ENGINEERING **SPECIFICATION**CONTROLLED BY APPLIED PRACTICES AND STANDARDS

Global Packaging Requirements

This cover sheet controls the revision status of this entire document. All sheets of this document have the same revision number.

Revision History:

Rev	Date Revised	ECR/ECO	By Whom	Why / Sections Modified
0-24	Various	Various	Shervey, D	See MyWorkshop for details on previous revisions
25	2021 Nov 30	ECR2332505	Wendling, S Nevins, M Roman, J	Revisions / Additions 4.11 Added battery requirements to Time Sensitive Materials section 5.1.11 Added section "Registration & Reporting" 5.2 Updated Environmental Requirements 6.1.2 Added PKG COE 7.2.5 Reworded for clarity 8.1.4.3.2 Updated Korea recycle label requirement 9.1 Updated USA address for receipt of Service Parts 9.3.4 Added battery requirements to Shelf-life Material section 9.3.5 Added note regarding lead acid batteries to Special Requirements for Batteries section Deletions 4.12 3 Removed "Special Requirements for Solid Wood Crating" 5.1.3.1 Removed reference to ISBP 15, no longer required by China 5.1.8 Removed "China RoHS" Section 11.12 Removed "Protection Level Selection Matrix" Section * All subsequent Section Numbers changed
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27	2024 May 22	ECR2381005	Rockwell, G	Revisions / Additions Effectivity statement Updated from 90 to 180 days 5.2.9.3.1 changed "shall" to "should" and added "Suppliers should provide certificates of conformance upon request from GEHC."

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This document helps to establish criteria for the design, distribution and/or manufacture of GEHC products. When this document is referenced, this new revision of the document is applicable to any new Purchase Order (P.O.) issued 180 days after the final release of this document. Exception: It is not applicable to P.O.s for existing designs unless called for by specific revision number on the drawing or P.O. When used in new design work it should apply within 180 days of final release of this document. During this time-period, Revision 25 or Revision 26 may be used.

The RDO for this document is ESB. The owner of this document is HC ISC-HCS-Advanced Manufacturing Engineering.

Supplier(s) Affected?	Yes
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1.0 General

1.1 Purpose and Scope

This document defines the domestic and international packaging requirements for all GE HealthCare (GEHC) products. These requirements apply to GEHC manufactured parts, supplier finished good parts & line-use parts, and all service parts (both GEHC-manufactured and supplier-manufactured).

The purpose of this document is to provide controlled, documented packaging and shipping label requirements for worldwide distribution of GEHC products. The requirements specified in this document are **minimum** requirements. They may be exceeded to comply with specific country or local regulations or requirements, but these minimum requirements are mandatory.

This document includes general and specific requirements, general reference information, and makes reference to other, more detailed specifications that are beyond the scope of this document. The goal is to provide global requirements to help ensure consistent, adequate, and economical product protection, and efficient and safe handling for all inbound and outbound GEHC products.

1.1.1 Use of Document

This document is to be used to define the requirements for the selection of different types and sub-types of packages and to help determine general protection requirements and shipment labeling for traceability compliance.

The reader should start with "Document Usage Roadmap" in Section 2 to identify which sections most apply to them.

1.2 Supplier Responsibility

GE HealthCare relies on the knowledge and expertise of its suppliers and their packaging/handling agents to ensure items are packaged safely and in compliance with all applicable laws and regulations. These requirements provide a basic understanding of GEHC packaging requirements, but the ultimate responsibility for safe and compliant packaging, shipping box labeling, validation testing, and all associated costs rests with the supplier. For questions on these requirements, the supplier or the supplier's agent should contact their GEHC Sourcing Leader or a GEHC Packaging Engineer to discuss their concerns.

1.3 List of Symbols, Abbreviations, Definitions, Acronyms

See Section 15.5

1.4 Order of Precedence

The following order of precedence shall be followed:

- 1. The drawing, purchase specification, or other part or assembly specific document
- 2. This document
- 3. Other GEHC Standards referenced
- 4. Industry Standards referenced

GEHC or Industry Standards not referenced may apply.

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2.0 Document Usage Roadmap

Determine which sections are applicable for user's respective role:

This matrix is meant to be a general guide for users to find which sections are applicable to them. It is not an exhaustive list of all the different roles within and outside GE HealthCare.

	Roles							
Sections of PRE	Product Engineering	Suppliers	Service Engineering	Ē	Manufact- uring	Packaging Engineers	Quality	EHS
1-General	х	х	х	х	х	х	х	х
2-Document Usage Roadmap	х	х	х	х	х	Х	х	х
3-Package Type	х	х	х	х	х	Х	х	х
4-General Package Requirements	х	Х	х	х	х	х	х	х
5-Regulatory & Environmental Requirements	х	х	x	х	x	х	х	х
6- Package Testing & Validation	х	х	х		х	х	х	
7- Material Handling & Distribution Safety & Efficiency	х	х	х	х	х	х	х	
8-Product Identification, Marking, & Labeling	х	х	х	х	х	х	х	
9-Special Packaging Requirements for Service Parts	х	х	x	х	х	х	х	х
10-Artwork Layout Guidelines	x	х	х		х	Х	х	
11-Size & Weight Limits for Distribution & Delivery	х	х	х			х		х
12- Packaging Optimization Best Practices	х	х	х		х	х		
13- Packaging Instructions for Common GEHC Parts	х	х	х		х	х	х	
14-Trial Shipment Testing Instructions	х		Х			х	х	
15-General Reference Documents & Specifications	х	х	х			х	х	15.4
16- Labeling/Packing List Examples		х			х	х		

^{*}LPI=Lead Process Integrator for NPI programs

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3.0 General Packaging Requirements

3.1 Package Types & Appropriate Use

3.1.1 Selection of Package Type

Parts shall be packaged as specified in the GEHC Purchase Order, the Purchase Contract, the Purchase Specification, or GEHC Drawing.

Engineering should determine packaging/product requirements before selecting and designing new packaging. Use DOC2853710 (Design Criteria Form) to help identify and track critical-to-quality design requirements. See Section 3.2 for more guidance on the packaging design process.

When Sourcing or Engineering documents do not explicitly define packaging requirements, select a package type which protects the product as required by this section of the document.

3.1.2 Determine the Type of Packaging Required

Step #1 - Define the <u>Type</u> of part:

It will be either a Manufacturing Part or a Service Part

Step #2 - Define the <u>Sub-type</u> of part (applies to **Manufacturing Parts** only):

A Manufacturing Part, will either be a Line Use Part or a Finished Good Part

Step #3 – Apply Type & Quantity:

Use the <u>part type and sub-type</u> to determine the <u>quantity per package</u> and the <u>number of trips per package</u> from the following table and the descriptions in Section 3.

Intend	Intended Use		Quantity Per Package		ips Per Package
Part Type	Part Sub-type	Individual	Multiple	Single	Multiple (Reusable/Returnable)
D. d. a. a. a. d. a.	<u>Line Use</u>	Optional	Preferred	Optional	Preferred
Manufacturing Finished Good		Required		Required	
<u>Service</u>	<u>All</u>	Required			Required

3.1.3 Package Type for Manufacturing "Line Use Parts"

Ship "line use parts" in "reusable/returnable containers" whenever possible.

Use "reusable/returnable containers" whenever the cost of the containers and the return transportation is justified. GEHC Sourcing Leaders will provide guidance to select or design containers and assure return to the supplier.

"Multi-pack" "line use parts" whenever possible to minimize packaging material cost and waste.

Do not use "individual packages" for "line use parts" except when the size, weight, or fragility of the part does not allow "multi-pack."

Use GEHC "milk run" carriers when possible to reduce the cost of delivering parts and returning packaging materials.

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3.1.4 Package Type for Manufacturing "Finished Good Parts"

Unless otherwise specified, always ship "<u>finished good parts</u>" in "<u>individual pack, single trip containers</u>" so that parts do not need repackaging before shipment to customer sites.

When specified, ship "<u>finished good parts</u>" in "<u>individual pack, double trip containers</u>" so that the damaged or defective parts being replaced can be returned in the same package without additional damage.

"<u>Finished good parts</u>" will often be reshipped individually. Supplier packaging must provide adequate protection from the rough handling anticipated during express or courier shipments.

3.1.5 Package Type for "Service Parts"

See Section 9 for additional requirements specific to Service Part packaging.

3.1.6 Other Packaging Definitions and Uses

<u>"Overpack"</u> refers to any packaging that is secondary or tertiary packaging, not applied directly around the product or component. It is packaging that is used to facilitate consolidation and handling. It is used ad-hoc and is not standard. An example of this would be a **pallet** used to combine multiple Finished-Good boxes (see Figure 3.1.6.1). Another example would be the **pallet**, large box, and void-fill air pillows used to combine and brace multiple small Finished Good boxes into a shippable container (see Figure 3.1.6.2).

Overpack is generally applied by GEHC manufacturing facilities, supplier facilities who drop-ship, GEHC distribution centers, and 3rd-party distribution centers.

Figure 3.1.6.1



Figure 3.1.6.2



<u>"Primary packaging"</u> or <u>"Finished-Good Packaging"</u> refers to any packaging placed directly around the product being shipped. This type of packaging is generally standard and used every time the part is shipped. An example of this would be a monitor shipped in a **box with foam endcaps and plastic bag**. All these packaging components would be considered the primary packaging. See Figure 3.1.6.3 & 3.1.6.4 for examples.

GEHC manufacturing facilities apply Primary packaging for Make Parts and occasionally Buy Parts. Suppliers apply primary packaging to Buy Parts, which is often re-used to ship to the customer.

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Figure 3.1.6.3

Figure 3.1.6.4







<u>FG Packaging:</u> 9 packaging components including crate, cardboard, bags, foam, straps, etc.

<u>"Secondary packaging"</u> refers to any packaging that combines multiple primary packaging containers, generally containing multiples of the same primary packaging. For example, a **bulk box** coming from a supplier that has 10 primary packaging boxes containing cables. Multiple secondary packaging boxes may then be placed into a larger tertiary crate or box to facilitate shipment and handling.

<u>"Tertiary packaging"</u> refers to any packaging that is not primary or secondary packaging, and which facilitates the protection, handling, and transportation of more than one secondary or primary packages in order to group everything into unit loads during transit. See Figure 3.1.6.5 for visual depiction of primary vs. secondary vs. tertiary packaging.

Figure 3.1.6.5



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3.2 Packaging Design Process

3.2.1 Packaging CTQs (Critical to Quality)

3.2.1.1 Product Protection

- Shock and vibration
- Surface protection
- Moisture protection
- Crush protection
- ESD protection
- Corrosion protection
- Cleanliness protection
- Temperature sensitivity

3.2.1.2 Material Handling

- Follow <u>Packaging "Golden Rules"</u>
- 4-way pallets or other
- Pallet jack access for all pallets
- Global equipment compatibility
- Design for parts that need special handling (Cranes, forklifts, etc.)

3.2.1.3 Efficient Pack & Unpack

- Minimize cycle time
- Minimize number of people required
- Minimize tools required & use only standard tools
- Safe packing and unpacking

3.2.1.4 Product Identification

- Clear identification during distribution
- Clear identification for Customs clearance
- Clear identification at customer site and installation

3.2.1.5 Size & Weight

- Efficient transport and distribution
- Efficient delivery
- Efficient weight to volume ratio

3.2.1.6 Reusability

- Reusable vs. disposable
- Cost effective return & reuse process required for reusables
- Secure crates with screws and other easy open fasteners instead of nails

3.2.1.7 Lean

- Efficient presentation for manufacturing use
- Efficient delivery and install at customer site

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3.2.1.8 Stability

- Minimize height of product center of gravity
- Design base footprint & fork access points to match center of gravity

3.2.1.9 Validation Testing

- Global shipping validation testing (Reference 46-316745 & 2252595PRE)
- Technical justifications

3.2.1.10 Packaging Materials

- Use material suppliers available near packing location
- Use standard packaging already in use at packing location
- Use environmentally friendly packaging when possible

3.2.1.11 Safety / EHS

- Ergonomic packing and unpacking
- No pinch points
- No sharp edges
- Comply with manual handling weight limits

3.2.1.12 Regulatory Compliance

- Comply with all shipper and receiver local and national regulations
- Comply with all hazardous material transportation regulations
- Comply with special wood import regulations (China, Brazil, United States, Canada, etc.)

