staff who may have been exposed
› Follow the facility's infection-control protocol · Document incident

⏱ Immediately on identification

Suspected data breach

› Do not attempt to investigate or restore data alone
› Notify the Data Protection Officer (DPO) immediately
› Notify the waste management lead and the partner from whose custody the device may have escaped
› Document the timeline of events
› Under GDPR Art. 33: notify national data protection authority within 72 hours of discovery

⏱ Notification to DPO within 1 hour · Regulatory notification within 72 hours

STORAGE

Safe, compliant, and organised

SETTING UP AND MAINTAINING STORAGE

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Dedicated storage area

Separate from general waste. Sub-areas for each of the 5 streams. Dry, ventilated, and protected from sunlight and heat.

Access control

Restrict access to authorised staff only. Lock the area outside working hours.

Fire safety for Stream 5

Dry-powder or class-D extinguisher on site. Never store damaged batteries near other streams.

Safe stacking

Avoid unstable or heavy container stacks. Respect manufacturer load limits for all containers.

Weekly inspection

Check for leaks, damage, and unauthorised access. Record inspection results.

Scheduled emptying

Empty per agreed schedule with PRO or logistics provider. Respect any volume or duration limits set by national legislation.

WHO Healthcare facility manager (waste management lead) sets up · Operators maintain daily

LABELLING

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Signage & labelling requirements

Every storage area and collection point must be clearly signed and consistently labelled.

Container labels

Apply colour-coded labels per Annex 7, including the stream number, stream name, and hazard icon for the relevant stream.

Room-level signage

Post at the storage area entrance: stream identification, hazard warnings, restricted access notice, and name/contact of the responsible person.

Label maintenance

Replace any damaged or faded labels within 7 days of identifying the issue. Do not allow unlabelled containers to remain in use.

Weekly check

Verify labelling completeness during every weekly inspection and record the outcome. Any gaps must be corrected before the next working day.

SMART COLLECTION MACHINES

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Smart collection machines

QR-code controlled access

The operator or user scans a QR code on the device before depositing. This pre-sorts at the point of deposit only matching device categories are accepted into each machine.

Unauthorised access alerts

The machine generates an alert if someone attempts to access stored items without authorisation. All access events are logged.

Periodic collection by operator

Stored devices are collected on an agreed schedule by the responsible organisation and transported to the appropriate downstream treatment or reuse facility.

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TRANSPORT & SHIPMENT

Permits, packaging, documentation, and traceability

AUTHORISATIONS, PERMITS AND COLLECTION

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Authorisations & permits

- WEEE collection & transport permit under Directive 2012/19/EU and national legislation
- Hazardous waste transport permit (Directive 2008/98/EC) where applicable
- Healthcare / infectious waste transport permit where applicable
- ADR certification for road transport of dangerous goods where applicable
- All permits must be verifiable on request, re-verify annually and at every contract renewal

Collection & packaging

1. **Verify first**
   Check the receptacle and label are correct before opening any container.
2. **No direct contact**
   Never handle loose devices manually, use the bag or tools. Maintain the integrity of containment at all times.
3. **Close and label bags**
   Close bags securely before removal. Label each bag with the collection point and date of collection.
4. **Report and replace damage**
   Replace any damaged or leaking bag or receptacle immediately. Do not transfer contents without proper containment.
5. **Register the collection**
   Record every collection in the operational system per the agreed internal procedure.

DOCUMENTATION, TRACEABILITY AND STORAGE

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Every shipment must be accompanied by complete and accurate documentation.

Consignment note

Issued for every single shipment. Must include: date and location of collection, type and quantity of devices, EWC code, transporter identity, and destination facility.

Countersignature on delivery

The receiving facility must countersign the consignment note on delivery. This confirms the chain of custody and closes the transport record. A missing countersignature is a compliance gap.

Archive retention

Archive all consignment notes per legal and contractual retention periods, typically 3 to 10 years depending on jurisdiction. Must be readily available for inspection or audit.

Interim storage registration

For any temporary storage: register material on entry AND on exit. Storage locations must be secure, clearly identified, and managed to prevent loss, contamination, or unauthorised access.

⚠ Missing transfer note = legal liability for the originating healthcare facility AND the logistics provider. Never move a device without documentation.

MENTI- THE HANDOVER MOMENT: WHAT HAPPENS WHEN DEVICES LEAVE YOUR FACILITY?

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1 **Do you know who collects your digital health devices and what permits they hold?**

Can you name the logistics provider, the PRO, or the treatment facility? Have you ever been asked for or provided a waste transfer note?