3.2.1.13 Environmental Considerations

- No loose fill cushioning/dunnage materials
- Avoid use of EPS (styrene) foam materials
- Comply with receiver material disposal requirements

3.2.1.14 Documentation

- Package specifications & part numbers
- Link between finished goods & packaging part numbers
- Packaging Taxonomy & attributes
- Package assembly instructions

3.2.1.15 Cost

• Total cost analysis (Product/Packaging/Distribution)

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3.2.2 Packaging DFSS (Design for Six Sigma) – Package Design Process for New Products

3.2.2.1 Define / Measure

- Determine & Document the Package Design Requirements
 - Use **DOC2853710** (Design Criteria Form) to capture details
 - Identify CTQ's
 - o Storage duration and conditions
 - Determine the Environment
 - Process map packaging life cycle
 - Determine Product Fragility
 - Simulation models (FEM), Product data sheets, Experimental data, Experimental modal analysis,
 HALT results, Product fragility shock testing, see Section 15.2 if estimating

3.2.2.2 <u>Analyze</u>

- Examine Failure modes of Product/Packaging
- Product Redesign Considerations

3.2.2.3 <u>Design</u>

- Preferred Package Option
 - Map package design objectives
 - New design vs. modifying existing design vs. reuse existing design
 - Concept design layouts
- Design to Meet Basic Protection Requirements
 - o Shock, Vibration, Moisture, Stacking, Static
 - Cushion curves
 - Packaging "Golden Rules"
- Design to Meet Sustainability & Regulatory Requirements
 - > REACH/RoHS
 - Labeling/Traceability
 - Hazardous Material shipping
 - Material and size optimization
 - Reusable packaging
 - Recyclability & recycled content
- Design to Meet Special Protection Requirements
 - Liquids, lumber, reusable packaging, strapping, ergonomics
- Design for Handling and Transportation
 - Size and Weight Limitations For Efficient Distribution & Delivery (Ref: Section 11)
 - Pallet design
 - 4 way access
 - Pallet jack and forklift access
 - Pallet quality requirements
 - Design for rigging
 - Easy/Safe product removal & packing
 - High CoG loads
 - Requirements for wheeled products

3.2.2.4 <u>Verify</u>

- Design Validation
 - Packaging Testing
 - Technical Justifications

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- Quality Plan
 - o Material evaluation, SOP's, Design of inspection process, FAI
- Production Plan
 - Supply schedule, vendor capacity, competitive pricing, storage plan

3.2.2.5 Control/Implement Solution

3.2.2.5.1 Documentation

- Package specifications & part numbers
- Link between finished goods & packaging part numbers
- Packaging Taxonomy & attributes
- Package assembly instructions

3.3 Packaging "Golden Rules"

The following rules must be adhered to for all shipments from GE HealthCare and its suppliers:

1) Products cannot ship on wheels.

Items are not to be shipped on dollies, system wheels, or wheels of any kind. Wheeled products must be braced and palletized so that they can be properly handled in distribution via forklifts, pallet jacks, and/or cranes.

2) Shippable products must be fully contained in packaging.

Do not design or ship palletized items without side and top walls-see examples below. Overpacks must be designed with ergonomics/efficiency in mind.

- Sidewalls, ends, and tops should be designed to be as light as possible. Individual packaging components should not weight over 35 lb (16kg).
- Fastening devices should be minimized and the required use of hand tools should be avoided when possible.
- Work duration and frequency at floor level should be minimized. For example, avoid designing pallets that require fastening underneath the pallet.

CORRECT



Palletized part WITH side & top walls

INCORRECT



Palletized part WITHOUT side walls

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3) Pallets should be designed for four-way handling.

All pallets should be evaluated for four-way handling unless impractical due to small width. The maximum number of sides should be accessible by lifting equipment (including manual pallet jacks) based on the evaluation. If the evaluation determines that it would be unsafe to pick it up from 1 or more directions that cannot be engineered through changes in the pallet designs, then that side should not be accessible for lifting.

4) Center of Gravity (CG) should be aligned with center of pallet in length and width directions.

Center pallet blocking & components must be aligned with the CG of part being packaged.

5) Packaged-parts must pass 22° tip test.

All packaged-parts must be able to withstand tipping 22 degrees without falling over. See <u>Section 4.4</u> for more information about tipping hazards.

6) Packaging should communicate transportation and handling hazards.

Handling hazards must be communicated via packaging printing or labels when applicable. Examples include center of gravity locator markings, top-heavy tip warnings, "Do not fork this side", etc. It should also be communicated on the packaging where crane sling locations should be located as well as fork tine locations where necessary. See Section 6.3 for more information about hazard labeling.

- 7) De-install should be considered during the packaging design phase.
- 8) Products that could potentially be crane lifted should have packaging that is designed to be crane lifted. See Section 4.5 for more information.

3.4 Basic Protection Requirements

3.4.1 Shock & Vibration

Provide adequate cushioning and dunnage materials to prevent damage from shock and vibration during shipment. The amount of protection required depends upon the fragility of the product and varies by the protective materials and mode of transport used. Cushion small products within their packages. Medium and large products can be protected with cushioned wood bases or special isolation systems built into the product itself.

3.4.2 Stacking / Crushing Protection

Provide adequate compression strength with the package and/or product to prevent crushing during normal anticipated distribution and storage stacking and handling conditions. All palletized or crated packaging must be designed to withstand stacking during transit up to a height of 228 cm (90 inches). Some package crushing is acceptable as long as there is no product damage or loss of package integrity, but it should be minimized.

3.4.3 Scuff Protection

Use scuff resistant materials to protect all painted, plastic, and other finished product surfaces that come in contact with wood, untreated corrugated fiberboard, other products, or anything that could potentially damage the part surface.

3.4.4 Labels & Tape on Cosmetic Surfaces

Do not apply temporary labels or tape to exposed product surfaces unless the adhesives used are specifically designed to not harm the surface, or have been tested and confirmed to release cleanly and not harm the surface. Consideration must be given to the length of time anticipated before removal due to adhesive hardening and bonding over time.

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3.4.5 Static-Electricity Protection

Package smaller, ESD sensitive parts in metalized, static shielding bags, and seal with a label identifying the contents as "ESD sensitive". Do not place any static generating material, such as instruction sheets, tape, or corrugated packing material inside of these bags.

Wrap and package larger products with exposed electronic components that are susceptible to static damage in antistatic materials. Use static shielding materials as required.

If a part is repacked in a shielding bag after the seal is broken, the seal must be replaced.

Printed wiring assemblies with batteries must include an insulator to prevent accidental discharge of the battery.

Printed wiring assemblies and printed wiring boards must not be packaged in "pink poly" or other plastic materials that use amines, or animal fats, as the static dissipating medium. These films or bags typically exhibit a slimy feel to the touch.

Protect all printed wiring assemblies and products with exposed electronic components from electrostatic discharge (ESD).

All electronic boards and parts containing sensitive, accessible components must be protected from damage due to electrostatic discharge (ESD). ESD sensitive parts shall be wrapped in a conductive antistatic bag or film. The bag must be closed using a tamper-proof label.

See Section 13 for more packaging guidance for specific components.

3.4.6 Moisture Protection

Moisture protection requirements apply when such conditions may be encountered during distribution. In a controlled system where rain, standing water, or similar extreme conditions are avoided (i.e., direct shipment from supplier to a manufacturing facility in a dedicated transport vehicle, small package shipping by express carrier, etc.), water resistant materials may not be required. The supplier must make this judgment based on knowledge of the distribution system being used.

3.4.6.1 Rain / Heavy Condensation

Cover products not contained in waterproof boxes or crates with a water-resistant shroud to prevent water damage during distribution.

3.4.6.2 Humidity

Protect products sensitive to damage from high humidity with sealed enclosures and desiccant.

3.4.6.3 Standing Water

Package bases that may come into contact with standing water must not lose their compression strength when submerged in water for up to 48 hours.

3.4.6.4 Rapid Temperature Changes

Rapid temperature changes can occur when aircraft land after prolonged high-altitude flight, or when products are moved from cold delivery vehicles to warm receiving docks. Heavy condensation can form on cold products when they come in contact with much warmer air. Protect products that will be damaged by short-term condensation with vapor barrier materials and desiccant to keep them dry. Products that will not be damaged by short-term condensation can be packed so that air circulates around the product allowing moisture to dry freely as the temperature changes.

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3.4.7 Corrosion Protection

Provide protection for products with exposed metal surfaces that are susceptible to corrosion. Package products susceptible to corrosion, in a manner, that will provide a dry, non-corrosive atmosphere around them during the expected time of shipment, and any storage. Vapor barrier materials from simple plastic bags and films to heavy foil laminated scrims must surround the product completely and be sealed to prevent moist air from coming in contact with the product. Desiccants must always be used with sealed systems to absorb moisture that is inside the vapor barrier material at time of packing and moisture that migrates through the barrier over time.

3.4.7.1 Metal Coating & Finishes

In most cases, metal surfaces that are susceptible to corrosion should be finished, painted, or coated in some way to provide permanent protection.

3.4.7.2 <u>Contact Preservatives</u>

Temporary corrosion prevention/protection materials can be applied directly to metal surfaces. Removal of these preservatives may or may not be required. Provide specific instructions if removal is required.

3.4.7.3 Part Surfaces in Contact with Wood

Part surfaces, either finished or unfinished, should not be in prolonged direct contact with wooden packaging. Moisture barrier materials must be used to isolate parts from all wooden packaging surfaces or components such as crates, blocking, or pallets.

3.4.7.4 Barrier Materials & Desiccant

The type of vapor barrier material used, and the amount of desiccant required are dependent on the size of the package, expected relative humidity and length of exposure time.

3.4.7.5 Plastic Materials

Plastic materials provide an economical barrier for short-term protection. However, all plastic materials allow moisture to migrate through fairly quickly, which will result in a wet, corrosive atmosphere around the product if exposure time is too long. Time is critical when using plastic barrier materials.

3.4.7.5.1 Foil Laminated Barrier Materials

Foil laminated barrier materials are much more expensive than plastic materials but allow moisture to migrate through at a much slower rate, providing protection for much longer periods of time.

Foil laminated barrier materials should have a water vapor transmission rate (WVTR) of $0.02g/100in^2/24$ Hrs. ($0.31g/m^2/24$ Hrs.) or less and it is recommended that the rate be $0.002g/100in^2/24$ Hrs. ($0.031g/m^2/24$ Hrs.) or less. (Ref. MIL B 131 H)

3.4.7.5.2 **Desiccant**

Desiccant absorbs moisture and is placed inside the vapor barrier material but must not be in contact with the product. The quantity required can vary by type of desiccant (clay or silica gel) and by manufacturer, but the general formula is 1 unit (33g) for each 90 in² (580 cm²) of exposed vapor barrier surface area. The quantity increases when wood, corrugated, and other materials that can contain moisture are packed inside the vapor barriers, so the quantity must be adjusted for specific applications.

3.4.7.5.3 **Dust Cover**

A dust cover is a simple plastic bag or sheet draped over a product to help keep it clean. It is not designed to prevent corrosion. This type of cover must be kept open to allow air to circulate around the product, or condensation will occur and promote corrosion.

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3.4.7.5.4 Tape Sealed Joints

Tape can be used to seal barrier joints to provide economical, short-term moisture protection.

3.4.7.5.5 **Heat Sealed Joints**

Heat sealed joints are more expensive than tape joints, but they provide greater protection from moisture migration and shall be used for longer-term protection.

3.4.7.5.6 **Vacuum Pack**

When barrier materials are heat sealed, it is most effective to vacuum excess air from inside of the barrier to provide the driest atmosphere possible at time of packing. Desiccant is always required when a vacuum pack is used to absorb moisture that already exists inside the pack, and moisture that migrates through the barrier material over time.