2 **Has a logistics or collection issue ever resulted in a device ending up in the wrong place?**

A WEEE container taken to medical waste incineration, a contaminated device mixed with standard WEEE, a data-bearing device handed over without wipe

LEGAL FRAMEWORK IN BELGIUM

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WEEE and healthcare risk waste: two parallel legal frameworks

WEEE Directive 2012/19/EU

Implemented by the three Belgian Regions:
- Flanders (OVAM)
- Wallonia (SPW)
- Brussels-Capital Region

Applies to discarded electrical and electronic equipment (WEEE) once appropriately decontaminated.

Healthcare Risk Waste

Applies to devices contaminated with blood, bodily fluids or infectious material.

Each Belgian Region regulates:
- Classification & packaging
- Storage, collection & transport

🚚 Federal & International

ADR applies where dangerous goods are transported (e.g. lithium batteries).
Federal occupational health & safety legislation protects workers involved in handling and transport.

Operational principle: healthcare institution classifies the waste

- Decontaminated device → WEEE collection chain
- Contaminated device → Healthcare risk waste chain first → WEEE treatment afterwards

TREATMENT

WEEE vs medical waste pathway selection

TREATMENT PATHWAY SELECTION AND REQUIREMENTS

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Is the device infectious / potentially contaminated?

YES → Medical waste pathway

- Verify consignment documentation and infectious-waste classification
- Apply treatment route: high-temperature incineration, OR disinfection then WEEE treatment where nationally permitted
- Disinfection: use processes validated under EN 14885 and Regulation (EU) 2020/1207
- After disinfection: document the process and route device to WEEE treatment
- Issue a Certificate of Treatment

NO → WEEE treatment pathway

- Verify consignment documentation and EWC code; reconcile with agreed shipment; weigh and record
- Depollution per EN 50625: remove batteries, capacitors, mercury components, and other hazardous fractions
- Data destruction: physical shredding of memory storage components for any device not pre-wiped
- Recover material fractions: PCBA (precious metals), clean plastics (ABS/PP), ferrous and non-ferrous metals
- Issue Certificate of Treatment + Data Destruction Certificate linked to device UDI

Disinfection routes are NOT permitted in every Member State. Verify availability with your logistics partner and national environmental authority.

WEEE facility requirements: environmental permit (Cat. 4 or Cat. 5) + WEEELABEX certification. Verify on weeelabex.org/operators-list before dispatch.

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REPROCESSING, RECYCLING & CROSS-BORDER

Legal verification, data destruction, and shipment rules

Prepare For Reuse & RECYCLING

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Reprocessing (Article 17 EU MDR)

Only permitted in Member States that have authorised single use device reprocessing. Verify first if prohibited; divert directly to recycling.

1. **Legal verification**
   Consult DiCE D6.2 Authorisation Map. Verify ISO 13485 cert + EUDAMED registration + validation under Reg. 2020/1207.
2. **Triage & decontamination**
   Primary deep cleaning (EN 14885) to neutralise pathogens before opening the device (e.g. Pill box)
3. **Battery & component replacement**
   Replace swollen batteries or those past rated charging cycles. Guarantees device autonomy for next user.
4. **Calibration & safety testing**
   Electrical and functional safety tests equivalent to a new unit (sensor accuracy, electrical safety). Check if the device is safe to use once more.
5. **Labelling & certification**
   Apply reprocessor ID + unique batch reference linked to UDI. Issue Certificate of Reprocessing; update EUDAMED.

Recycling prep & data destruction

PCBA recovery
Manual extraction of circuit boards for precious metal recovery.

Plastics
Segregate clean polymers (ABS/PP) for circular economy processes.

Batteries
Separate handling per EU Battery Regulation 2023/1542.

Data destruction
Reuse path: certified logical wipe. Recycling path: physical shredding. Issue a Data Destruction Certificate linked to the Unique Device Identification.

Cross-border shipments

Non-hazardous WEEE on the green list: Annex VII documentation required but no prior consent needed between EU Member States.

Hazardous WEEE: prior written notification and consent of competent authorities in dispatch, transit, and destination countries.

Outside EU: Basel Convention prohibits hazardous waste exports to non-OECD countries. Reuse claims must comply with WEEE Directive Annex VI.

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SUMMARY OF OPERATIONAL MANUAL

FOR HEALTHCARE FACILITIES

IF YOU WORK IN A HOSPITAL OR CLINIC...

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Operational staff (nurses, cleaners, technicians)

Sort correctly at source
Apply PPE
Label and route

Managers (waste leads, procurement, biomedical)

Set up the system
Select & contract partners
Train staff

Infection-control officers

Classify contamination risk
Approve handling procedures
Oversee incidents

Key things the manual gives you

5-stream sorting system

A clear sorting guide with labelled bins, colour codes, and icons ready to print for your collection points.

Reuse before you recycle

Step-by-step assessment: is this device functional? Can it be reused within the facility, transferred elsewhere, or repaired? (Chapter 7 + Annex 2)

Data protection built in

GDPR-compliant procedure for labelling, isolating, and clearing devices with patient data before any handover to third parties (Chapter 9, Table 19).