3.4.7.5.7 Wood Inside Barrier

Do not seal green, un-dried, non-treated wood, or any wood materials with a moisture content over 19% (26% for hardwood), inside of a vacuum pack or any other type of airtight cover. The acidic nature of wood moisture will cause severe corrosion.

3.4.7.5.8 **Vapor Corrosion Inhibitors (VCI)**

Parts or entire products can be protected from corrosion by controlling the atmosphere around the item and filling it with vapor corrosion inhibitors. The VCI material is available in paper, plastic film, foam pads, emitters, and many other delivery systems. It vaporizes around a product, condenses on bare metal surfaces, and prevents corrosion.

<u>WARNING</u>: Because VCI materials condense on all, bare metal product surfaces, they must be tested to insure no negative effects on the electronics or any other sensitive components of the product.

The type and amount of VCI material to be used is dependent on the type of metal to be protected and the style and cubic dimension of the package being used. Follow the manufacturer's recommendations when selecting a VCI material, and the required quantity for a specific application.

3.4.8 Temperature Protection

Normal environmental extremes anticipated during distribution are -40°C (-40°F) to +70°C (158°F), relative humidity of 10% and 95% (general cargo). When engineering identifies items which are susceptible to damage in this range (requires tighter limits), special handling must be defined, and special carrier handling arrangements must be made. Printing the limits on the packaging, on its own, does nothing to prevent the product & packaging being exposed to temperatures and humidities outside of the printed limits.

Design Controls and Risk Management (i.e., CMT (cause mitigation table)) will indicate when temperature and/or humidity requirements are more specific (tighter) than those stated in Thermal Test Guideline. When temperature/humidity conditions are fully tested per the Thermal Test Guideline 2252595PRE and no tighter limits or additional engineering specifications have been defined, then product can be distributed in the same range and considered general cargo.

3.4.9 Contamination & Cleanliness Protection

- Cover larger products on pallets with plastic bags or other acceptable coverings to keep them clean during distribution.
- Bag or wrap smaller products that are susceptible to contamination to keep them clean and free from contaminates, including dust from cushioning and dunnage materials.
- Sterile products must be packaged following all requirements listed in ISO 11607-1 and ISO 11607-2, or equivalent.

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3.5 Packaging Organization and Optimization Requirements

3.5.1 Loss of Small Parts, Papers & Packages

Consolidate very small parts with other parts and packing materials to prevent loss and/or misplacement. Place lose papers, e-License, and other documents in an envelope, pouch, or other containment as necessary, to prevent loss.

When packaging several items in one box, identify hidden and/or small parts contained within that box using bright labels (i.e. "Additional parts inside"), oversized bags, zip-ties or other visible means. Also consider placement inside of the box for visibility. Visibility is especially important for very small items such as USB drives.

3.5.2 Package Arrangement for Sub-Assemblies

Whenever possible, package accessories and all items necessary for the assembly of a sub-assembly, together in the same package, or in the case of many small packages, in the same large over-pack.

3.5.3 Standardization, Size & Consistency

- Minimize the number of different box sizes and other packaging materials used.
- Consistently package products in the same container, for every shipment, to help in pre-planning, and to avoid confusion on the receiving end.
 - Suppliers: Do not change packaging once approved by GEHC. If packaging needs to be updated, follow the SCR process. GEHC relies on consistent, standard packaging from suppliers.
- Select packages that allow adequate space for cushioning and dunnage material, but minimize unnecessary space, so that the overall package size is as small and compact as possible.

3.5.4 Packaging Right-Sizing

Condense products as much as possible in packages and crates to reduce air space and provide a high-density package. Transportation costs are typically determined by weight, but many carriers add additional charges when the volume of the crate or package is much larger than the weight of the unit. Reference the following websites to learn more about DIM weights and how to calculate what the DIM weight is for a package or crate. Dimensional Weight Information

Dim Weight Calculator

3.6 Reusable Containers & Materials

- Use reusable containers and packing materials when mutually acceptable between shipper and receiver.
- Reusable packages must be designed to easily open and re-close and be durable enough to withstand multiple distribution cycles.
- Reusable containers are usually more expensive than disposable containers, so they should not be shipped directly to a customer site unless a return system is in place.
- Always identify the country of origin on reusable containers for customs purposes.

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3.7 Reused Containers

- Reused containers must provide the necessary protection for the product and meet all legal and regulatory requirements/compliance.
- Remove or totally obliterate all old labels and markings that do not specifically apply when a container is reused.
- Never package materials regulated as hazardous in a used container unless it is the exact, same product that the package was originally designed and certified for, and reuse is acceptable in the regulations.
- The outer package of a combination package may be reused to ship a non-regulated material as long as all hazardous reference markings and labels have been removed or totally obliterated.
- Reused containers must identify the country of origin for customs purposes.
- Corrugated containers must not be reused if they are ripped, damaged, have any signs of exposure to water, or
 prior exterior labels cannot be removed. They must be able to hold all inner pack in a proper manner, equivalent to
 a new container.
- Crates and pallets that are unstable or moderately-heavily damaged should not be used or should be repaired before using for shipments.

3.8 Handholes in Shipping Containers

Hand holes can be added to shipping containers to allow more efficient manual handling. However, hand holes are not recommended because they allow access to small animals, birds, insects, and other contamination. When hand holes are used, the parts contained must be protected from contamination that could enter through the holes.

It is recommended that hand holes not be used with containers that will exceed 35 lbs. (16 kg). Hand holes encourage one person lifting and GE HealthCare EHS policy limits one person lifting to 35 lbs. (16 kg). Higher weights can also result in the hand holes tearing out on corrugated boxes, increasing the risk of product damage or personal injury.

3.9 Packaged Products Containing Liquids

Products and primary packages containing liquids should be sealed in moisture proof bags or liners to create a "Leaktight" package that will prevent leakage in case of damage. This requirement does not apply to large machines or assemblies that include components containing liquids.

3.10 Lumber & Wood Material Requirements

3.10.1 Conformance

All wood materials must conform to the minimum requirements and standards of their industry and must be in compliance with Global Wood Standard ISPM 15.

3.10.2 Moisture Content

The water content of lumber used in wooden pallets, crates, or product blocking, must not exceed 19% for softwood, or 26% for hardwood material 5 cm (2 inches) or less. The moisture content of all hardwood lumber and softwood lumber greater than 5 cm (2 inches) thick shall be 26% or less.

3.10.3 Bark & Plant Pests

All solid wood materials must be free from bark, live insects and insect larva.

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3.10.4 Defects

Lumber shall be free from the following defects:

- Knots or knot clusters whose diameter exceeds 1/3 of the board width, knots existing at both ends or knots existing at mechanical fastening locations
- Knotholes, borer holes, dead knots, loose knots or the like of 1.2cm or larger in diameter
- · Cracks, mold, decay, warping or other defect that jeopardizes the integrity of the material

3.10.5 Formaldehyde Limits for Processed Wood

See Section 5.2.4.2.

3.11 Strapping Requirements

3.11.1 General

Use break-resistant strapping for crate and package reinforcement, carton closure, securement, unitizing, bundling, bracing, palletizing, and other applications. Use adequate corner protectors, cushioning, etc., as required to ensure package integrity and product protection. See Figure 3.10 for example of correct strapping and use of edge protectors.

3.11.2 Security Strapping Requirements

All individual packages weighing over 150 lbs. (68kg) that ship by air with an origination or destination in the United States, must have banding on all sides, ends, top and bottom.

3.11.3 Edge Protector Use

Edge protectors, whether made from plastic or paper, shall be used whenever corrugated material is banded to a pallet to prevent crushing of the box(es).

3.11.4 Strapping Materials

3.11.4.1 Plastic

Use plastic strapping for all applications inside of wood crates and boxes, and for reinforcing corrugated boxes and other applications.

Select the type of plastic strapping that best meets the strength and other requirements of the application.

3.11.4.2 Woven Fabric / Plastic Cord

Use woven plastic cord strapping for applications that require a softer, less sharp material, to prevent product damage or injury. This type of strapping is secured by tying or with a metal or plastic buckle.

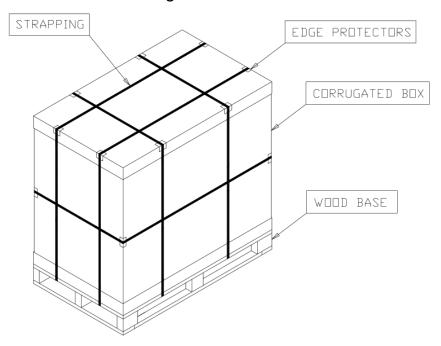
3.11.4.3 Metal

Metal banding is no longer allowed due to EHS concerns and its use is not permitted.

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Figure 3.10



3.12 Use of Tilt Indicator and ShockWatch Labels

Tilt Indicator labels are reference only and should only be used where the trip angle matches the angle at which the product inside the package will sustain damage. They only provide a notice that the unit tipped to that angle, not when or where it happened. It is not necessarily an indication of an actual tip or damage.

ATTENTION: ShockWatch impact indicators are no longer to be purchased as the product does not provide proven value to product quality or reliability. GE HealthCare no longer requires or endorses the use of ShockWatch impact indicators for any transportation or packaging applications.

3.13 Ergonomic Package Designs

Include ergonomic considerations in all packaging design and handling practices. Design packages to minimize strain on people during product removal and repacking.

Boxes weighing between 16 kg-32kg (35 lbs.-70 lbs.) should be palletized for mechanical handling or have labeling to identify box as a 2-person lift. Individual boxes over 32kg (70 lbs) should be labeled for mechanical lift only. These requirements apply to all inbound and outbound packaging & parts. See Section 6.3.3 for more information on labeling requirements.

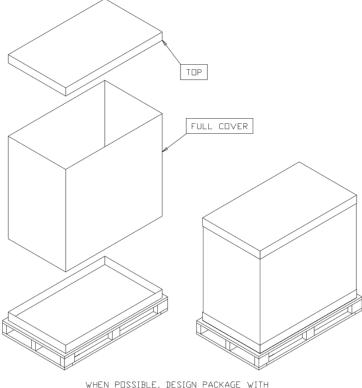
If feasible, keep boxes under 35 lbs. (16kg) so that they can be handled safely by one person.

Design crates with a removable top and sides to reduce back strain from bending and lifting while removing the product. An example of a package that reduces back strain during product removal is shown below.

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PREFERRED DESIGN COVER LIFTS OFF, MINIMIZING BACK LIFTING REQUIRED TO REMOVE PRODUCT.



WHEN POSSIBLE, DESIGN PACKAGE WITH REMOVABLE COVER TO EASE LIFTING OF HEAVY PARTS AND REDUCE POTENTIAL FOR BACK INJURIES.

3.14 Time Sensitive Materials

Materials that are classified as having a shelf life must have a visible expiration date on the external packaging in human readable format. The date format shall indicate expiration month and year. Recommended format is: "Expires DD/MMM/YYYY" or "Expires MM/DD/YYYY" or "Expires MM/YYYY".

Batteries shall have an install by date stated on the outside of the package. The install by date should be either documented in the engineering design outputs or PDM system, if not documented, it shall be no greater than 1 year for rechargeable batteries (secondary batteries). For non-rechargeable batteries (primary batteries) the install by date shall be no greater than 85% of the manufacturer suggested install by date. Example alkaline batteries have a 10-year shelf life so 8.5 years from the manufacture date shall be the install by date. Recommended format is: "Install by MM/DD/YYYY", "Install by YYY/MM/DD" or "Install by MM/YYYY". The format shall be written below the date.

Batteries that require recharging must have a visible recharge by date on the external packaging. The date format shall indicate recharge by date, month and year. Recommended format is: "Recharge before: MM/DD/YYYY" or "Recharge before: MM/YYYY". If the battery has exceeded the recharge by/before date and not received the recommended recharge the battery is to be classified as defective.

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4.0 Handling, Rigging, and Lifting Requirements

4.1 Pallet Design Criteria

4.1.1 General

The design of the pallet is very important, because it provides the basis of the strength of the entire package, and it also provides the means for mechanical handling and securement of the product.

4.1.2 Standard Design Characteristics

Some characteristics of the base design are consistent for all products, including height of runners, runner spacing, fork hole openings, etc. See **Figure 4.1.2.1** for typical base designs and specifications.

Additionally, all pallets, both for incoming and outgoing materials, should follow the following principles:

- All pallets must be large enough to be handled by a standard pallet jack on at least one side.
- Every pallet should have bottom deck boards to ensure the blocks or lumber that give height to the pallet are not easily knocked off while being manipulated by handling equipment (see graphic below)



• Do not use foam blocks as the block or stringer material of a pallet. They are not a good material for fastening and frequently come loose during shipping and handling.



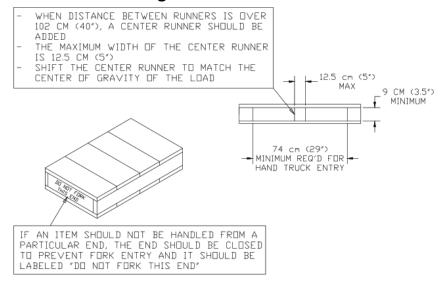
4.1.3 Pallet Cushioning

If a pallet requires cushioning due to product fragility, a wood base with foam cushion or shock mount runners can be used to reduce shock to the product. See **Figure 4.1.2.2** for examples.

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Figure 4.1.2.1



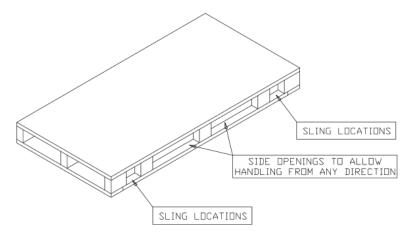
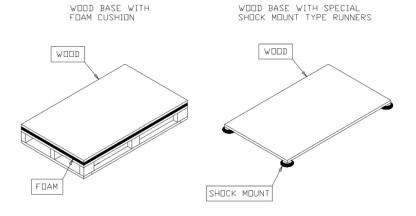


Figure 4.1.2.2



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4.2 Fork Lift & Pallet Jack Handling

4.2.1 Fork Positioning

The fork pocket positions shall be as wide as possible as the design would allow for stability. The fork pockets should also be centered in relation to the loads anticipated CG location. If spreading the forks is necessary for handling it should be communicated through graphics on the package.

4.2.2 High Center of Gravity (C.G.) Loads

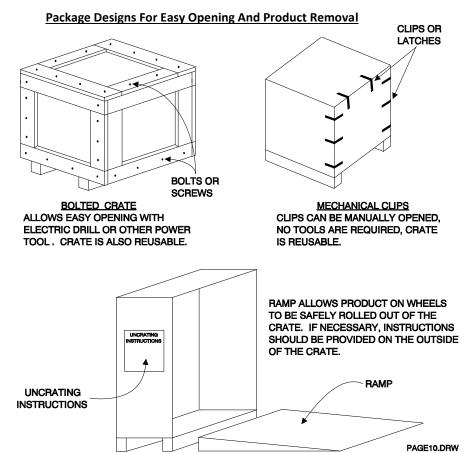
It is permissible and encouraged to strap a palletized load with a high C.G. to the carriage of a forklift for safety purposes. C.G. shall be identified on all sides, see <u>Section 6.3</u> for C.G. label examples.

4.3 Package Opening & Product Removal

Easy opening and product removal shall be incorporated into the designs of wood crates and boxes to minimize uncrating time and the chance for product damage at the receiving pole and/or customer site. **Bolts, clips, latches or screws should be used INSTEAD OF nails and or staples to secure wood crates and boxes.**

Provide a ramp for products on wheels to allow them to be safely rolled off their shipping base.

In all cases, if there is a specific method for safely opening a crate or removing a product, instructions shall be included on the outside of the crate to provide guidelines for the person doing the uncrating.

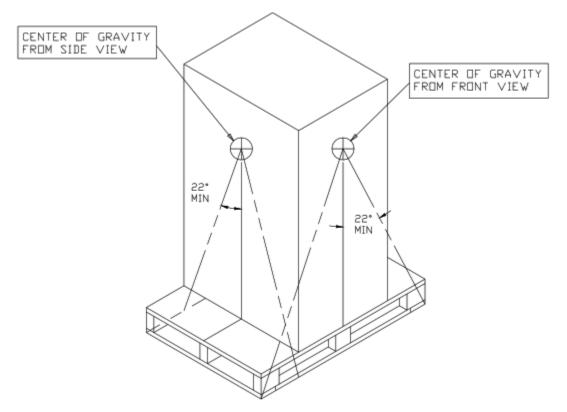


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4.4 Design for Stability

All crates and boxes that are tall, top heavy, or otherwise unstable, shall have wood bases designed to prevent accidental tipping during shipping and handling. Unstable is typically defined as an item in its shipping configuration having a tip angle within 22 degrees in any direction.



A standard test to determine stability is the **22-degree tip test**. (Tip the product 22 degrees from vertical and release. It should right itself without tipping over in either direction). The maximum tilt angle expected during distribution is 20 degrees. This can occur when a product is moved from a truck bed to the ground using a ramp.

4.5 Design for Rigging / Lifting

Packaging designed for handling via an overhead lifting device such as a crane or hoist will require a complete analysis performed by a qualified individual.

4.5.1 Material Considerations

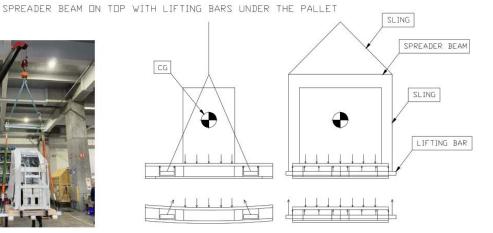
The material selected as the structural components of the pallet must be able to withstand the various forces imposed on the pallet from the sling loadings. See the "Loadings from rigging" section below. Materials selected shall be able to handle the forces in its various states, for example- wood moisture content level should be taken into consideration when determining strength requirements of wood.

4.5.2 Loadings from Rigging

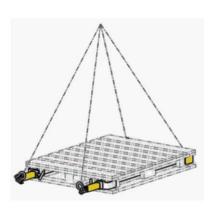
The loadings within the pallet are directly related to how the rigging is set up to lift the pallet. Several examples are below to show exaggerated deflections and loadings the pallet will see based on how the rigging is configured.

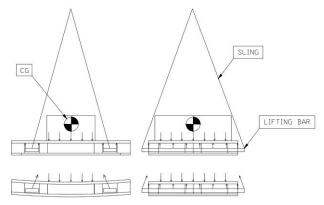
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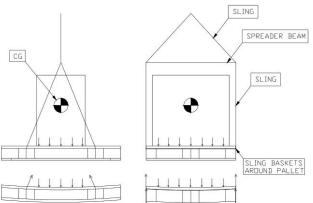
SLINGS DIRECTLY CONNECTED TO HOOK ON TOP WITH LIFTING BARS UNDER THE PALLET





SPREADER BEAM ON TOP WITH SLINGS BASKETED UNDER THE PALLET





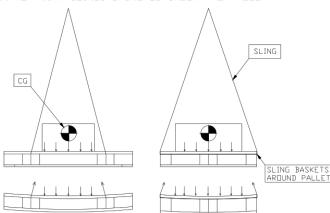
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Because there is little to no control over how the pallet is rigged on site, it is necessary to design the pallet to handle the worst-case rigging configuration. This worst-case rigging configuration is typically a 4-point sling basket as shown below.

SLINGS DIRECTLY CONNECTED TO HOOK ON TOP WITH SLINGS BASKETED UNDER THE PALLET





4.5.3 Center of Gravity (C.G.) Considerations

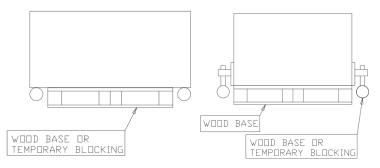
When any load is lifted via an overhead device, the load will always orientate itself so that the C.G. is directly underneath the hook of the lifting device. The rigging locations on the pallet or package must take this into consideration and be positioned symmetrically around the C.G. to ensure a safe lift. C.G. labeling shall be identified on all sides, see Section 6.3 for C.G. label example.

4.6 Product & Package Height

Minimize total shipping height to allow efficient global transport. Reference "Key Height Limits for Air Transport" and other information in Section 11.2.1.

4.7 Mechanical Handling for Products on Wheels

Items cannot be shipped on dollies, system wheels, or wheels of any kind. Wheeled products must be braced and palletized so that they can be properly handled in distribution via forklifts, pallet jacks, and/or cranes. When an item on wheels is shipped on top of a wood base or other type of blocking arrangement, **consideration must also be given to providing a method for safely returning the item to the ground**. All other standard considerations for safe handling covered in this guideline must also be followed. Reference the diagrams below for typical examples of methods of incorporating mechanical handling with items on wheels. See graphic below for acceptable examples.



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5.0 Sustainability & Environmental Requirements

All packages and packaging materials used for GEHC products must be in full compliance with all legal and environmental regulations and requirements for all countries where these products are distributed. Research full documentations, links, or GEHC documents to ensure proper compliance.

5.1 Environmental Packaging Design Requirements

These requirements are not only for GEHC Finished Goods Packaging, but also required of suppliers to GEHC (line use, finished goods, and FRU packaging).

5.1.1 Packaging Material Selection

See *Eco-Friendly Packaging Selection Guide- DOC2856619*- for recommendations on more sustainable packaging materials and uses. This guide can be referenced both internally and externally (suppliers).

- Design packages using materials that promote recyclability.
- Do not use packaging made from Styrene polymers (PS, EPS, XPS) (i.e. Styrofoam) or PVC.
- Do not use free flowing dunnage material (i.e. loose peanuts).
- Use compostable paper-based packaging materials whenever possible, such as corrugated fiberboard, molded pulp, paper filler, cellulose, etc. Use plastic sparingly.
- Use packaging material with the highest amount of PCR (Post-consumer-recycled) content as possible.
- Wood-based packaging (e.g. fiberboard, card, paper) shall be from recycled or certified sustainable sources (i.e. FSC / PEFC certified)

5.1.2 Waste & Optimization

- Design packages with the least amount of materials that will still provide adequate protection for the products contained.
- Design packaging in the smallest size package possible while still protecting the product.
- When possible, packages should be designed using materials that minimize impact on the waste stream.
- Design packaging so that components can be easily separated.
- Avoid gluing multiple materials together, if possible.
- Include instructions on how to separate packaging materials if packaging is assembled with more than one material.
- If using plastic, must be comprised of a single resin, or a combination of resins (e.g., a blend) that are compatible for recycling, and separable by hand or with commonly available tools from other plastic parts that are not compatible together for recycling. ESD/anti-static plastic products and moisture-vapor barrier bags are exempt.
- Use reusable packaging when appropriate (i.e., closed-loop-shipping from supplier to GEHC, less than 100 miles).

5.2 Regulatory Requirements

Note for Suppliers: The Supplier is the original "Shipper of record" and must comply with the information below to ship material to GEHC. As regulations change and apply differently to different materials GEHC cannot interpret regulations for each Supplier. Approved Suppliers are chosen based on their ability to meet these requirements.

5.2.1 Hazardous Material / Dangerous Goods

Package, mark, label, and document any material, product, and product outer package that is regulated as hazardous by the International Air Transport Association (IATA), or the International Civil Aviation Organization (ICAO) for air shipment, or by the International Maritime Organization (IMO) for ocean shipment, or any other regulatory body, to meet all regulatory requirements for the mode of transport being used.

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Packages that contain batteries usually require specific markings and labeling to be applied-consult with local EHS and Logistics prior to packaging and shipping.

When required by the regulations, packages for these materials must be tested and certified to meet the performance-oriented-packaging (POP) UN testing requirements. There are specific regulations about documentation and packaging printing that need to be followed.

Examples of hazardous materials (non-exhaustive list): Lithium batteries, aerosols, alcohols, flammable liquids & gases, fuels, paints, refrigerant gases, dry ice, Helium. Reference free tool to look up hazmat materials under US Domestic Surface Transportation: ECFR Hazmat. Each authority has their own list of hazardous materials. Contact EHS for more information.