Partner selection checklists

How to find and vet a PRO, logistics provider, and treatment facility — including what to ask and what permits to verify (Chapter 5 + Annexes 12-13).

This manual is intended to complement existing legislation, standards, and internal procedures; it does not replace them.

FOR PROs & LOGISTICS OPERATORS

IF YOU COLLECT, TRANSPORT, OR TREAT THESE DEVICES…

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Producer Responsibility Organisations (PROs)

What the manual expects from you

Organise compliant collection, provide containers and documentation, select authorised treatment partners, report recovery rates to members and authorities.

Your relationship with healthcare facilities

The manual sets out how hospitals select a PRO, meaning you may be evaluated against these criteria. Section 5.1 lists exactly what a healthcare manager will ask for.

Data & documentation

Chain of custody documentation, permit verification, and annual reuse/recycling/recovery reporting are all specified. The manual provides a contract reference checklist.

Logistics Operators

Permits & authorisations

You must hold valid permits for WEEE transport and, where applicable, medical (infectious) waste transport in each country you operate. The manual specifies what to verify and what a healthcare facility will ask for before handover.

Packaging & transport standards

Container type, labelling, and packaging requirements differ by stream. Infectious devices require dedicated packaging compliant with ADR transport regulations.

Documentation required

Waste transfer notes (or CMR for cross-border) are mandatory for every collection. A missing transfer note creates legal liability for the originating healthcare facility and for you.

FOR TREATMENT & RECYCLING FACILITIES

IF YOU TREAT, RECYCLE, OR REPROCESS THESE DEVICES…

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The first decision every treatment facility faces:

Is the device infectious / potentially contaminated?

YES → Medical waste pathway

- Infectious / potentially contaminated devices must not enter the WEEE stream
- Applies to devices with blood-borne pathogen exposure or devices from surgical/clinical use where contamination cannot be excluded
- Treatment: incineration or validated disinfection/sterilisation before any material recovery
- Chapter 12, Table 31 gives the step-by-step operational instruction
- Cross-reference with ADR transport regs and health & safety law

NO → WEEE pathway

- Non-infectious devices enter the WEEE treatment stream
- WEEELABEX / EN 50625 certification recommended for facilities treating health-sector WEEE
- Secure data destruction must occur BEFORE any material recovery — document it
- Battery removal and depollution apply per EN 50625 requirements
- Chapter 12, Table 30 provides the step-by-step instruction

⚖️ Reprocessing of single-use devices (Article 17 EU MDR) — only permitted in countries that have authorised it. Chapter 13 covers the full legal verification and reprocessing workflow.

DECISION TOOLS

6 DECISION TREES, DESIGNED TO BE USED ON THE FLOOR

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The annexes contain ready-to-print decision tools. No need to read the whole manual to use them.

Annex 2

Reuse vs. Waste Treatment

❓ Is this device safe, clean, and functional?

✅ Reuse / redeploy

❌ Waste treatment pathway

👤 Operational staff at healthcare centres

Annex 3

Refurbishment & Repair

❓ Can this device be economically repaired?

✅ Refurbishment partner

❌ WEEE or medical waste

👤 Biomedical technicians, waste coordinators

Annex 4

Sorting & Stream Routing

❓ What is the contamination status?

✅ WEEE stream (Streams 1-3)

❌ Medical waste (Stream 4)

👤 All operational staff at point of collection

Annex 5

Damaged / Contaminated Devices

❓ Is there physical damage or biological risk?

✅ Specialist handling required

❌ Standard WEEE pathway

👤 Operators, infection-control, logistics

Annex 23

First Sorting , Clinical Setting

❓ Has the device been in direct patient contact?

✅ Infectious assessment required

❌ Non-contaminated pathway

👤 Clinical staff, nurses

Annex 24

Reuse vs. Recycling, Terminal

❓ Does device meet reuse criteria after assessment?

✅ REUSE

❌ RECYCLING

👤 Biomedical service / reuse coordinators

This manual is intended to complement existing legislation, standards, and internal procedures; it does not replace them.

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Discussion and Q&A

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1. **What is the main reason a device's disposal route becomes unclear?**

   (No contamination label, mixed-use device, missing procedure, unclear owenership)

2. **What is the hardest part of managing digital health devices safely ?**

   (Contamination classification? Documentation? Knowing which stream? Staff awareness?)

3. **Is the boundary between WEEE and medical waste clear in your daily operations?**

   (Where does it get blurry? What would help?)

4. **Have you ever dealt with a device that contained patient data and needed to be recycled or sent for treatment?**

   Did you have a data destruction procedure? A certificate? Or did it go into the stream without formal verification? What would a workable data destruction process look like for your setting?

THANK YOU!

Thank you for your time and your input.

Your experience is what will make this guidance work.

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