Hazmat Authorities

Air Transportation- IATA Dangerous Goods Regulations

https://www.iata.org/en/publications/dgr/

Ocean Transportation- International Maritime Dangerous Goods Code (IMDG)

https://www.imo.org/en

<u>US Domestic Surface Transportation -</u> U.S. Department of Transportation, United States Code Of Federal Regulations, CFR 49, Parts 100 to 199.

https://www.ecfr.gov/

International Atomic Energy Agency (IAEA) - Radioactive materials only

https://www.iaea.org/

5.2.2 Hazardous Materials-EU: UN Globally Harmonized System (GHS) and CLP Regulation (EC) No 1272 / 2008 on Classification, Labeling and Packaging of Substances and Mixtures

The EU's Classification, Labeling and Packaging (CLP) Regulation, (EC) No 1272/2008 presents the EU's implementation of the UN Globally Harmonized System (GHS) for the Classification of Chemicals. The goal of the GHS and the GHS regulations adopted by or to be adopted by various countries is to implement a global system of defining chemical hazards, classifying chemicals by their hazards, and communicating those hazards by a standardized system of labels, signal words, hazard pictograms, and Safety Data Sheets. US OSHA issued a final rule in March 2012, revising its Hazard Communication standard to align with the GHS and requiring GHS labeling of all chemicals by June 1, 2015. The EU now requires chemical substances to be labeled in accordance with CLP, and mixtures are also required to have CLP compliant labels. The specific regulation for the country to which the chemical is being shipped should be consulted to ensure compliance.

Labels meeting the requirements of GHS must be affixed to the immediate container of a hazardous chemical, substance or mixture or to the outside packaging. Labeling of packaging in accordance with GHS regulations must be compatible with labeling required by the rules on the transport of dangerous goods if the chemicals are to be shipped. For the EU, Article 33 of the CLP regulation provides specific rules for labeling of outer packaging, inner packaging, and single packaging to be compatible with both CLP and the rules relating to the transport of dangerous goods.

In addition, Article 35 of the CLP regulation provides general rules related to the structural integrity of packaging of hazardous chemicals. These requirements, as applicable to GE HealthCare's products, are satisfied by complying with the rules regulating the transport of hazardous materials\dangerous goods discussed in Section 5.2.1 of this document.

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5.2.3 Safety Data Sheet (SDS)

When required, ship chemicals and materials which present potential health hazards with one copy of their SDS in a pouch, on the outside of the package, and a second copy inside the package with the product. When shipping to a GEHC manufacturing facility for "Line Use", only one copy is required for the entire shipment.

Note: Many chemicals and materials not regulated under the transportation regulations defined in Section 5.2.1 do require SDS documentation to communicate important safety information.

5.2.4 Wood Packaging Materials

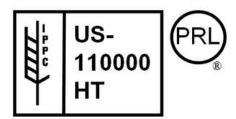
5.2.4.1 SPECIAL REQUIREMENTS FOR COMPLIANCE WITH WOOD IMPORT REGULATIONS

Due to expanding global wood import regulations on unprocessed raw wood packaging materials, processed wood should be used for all wood packaging shipped to GEHC whenever possible.

When unprocessed raw wood packaging material is used in the construction of bases, pallets, boxes, crates, blocking, and all other packaging materials, it must meet the treatment and stamping requirements of the International Standards for Phytosanitary Measures, ISPM #15, issued by the International Plant Protection Convention (IPPC). All wood packaging materials (solid and processed wood) must be free from blue stain, worm holes, and any bark.

Plywood, particleboard, and corrugated fiberboard are examples of processed wood that are not included in this requirement.

The figure below provides a typical example of an ISPM #15 certification mark where the "XX" stands for the ISO two letter country code, "000" a unique number assigned by the National Plant Protection Organization (NPPO) to the producer of the wood packaging material, and "YY" the IPPC abbreviation for the approved treatment measure used.



Typical ISPM # 15 Wood Packaging Certification Marking

This marking must be legible, clearly visible, permanent & not transferable, and must be on at least two opposite sides on the outside of all packages that include any unprocessed raw wood materials.

The use of red or orange color should be avoided.

For additional information, the following is the link to the IPPC Web site: https://www.ippc.int/

The following is a link to the ISPM # 15 document in multiple languages (Next to "Publication"): https://www.ippc.int/publications/regulation-wood-packaging-material-international-trade-0

NOTE: This section contains relevant links to an external website. The intent of this section is to guide the reader of this document to places where additional information can be found on the given topics discussed in this document. The above links and information located at these links are subject to change and are intended as reference only.

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5.2.4.2 <u>Formaldehyde Limits in Processed Wood Packaging Materials</u>

Processed wood packaging materials (plywood, particle board, oriented strand board (OSB), etc.) shall have a formaldehyde level less than or equal to 1.5mg/L using the ASTM 5582 desiccator test or an equivalent test.

5.2.5 RoHs

Packaging materials are not included in RoHS, but have specified restrictions in 94/62/EC.

It is still best to avoid the following ten RoHS restricted substances:

- Cadmium (Cd)
- Lead (Pb)
- Mercury (Hg)
- Hexavalent Chromium: (Cr VI)
- Polybrominated Biphenyls (PBB)
- Polybrominated Diphenyl Ethers (PBDE)
- Bis(2-Ethylhexyl) phthalate (DEHP)
- Benzyl butyl phthalate (BBP)
- Dibutyl phthalate (DBP)
- Diisobutyl phthalate (DIBP)

Note: PBB and PBDE are flame retardants used in some plastic materials

94/62/EC Article 11 "Concentration Levels of Heavy Metals Present in Packaging", states:

- 1. The sum of concentration levels of lead, cadmium, mercury and hexavalent chromium present in packaging or packaging components shall not exceed 100 ppm by weight.
- 2. The concentration level referred to in # 1 (above) shall not apply to packaging entirely made of lead crystal glass as defined in Directive 69/493/EEC (1).
- 3. All Exemptions to #1 (above) must be approved by the EU Commission including:
 - The conditions under which the above concentration level will not apply to recycled materials and to product loops which are in a closed and controlled chain,
 - The types of packaging which are exempted from the requirement referred to in # 1 (above).

In addition to the list above, special attention must be paid when choosing **desiccant** materials. Do not use desiccants that contain more than 0.1mg/kg of DMF(Dimethylfulmarate)-an anti-fungal biocide. Reference EU Directive 2009/251/EC for more information.

5.2.6 REACH – EU Regulation (EC) No 1907 / 2006

Packaging materials are considered to be an "article" according to the EU REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) regulations. As a result, reporting may be required under specific circumstances when Substances of Very High Concern (SVHC) are included in the packaging materials.

<u>Suppliers:</u> All packaging materials used for GEHC products must comply with the latest revision of GEHC document **5396068GSP**, "GEHC REACH Requirements for Suppliers to GEHC Legal Entities". See <u>Section 15.4</u> for additional reference information.

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5.2.6.1 Following Steps will help ensure compliance

- Step 1: Identify packaging materials used for GEHC products
- Step 2: Confirm that these materials meet the REACH definition of an "Article"
- Step 3: Identify items that meet the requirement for "Intended Release"
- Step 4: Ensure that all materials comply with the latest revision of GEHC document "5396068GSP, "GEHC REACH Requirements for Suppliers to GEHC Legal Entities".
- Step 5: Primary means of reporting Reach Compliance (SVHC, Authorization, Restricted) is via www.Bomcheck.net. For alternative reporting options please contact Material.Compliance@ge.com

5.2.6.2 <u>Compliance Statement</u>

All suppliers must confirm compliance with the REACH requirements. Suppliers must have REACH declarations for SVHC's, Authorizations (Annex XIV), and Restrictions (Annex XVII) archived in MyWorkshop Material Compliance Module for all products <u>AND</u> packaging.

5.2.7 Recycling Markings

Recycling marks are required on most packaging materials. Follow https://how2recycle.info/labels for best practices on how to communicate end of life packaging instructions. Include international and country specific recycling marks and symbols on packaging materials.

Corrugated fiberboard (cardboard) boxes and crates must be marked with a Mobius Loop

Mobius Loop



Mark must be applied as follows:

- Minimum of one mark per package
- Size to be 20mm, 40mm, 60mm or 80mm wide
- Easily visible
- The color green is recommended, but not mandatory
- These marks can be preprinted on the box or added with a permanent label

Wood crates and boxes do not require a recycling mark. However, all wood materials do require treatment certification markings as defined in Section 5.2.4.

Plastic packaging requires marks and material codes that will comply with China requirement GB 18455-2022 & 97/129/EC. Material markings according to the Industry Standards ISO 1043 and ISO 11469 may be used if it is confirmed that they will comply with the above standards. Examples include:



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Metal outer packages require marks and material codes that will comply with China requirement GB/T 18455-2022. Examples include:







Green Point (Dot) Mark is a symbol that indicates the manufacturer has purchased a license for the right to use the symbol and has a process in place for recovering and recycling the material. Do not use this symbol unless all requirements have been satisfied. This mark is commonly used in EU and is referenced in 94/62/EC.



5.2.8 European Union Packaging Requirements

If material markings are included on the packages, they must be in compliance with European Community Directive: 97/129/EC – "EC Identification System For Packaging Materials". This is similar or equivalent to ISO 1043.

The European PPWD Directive 94/62/EC defines requirements for the design and environmental impact of packaging and packaging waste (PPW).

Packages must be designed for compliance with EU Directive 94/62/EC per GEHC documents:

- DOC1141717, "GE HealthCare Packaging Requirements Document for EU Directive 94/62/EC"
- DOC1220258, "GE HealthCare Functional Requirements for Compliance with EU Directive 94/62/EC and Amendments"

5.2.9 Registration and Reporting – Country Specific

A site that engages in packaging may have certain local or country specific obligations, including registration, reporting and recycling targets. Each location must identify and comply with their specific requirements. Member states of the EU also have reporting requirements, reference DOC1220258 for more information.

5.2.9.1 South Korea

Promotion of Resource Conservation and Recycling Act [Act No. 16083], Article 9-3 requires the reporting of the material structure of all product packaging placed in the country on an annual basis. Based on the evaluation of the report by the Korea Environment Corporation (KEC), a label indicating "difficult to recycle" may be required to be placed on the packaging of the product.

5.2.9.1.1 Measuring the Amount and Type of Packaging

As packaging may vary product to product and site by site, sampling of (10) international shipments of a product is needed to gather the data required for submission to Korea Environment Corporation (KEC). The data for packaging material can then be averaged to set the estimate for packaging for the product for future shipments.

5.2.9.1.2 Reporting the Amount and Type of Packaging

The regional EHS team shall be responsible for submitting the report on an annual basis. Sales information can be used to identify which products were sold in the previous year and combine the list of products with the

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packaging information measured in the previous section to aggregate the report for Korea Environment Corporation (KEC).

5.2.9.1.3 Labeling

In the event that Korea Environment Corporation (KEC) determines the product packaging requires a "difficult to recycle" label, regional EHS will inform the specific product team of the requirement to produce a label to be applied to those products shipping to South Korea.

5.2.9.2 Singapore

The Resource Sustainability Act (RSA) and the Resource Sustainability (Prescribed Regulated Products)
Regulations 2019 requires the reporting of the material structure of specific product packaging placed in the country on an annual basis, however, medical devices and components of medical devices are excluded from this reporting. The list of regulated consumer and regulated non-consumer products is given in the first and second schedules of the Resource Sustainability (Prescribed Regulated Products) Regulations 2019.

5.2.9.2.1 Measuring the amount and type of packaging

As packaging may vary product to product and site by site, sampling of (10) international shipments of an inscope product is needed to gather the data required for submission to National Environment Agent (NEA). The data for packaging material can then be averaged to set the estimate for packaging for the product for future shipments.

5.2.9.2.2 Reporting the amount and type of packaging

The regional EHS team shall be responsible for submitting the report on an annual basis. Sales information can be used to identify which non-medical device products were sold in the previous year and combine the list of products with the packaging information measured in the previous section to aggregate the report for National Environment Agent (NEA).

5.2.9.3 India

Promotion of Plastic Waste Management (Second Amendment) Rules, 2022 requires several rules to be followed when shipping items to India. This law was amended to fast-track the elimination of single-use plastics and to promote alternative materials that do not cause litter and waste problems.

5.2.9.3.1 Packaging expectations & bans

- Plastics less than 50 micron (1.97 mil) are no longer allowed to be shipped into the country. This includes common plastic items such as stretch wrap, plastic bags, bubble wrap, air pillows, etc.
- GEHC should obtain valid certificates or statements from the respective plastic packaging suppliers to ensure compliance with the above requirements. A copy should be retained to ensure compliance with the requirements and shall be shared as needed. Suppliers should provide certificates of conformance upon request from GEHC.
- This applies to all items (products / parts / accessories / components) shipped to India.

5.2.9.3.2 Labeling

It's recommended that all items shipped to India carry a self-declaration seal / imprint on the packaging box stating that "All plastics used for packaging have thickness greater than 50 microns" along with the respective Shippers "Legal entity name". This could be a sticker added to outside of box or a printout included with the packing list.

5.2.9.3.3 Reporting the amount and type of packaging

The regional EHS team shall be responsible for submitting a material summary report on an annual basis; Packaging CoE & Product Compliance shall assist with calculations.

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6.0 Product Identification, Marking, & Labeling

6.1 Identification of Manufacturing & Service Parts

6.1.1 General Requirements for "Line Use", "Finished Good" & "Service" Parts

Identify parts contained in all packages with the following as a minimum:

- GEHC order number
- Part number or Catalog number with latest revision (i.e., PN 123456 Rev. 3) (as referenced on the order)
- Description
- Production Control Identifier(s) (e.g., Serial number, Lot number), if applicable
- Unique Device Identification number (UDI), if applicable
- Quantity on outer package(s) and inner package(s)
- Shelf Life Expiration Date if Applicable

Include any additional information required for reshipment or direct shipment to a GEHC customer or any special information as specified in the GEHC order.

Do not include the part name, description, or graphics on the outside of the package if it will encourage theft or any other security risk during distribution. (i.e. TVs, computers, monitors, cameras, etc.)

6.1.1.1 Packing List

Include a packing list that identifies the major components of the shipment and a cross-reference to the catalog number of the item that they are a part of and the production control identifier(s) in Barcode with Human Readable format for each item if applicable. Reference the example provided in Section 16.1 for specific details.

Attach the Packing List on the outside of one of the packages in an envelope or pouch labeled "Packing List Enclosed" or similar.

Attach the Packing List on a side of the package rather than the top if possible.

6.1.1.2 Item Traceability

Items identified as requiring traceability shall have either a shipping container label, as defined in <u>Section</u> <u>6.2.1</u>, or <u>Product Locator Cards</u>. Reference GEHC Document 5215680GSP "Supplier Product Locator Card Procedure" for specific requirements.

The Unique Device Identification number (UDI), if applicable, is also required to be provided on the shipping box label. Reference GEHC_GQP_12.04 Identification and Traceability Procedure, DOC0373356 for specific product identification and traceability requirements.

Items requiring traceability shall have their item number and production control identifier entered in Quality Plan if purchased from a supplier, or captured in GLPROD/eDHR if manufactured.

6.1.2 Specific Requirements for "Line Use" Parts and GEHC Affiliate Shipments

6.1.2.1 Barcoded Receiving Label

• For GEHC Affiliate Parts – All shipments between Oracle Apps enabled GEHC affiliates require the ISO Receiving Label. Attach barcoded ISO Receiving Label to each box in the shipment. Refer to ISO Receiving Label SOP for instructions on generating this label for your affiliate shipments.

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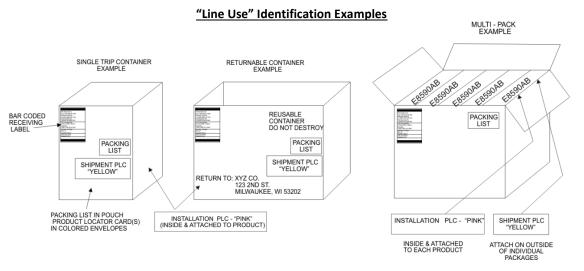
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6.1.2.2 Packing List for "Line Use Parts"

Each shipment to GEHC must include a minimum of (1) packing list including the following information (as a minimum):

- GEHC ship-to address
- GEHC modality (X-Ray, MR, US, etc.)
- GEHC PO+RELEASE number (13 digit number)
- GEHC part/catalog number, (as referenced in the GEHC PO)
- GEHC part/catalog description
- Production Control Identifier(s) (e.g., Serial number, Lot number), if applicable
- Unique Device Identification number (UDI), if applicable
- Quantity
- ASN#
- Shelf Life Expiration Date if Applicable

Section 16.2 provides a typical example of supplier packing list.



6.1.3 Specific Requirements for "Finished Good" Parts

6.1.3.1 Multiple Packages

Clearly identify the outside of each package as "Box 1 of 4", "Box 2 of 4", etc., when more than one box or package is used to contain an item. Position the box number close to the product identification number to avoid confusion with other multiple package items and the case numbers used to identify an entire system.

6.1.3.2 Multi-pack

The outside of all multi-packs must clearly identify the number of pieces contained.

Do not mix part/catalog numbers. Each multi-pack must contain only similar items.

Each individual package contained in a multi-pack must be identified with the part/catalog number as a minimum and any additional information as specified in the order.

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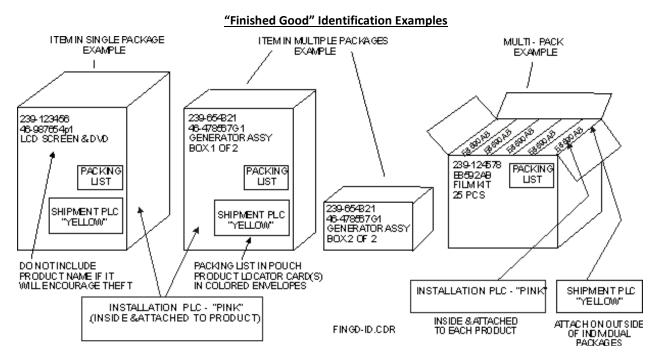
6.1.3.3 Checklist

Include a checklist in all packages containing loose parts that adequately identifies and states the quantity of each part contained. It is also highly recommended that a simple, graphic picture of each item be included.

6.1.3.4 Packing List for "Finished Good Parts"

Include a packing list that identifies the Order number and product identification information and traceability information for all materials included with the shipment. Reference Section 16.2 for a typical example.

Clearly identify items shipped in multiple packages. Include a reference on the packing list for the Case/Box #(s) in which each item is packed.



6.1.3.5 Packing List for "System Shipments"

Include a packing list that identifies the components of the shipment and a cross-reference to the part/catalog number of the item that they are a part of. Include a reference to the Order number and/or customer order number, as specified in the purchase agreement. Reference Section 16.1 for a typical packing list example.

Attach the Packing List to Case #1 of the system shipment.

6.1.4 Special Requirements for Direct Shipments to GEHC Customer

Mark systems shipped directly to GEHC customers with the same information as those shipped to a GEHC facility, plus additional information that will be required by the customer. The special information will typically include the GEHC order number, customer PO number and the customer ship-to address. The buyer will provide this information in the purchase agreement or through special communications.

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6.2 Shipping Container Marking & Labeling

6.2.1 General Requirements

Include the general shipping information contained in the purchase order. This typically includes: shippers name and address, GEHC ship-to address, and any required precautionary information (i.e., fragile, handle with care, static sensitive, etc.). Avoid abbreviations as much as possible.

The shipping container label must contain, in Barcode with Human Readable format: the item number, production control number(s), FDA Code and FDA Code Description if applicable, and UDI number if applicable. Production control numbers include serial number, lot or batch number, expiration date (shelf life), and/or manufacturing date. Information on the shipping container, product, and shipping documents must match. All information must match country specific licensing and registration.

When using overnight carrier services or other express delivery systems; the carrier labels should be applied to what is considered the top of the package. These carriers use automatic scanning systems that require their barcodes to be face up. Placing the labels on the top of the package will aid in keeping the package in the desirable upright orientation.

All prior shipment and other non-required markings and labels shall be removed covered or otherwise obliterated. When an over pack or consolidation pack is used, it is acceptable for the outer packaging to cover the markings and labels on the individual packages. Safe handling information (Fragile, This End Up, etc.) and other information critical to the safety of the shipment (i.e., temperature limits, "Do Not Freeze", etc.) needs to be duplicated on the outer packaging.

All regulatory and environmental marks and labels defined in <u>Section 5.2</u> must also be included in labels on inner and outer packaging components when required.

All labels must be securely affixed with water resistant, permanent adhesive. Add staples or other mechanical fasteners as required when attaching to wood or other surfaces where adhesive alone may not permanently hold the label. Print labels with permanent ink on a contrasting background. Avoid using inks in the red tones unless the ink is specifically designed to be fade resistant.

6.2.2 Marking

6.2.2.1 Method of Marking

Use labels, stencils, printing or tagging to mark the exterior of packages and shipping containers. The item number, production control identifier(s) and UDI number must be in Barcode with Human Readable format. Handwriting or lettering should be avoided.

6.2.2.2 Stenciling

Stencil by brushing, rolling, or spraying a sharply cut stencil with waterproof, black stencil ink.

6.2.2.3 Labels

Print, type or reproduce the required marking on labels. The item number, production control identifier(s) and UDI number must be in Barcode with Human Readable format.

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6.3 Labeling Requirements

6.3.1 ISO Warning Labels

When possible, use labels with international symbols per ISO 7000, following international labeling Standard ISO 780.

When a symbol is required that is not included in ISO 7000, it is acceptable to use a custom design symbol, as long as that symbol communicates a globally recognizable message. The following are typical examples of ISO 7000 symbols and commonly used custom design symbols:

International Warning and Information Symbols

	international warning and information Symbols					
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ISO 7000-0615: Protect from heat and radioactive sources	ISO 7000-0621: Fragile; handle with care	ISO 7000-0622: Use no hooks	ISO 7000-0623: This way up	ISO 7000-0624: Keep away from sunlight	ISO 7000-0625: Sling here	ISO 7000-0626: Keep away from rain
#	个	<u>*</u>	¥	→ ■ ←		
ISO 7000-0627: Centre of gravity	ISO 7000-2405: Do not roll	ISO 7000-0629: No hand truck here	ISO 7000-0630: Stacking limit by mass	ISO 7000-0631: Clamp as indicated	ISO 7000-0632: Temperature limit	Perishable
	≥					*
Handle with care	ISO 7000-2402: Do not stack	ISO 7000-0533 Upper Temp Limit	ISO 7000-0534 Lower Temp Limit	Do not freeze	Keep frozen	Keep away from cold
ISO 7000-1065:	Caution top heavy	→ 	IEC 60417-5134:	Do not drop	Lift by inner	\$50,7000-2406:
Support at center	cadion top heavy	not clamp as indicated	Electrostatic sensitive devices	Do not drop	fastening	Use no forks
<u>%</u>			w _z		XIII	\$• \$
ISO 7000-2620: Humidity limitation	Keep away from magnets	Do not step on	Tilting limit	Do not tip	ISO 7000-2403: Stacking limit by number	ISO 7000-2621: Atmospheric pressure limitation
8		STERRAZE	(A)			NON STERILE
ISO 7000-0659: Biological risks	ISO 7000-1051: Do not re-use	ISO 7000-2608: Do not resterilize	ISO 7000-1135: General symbol for recovery / recyclable	ISO 7000-2401: Protect from radioactive sources	ISO 7000-2606: Do not use if package is damaged	ISO 7000-2609: Non-sterile

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6.3.2 GEHC Commonly-Used Hazard Warnings

Use the following hazard labels when the product requires them. Labels are listed with North American suppliers and part numbers for ordering purposes.



CoG (Center of Gravity) Locator- Use to mark loads with high CoG's and/or off-centered gravity Example: Part Number: IEC6199-PA (3in x 3in); Supplier: Clarion Safety



Tip Warning Label- Use to loads that have high CoG's and are a tipping hazard if mishandled Example: Part Number: IS5157-PA (3in x 3in); Supplier: Clarion Safety



Forklift Point- Use to communicate proper fork tine lift location Example: Part Number: SSL-1709 (3in x 5in); Supplier: HCL



or



Sling Lift Point- Use to communicate sling lift location

Example: Part Number: IS6071-PB (2in x 2in); Supplier: Clarion Safety

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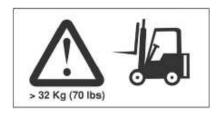
6.3.3 Special Labeling Requirements for Heavy Packaging

All crates and packages over 16 kg (35 lbs.) are to be identified according to their weight range. Graphics shall be used to indicate the package weight range, as well as number of people required to manually lift it, and when a mechanical lift is required per the pictograms below.

- 1. Packages 16 32 kg (35 70 lbs.) 2 FEs or Mechanical Lift (For labels, use black characters on yellow background)
 - Part number 5325887



- 2. Packages > 32 kg (70 lbs.) Mechanical Lift (For labels, use black characters on red background)
 - Part number 5325888



Label Ordering Options:

There are multiple suppliers that labels can be purchased from-two are listed below. Any label supplier can be used as long as they meet requirements listed in the part numbers' (above) specifications.

Marek

Email - mailto:georders@marekgroup.com, USA Phone Number - 262-549-8924 or 262-549-8900.

Suppliers must provide to Marek Group Inc., their shipping address, shipping contact, phone number, and billing address for package seals. **NOTE:** Marek Group Inc. will direct bill Suppliers for all labels

Duratech

See <u>contact information</u> in 9.7.

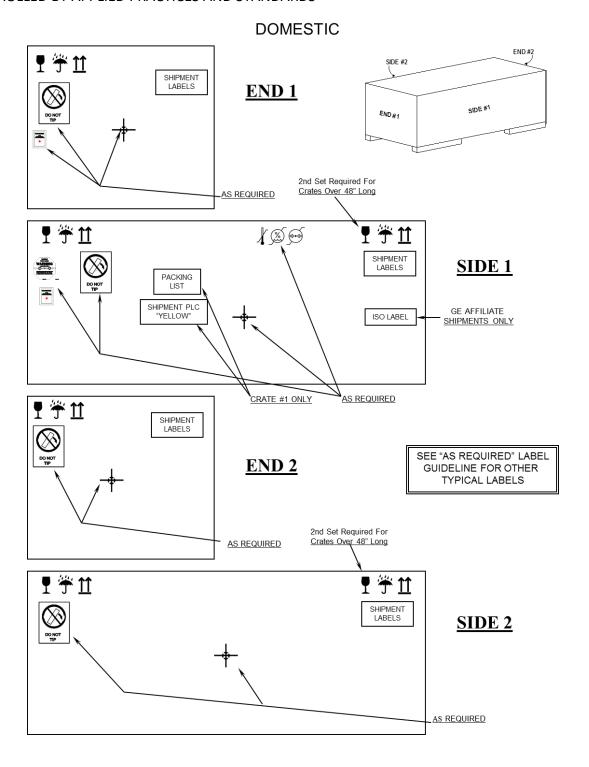
6.3.4 Special Labeling Requirements for System Shipments by Location

6.3.4.1 Domestic Shipment

Some products may ship on a dolly or pallet and not include a shipping container. For these products, only the shipment labels and other shipment related information is required.

Mark and label packages as closely as possible to the layout on the following page:

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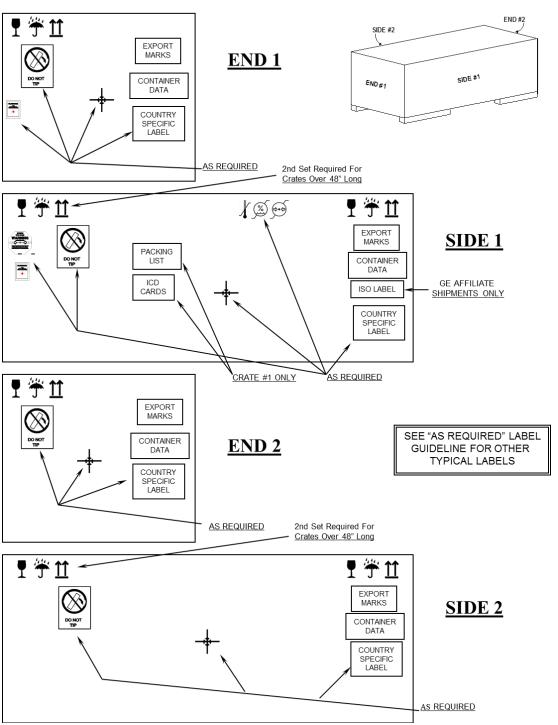


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6.3.4.2 International Shipment

International Shipment Marking and Labeling Layout

INTERNATIONAL



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6.3.4.2.1 Standard Export Marks

The standard exterior marking requirements for international packed and containerized units shall include the following information:

From: Shippers Name & Address

Ship To: Consignee Name & Address

Shipment Info: - Purchase Order Number:

Order Number:Invoice Number:Manifest Number:Catalog Number:

Container Data: - Item Number:

- Outside Dimensions:

Net Weight:Gross Weight:

Made In: Country of Origin

6.3.4.2.2 Net Weight and Gross Weight

The net and gross weight values shall be followed by the unit of measure (pounds or kilos) in capital letters. All weights shall be rounded to the nearest whole number.

6.3.4.2.3 Outside Dimensions

Outside dimensions shall be shown on all shipping containers, having a cube of 493 cubic cm (30 cubic inches) or over, or having any single dimension of 183 cm (72 inches) or over. Outside dimensions shall be shown in the order of length, width, and height. Dimensions shall be rounded to the nearest cm/inch.

6.3.4.2.4 Location of Marking

It is assumed that the container will have two ends, two sides, a top and a bottom. Open crates and other irregular containers shall be marked to conform to this specification as closely as available space and shape of the container permit.

6.3.4.2.5 <u>Container End Marking</u>

When the container is .3 cubic meters (10 cubic feet) or under, the container data marking and destination address may be omitted from the end.

6.3.4.3 Special Labeling Requirements for System Shipments to China

Packaging and/or containers carrying products or devices for sales and distribution in China shall be marked/labeled per the requirements in GEHC document DOC0062044, *China Labeling and Language Requirements and Procedure*, Section 5.2.6.

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6.3.4.4 Special Labeling Requirements for System Shipments to Korea

Full system shipments to Korea require specific information in Korean characters per GEHC document IQP12000/DOC0275476, "Korea Labeling and Language Requirements Procedure". This requirement does not apply to accessories and suppliers that are not registered separately.

In the event that Korea Environment Corporation (KEC) determines packaging for a product is "difficult to recycle", a label indicating "difficult to recycle" shall be placed on the packaging of the product.

Warning and handling information (i.e., "Fragile", "This End Up", "Sling Here", etc.) on the outer package shall be International Standard markings:

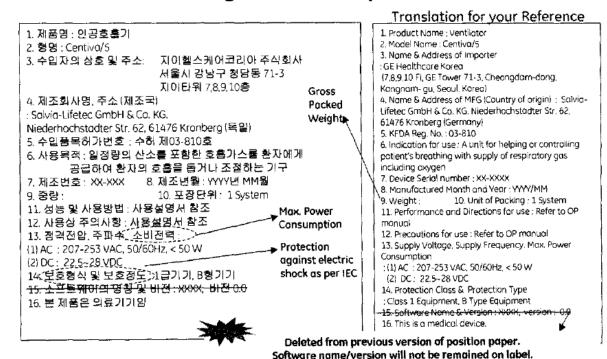






Product identification labels are required in a combination of English and Korean characters. The following is a typical example from IQP12000:

Packing Label.....Template



6.3.4.5 Special Labeling Requirements for System Shipments to Venezuela

Full system shipments to Venezuela require special labeling per the requirements of GEHC document DOC1060518, "GEHC Venezuela Labeling Requirement". This requirement does not apply to upgrades, repair parts, Gold Seal, or any other shipments that are not part of a new system order.

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When applicable, a minimum of one label is required on the outside of each final export shipping crate. Labels should be placed in the vicinity of other shipping labels but shall not cover any existing labels.

The following is a typical example of the required label:



6.4 Shipping Container Artwork

6.4.1 General Requirements

Refer to Section 10 for guidelines around artwork placement and layout.

When the GE HealthCare logo is used on packages, specific guidelines must be followed for placement, size, and color of all logo graphics. See the GE HealthCare <u>branding web site</u> for specific details.

The use of the GEHC logo and branding graphics is recommended for manufacturing finished good parts but is not a requirement.

6.4.2 Requirements for Updating to GE HealthCare Branding

As part of our separation from GE, GEHC entered into a Trademark License Agreement (or "TMLA") that includes a number of requirements. One of those requirements is that we fully implement our new Visual Identity expressed in our Brand Guidelines "as soon as reasonably practicable." This requirement extends to packaging and labeling.

This requirement translates to applying new GE HealthCare branding on <u>new</u> products going forward to the new GE HealthCare brand (e.g., applying the new GE HealthCare logo, changing all text on labels and shipping packaging from GE Inspira to Source Sans Pro, and applying our new color palette).

If hardware is being modified or a new iteration will be introduced the packaging should also be updated if still containing outdated GE artwork. Any questions about this should be directed to brand.health@gehealthcare.com.

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6.5 Smart Labels for Delivery & Installation

Smart Labeling utilizes color coded or other special labeling on the outside of finished good packages to provide visual identification for how the package should be handled, or where it needs to be delivered at a customer site. The label can identify a specific room, location in a room, or provide other direction that will help direct it to the correct site location during delivery so the installer can quickly locate it during the installation process.

The following example shows colored labels used to identify the specific room packages need to be delivered to during a MR system delivery.



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7.0 Distribution Testing Procedures & Documentation

7.1 Validation Testing

7.1.1 Scope

All shippable components and parts require packaging testing unless there is a valid technical justification for not doing so.

Examples of parts not requiring testing: low-value/inconsequential parts such as some cords, cables, generic keyboards, computer mouse, USB sticks, etc.

Another example: An NPI has a new system cabinet being introduced that has the same shape and very similar internal structure to the existing system cabinet which already has packaging that has passed packaging testing. Assuming there are no known issues with the current packaging, the testing was at least to Rev. 10 of the 46-316745, and the structural members of the pallet or crate base have not changed, that part does not need new testing and may be technically justified to go without.

Testing history before Rev. 10 of 46-316745 is not acceptable to use for technical justifications because there were important safety testing sequences added at that revision, such as tip-tests, harsher shock tests, and handling tests.

All new parts and/or parts with new packaging should be tested to the latest revision of 46-316745 listed in MWS.

7.1.2 Packaging Testing Requirements Summary

Packaged parts should be capable of passing the GEHC shipping and handling tests defined in GEHC Document **46-316745**, "Mechanical Environment Test Standard" and should comply with the environmental requirements defined in GEHC Document **2252595PRE**, "Thermal Environment Test Guideline" when this packaging Standard is specified on GEHC engineering documentation. **The supplier is responsible for all testing and validation required to ensure their packaged part complies with the above requirements.**

Testing consists of exposing packaged products to hazards expected in the distribution environment utilizing mechanical devices to replicate:

- Drop
- Shock
- Vibration
- Stacking / compression
- Horizontal impacts
- Powered and manual handling
- Tipping

NOTE: The GEHC Packaging CoE and GEHC Advanced Technology Center are available for consultation to help understand the requirements of 46-316745 and 2252595PRE. It is recommended that one or both be consulted for questions related to these two documents and before testing or creating engineering technical justifications in lieu of the testing requirements defined in them.

7.1.3 Altered Package Validation

When a package is opened and changed by adding or removing components, the dynamics of the original package may be changed enough to impact packaging performance. When this situation applies, the package must either: be tested in both configurations, or have a documented technical justification why testing is not required.

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7.1.4 Trial Shipment Testing

Trial shipment (also known as a road test) can be performed in addition to the testing listed in 46-316745. These shipments are optional and are considered supplemental. Trial shipments may not be performed as a replacement for the standard validation testing. An instance where this rule doesn't apply is for components that exceed the safety parameters for lab testing- for example a CT gantry.

See Section 14 for instructions on performing trial shipments.

7.1.5 Lifting Testing

When it is likely that a product will require lifting via an overhead source with rigging, an analysis of the pallet must first be completed by a qualified individual. Once completed, the pallet shall be tested to 125% of pack weight in worst-case loaded configuration (this is the safety factor). The load position, load footprint, load height and center of gravity position shall be duplicated in the test. The rigging configuration shall be setup such that it produces the worst loading into the pallet. (Typically this is with slings wrapped around the bottom of the pallet with a 4-point configuration to the lifting hook)

Test procedure shall be as follows:

- Visually inspect the pallet for any deformations, cracks or defects
- Place the test weights on the pallet such that the C.G. is positioned correctly in the length and width position
 - o Test weights shall be within 125% +/- 2.5% of the heaviest load anticipated on the pallet
 - Test weight footprint must be the same as the footprint of the heaviest load anticipated on the pallet
- Configure the rigging to lift the pallet to induce the worst loading on the pallet
 - Rigging height shall be only tall enough that the expected load will fit with no interference with the spreader beam or slings
- Lift the pallet and test weights off the ground a few cm/inches and hold for 10 minutes
 - Observe the pallet during the test lift and note any excessive deflections, cracking or areas of concern
- Lower the pallet to the ground and perform a post-lift inspection
 - Note and document any permanent deformations, cracks or defects

7.1.6 Post-Testing

Products and parts that were physically tested must not be shipped to GEHC as new or repaired material unless all original inspections and testing are passed. Follow the business segment or manufacturing site procedures, some products can not be sold after performing testing.

7.2 Validation Testing Documentation

7.2.1 Information Required Prior to Testing

- Part specifications size, weight, and fragility in all orientations
- Known or anticipated weak points on the product or damage history if existing
- Packaging specifications
- Acceptance Criteria both package and product
 - Product failure defined by product engineering
 - Packaging failure defined by package engineering and/or product engineering
 - If specific types of packaging damage are not acceptable, that must be included in acceptance criteria before start of test

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- 7.2.2 Testing Documentation Requirements
 - Detail of packaging used in testing (part numbers, description, intake form for suppliers)
 - Test conditions (temperature & humidity)
 - Test methods (vibration, drop, etc.)
 - Test procedure (duration, frequency, orientation, height, etc.)
 - Results (pass, fail, comments)
 - Test equipment (model, serial number)
 - Name of person who performed test and date performed
 - Name of person who approved test and date approved
- 7.2.2.1 GEHC Document **DOC0359234** "AME Lab Environmental Testing Template," provides a test report form that can be used to meet the minimum requirements. Suppliers may use their own report form if it includes the minimum required information. Supplier shall maintain test reports and submit to GEHC.
- 7.2.2.2 When testing is successful and complete, all test reports and documentation related to the testing and package design shall be collected and added as a reference file or specification to the Finished Good via MyWorkshop.

 This information will serve as the validation for the package.

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8.0 Documentation Requirements

8.1 General Documentation Requirements

8.1.1 Part Numbers, Part Organization, and Packaging Taxonomy Requirements

New packaging components require MWS Packaging Classification and relevant attributes to be completed- see *DOC2918356* for instructions on how complete. <u>Note:</u> Adding a Packaging Classification to an existing part does **NOT** require an ECR/ECO.

Note: The term "Finished Goods" includes any part that shows up on a customer invoice and is a physical part that is packaged and shipped to the customer.

8.1.1.1 Packaging Documentation Requirements for Make Finished Goods

- All standard packaging parts associated with the respective Make finished good should have part numbers
 and proper packaging drawings documented in MyWorkshop (see section 8.2 of this document for
 minimum drawing requirements). These parts require Packaging Classification and relevant attributes to
 be completed.
 - Make sure to document every packaging component used, do not exclude any components.
 - Note: MWS Doc's are not an acceptable documentation method for documenting packaging parts. Packaging components require individual part numbers.
- Out-of-Catalog packaging components require part numbers and Packaging Classification/attributes to be completed if not in existence. See section 8.2.2 for more information.
- Packaging parts, assemblies, collectors, etc should be children parts to the Finished Good they are being used for. This is required for packaging material regulatory reporting purposes and proper traceability.
- Overpack/Consolidation packaging/non-standard packaging is excluded from documentation requirements (click on link for definition).
 - Note: Lean carts are not considered overpack if they are used for a standard set of parts. They
 should be documented and attached to one of the Finished Goods they are associated with.

8.1.1.2 Packaging Documentation Requirements for **Buy** Finished Goods

- Packaging re-used from supplier-packaged goods do not **REQUIRE** GEHC part numbers but are recommended to do so for high-risk (hard to handle, large, expensive, critical for installation) goods.
- These parts require Packaging Classification and relevant attributes to be completed.
 - The classification may be associated with either the GEHC packaging part numbers (if they exist), or the Finished Good part number. Multiple classifications can be tagged under a single part number.
 - If GEHC part numbers are created, packaging parts, assemblies, collectors, etc. should be children parts to the Finished Good they are being used for. This is required for packaging material regulatory reporting purposes and proper traceability.
 - Make sure to document every packaging component used, do not exclude any components.
- Overpack/Consolidation packaging/non-standard packaging is excluded from documentation requirements.

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8.2 Packaging Drawing Guidance

8.2.1 Drawing Prints

- It's preferred to have packaging drawings on a GE HealthCare title block, but supplier title blocks are also acceptable.
 - o If drawing is on a supplier title block, there should be a note on the drawing expressing that the drawing is owned by GEHC.
- All new prints must be dual dimensioned Metric and Imperial measurements.
- Part number is part of title block on drawing prints.
- Material specifications clearly stated on drawing prints.
 - o Examples:
 - For corrugated paperboard the flute and ECT or Mullen Burst Strength is specified.
 - For foam components, the foam material and density along with any properties is specified.
 - For bags, the thickness, material, and properties are specified.
- Revision on the drawing sheets match the MyWorkshop drawing print.
- Drawings list an author and date on every sheet.
- Location of special labels on the packaging are called out. For example, ISPM wheat stamp location or note to include in two visible locations is indicated in drawing prints.
- Recycling and disposal requirements are called out if needed.
- Ensure all dimensions are in the same units as designated in the title block.
- Title block should display tolerances for the packaging dimensions. Unless otherwise specified, all tolerances apply in a free-state condition.
 - O Corrugated paperboard and foam: +- 1/8 in, +-4mm
 - Wood: +-1/4 in, +-7mm
- Ensure BOM information (mark numbers, quantities, unit of measure) matches drawing. BOMs are reviewed
 at the same time the assembly drawings are reviewed. Verify quantity and unit of measure is
 appropriate/correct for the individual parts.
- Review hardware and material for commonality optimization if possible.
- Make sure all required dimensions are called out on the drawing. The drawing should include all dimensions and notes needed to build part without having a sample.

8.2.2 Out-of-Catalog Items Only

- Off-the-shelf Parts— A Supplier that provides a commercially available part or product that is not a FMD (Finished Medical Device) and that is not designed nor customized for GEHC.
- Must have supplier name and part number in Manufacturer's Equivalents in MyWorkshop.
- All relevant suffixes (dash numbers) must be specified in the part number.
- Part number must be the number the part is ordered by, and the number marked on the part and/or its package.
- There should be an attachment loaded to clearly identify the part. This may be a scan of a catalog page, product manual, technical specifications, etc. A text description of the part is not sufficient.

8.3 NPI Packaging Documentation Requirements

It is a recommended best practice for NPI teams to use the **NPI Packaging Gap Assessment** form (*DOC2891013*). This form was created to provide evidence that a product family or PCM of an NPI is in accordance with the Global Packaging Guideline (2100268PRE). Assessment should be completed as an output of FDR1.

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9.0 Special Packaging Requirements for Service Parts

9.1 Overview

This procedure applies to all parts supplied to Service, both new and repaired parts, when no other specific document is associated with the parts. Some high value parts will have specialty packaging that will be defined by part number on the drawing or in the purchase specification. The specialty packaging requirements take precedence over the general requirements of this guideline.

*Certain parts can be excluded (bin bulk, <\$20 dollars, etc.), except when indicated by GEHC.

Service part orders should be identified on the purchase order, but all shipments to the following addresses will be Service Parts and must follow the special packaging requirements in Section 9 as well as Sections 3-8.

USA:

UPS Supply Chain Solutions

775 East Dr.

Carol Stream, IL 60188

Singapore:

UPS House

22 Changi South Ave 2

Singapore 486064

Japan:

GEHC Tobu Parts Center

Yako 2-4-1 Kawasaki-ku, Kawasakish

Kanagawa, Japan 210-0863

France:

UPS Logistics

Group Parc d'Activities

de la Guepelle Bat C

St Witz, France 95470

9.2 Scope

Most GE HealthCare Service parts will be reshipped individually using an overnight type express courier. This environment produces greater shock levels and compression loads than most other types of transportation, so

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compliance with the requirements of this document is critical. It is assumed that most service parts are shipped 5+ times before being consumed at a location.

In addition, service parts require individual labeling and sealing in order to comply with the needs of the service parts logistics network. These requirements comprise a global standard used by all poles of GEHC Service Operations, for shipments to GEHC service parts stocking locations.

All requirements defined in this document (2100268PRE) apply to service parts, as well as the unique requirements in this section.

9.3 Service Packaging Requirements

9.3.1 Individual Packaging

All service parts exceeding \$20 unit cost must be packaged in **individual packaging** enabling shipment directly to customers. It is allowable to ship multiple packages in one, larger container to reduce shipping costs. However, all parts shipped inside the larger container must be individually packaged as defined in this document.

9.3.2 Reusable/Returnable Containers

Service Parts will be shipped individually between GEHC distribution facilities and customer sites and unpacked and repacked multiple times. All packages must be capable of multiple shipments and multiple openings and closings. Packaging must provide adequate protection for the rough handling that is normal for express and courier type shipments.

The outer packages of Service Parts must be received in good condition so they can be reshipped to GEHC customers.

Key considerations to protect outer packages:

- Corrugated containers must not be reused if they are ripped, damaged, have any signs of exposure to
 water, or prior exterior labels cannot be removed. They must be able to hold all inner pack in a proper
 manner, equivalent to a new container.
- Use corrugated material that is strong enough to support stacked and palletized loads and durable enough to avoid scuffing and tearing from minor impacts.
- When pallets are used, they must be durable enough to withstand handling during shipment. Pallets that collapse or breakdown result in damage to the items they carry.
- When corrugated boxes are palletized, protect the bottom layer from accidental fork damage.
- When corrugated boxes are palletized, it is recommended that corner supports are added to both increase stacking strength and to protect the corners of the boxes from impacts.

9.3.3 Packaging Assemblies, Kits, & Multi-piece Items

When multiple pieces are required for a part or an assembly that is considered a single part, the entire assembly must be individually packaged in a SINGLE package so that no repacking is required at the GE HealthCare facility, and assemblies are not separated.

9.4 Repairable/Exchange Program/Harvest Parts

Repairable/exchange program/harvest parts must be contained in packages, which facilitate their return to a warehouse, repair center or exchange center. The packaging must be replaced after each return to obtain a clean package ready for the next shipment, except if the package is considered as a Reusable package.

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9.5 Service Packaging Ergonomics & Safe Handling

There is usually only 1 GEHC employee on-site available for moving and handling service items. Packaging for service items must accommodate this restriction. Parts heavier than 35 lbs. should always be palletized or have wheels to be easily moved (however part must **ship** palletized and not on wheels). Consider this type of design in the image below when large parts need to be moved, especially if return-shipping of an old part is necessary. Packaging designs for awkward and heavy service items should include feedback from GEHC FE's and EHS. Below is an example of packaging that can make transporting a heavy Xray tube easier and can also be used to ship the old tube back(reference part # 5775036 for packaging specifications).



9.6 Package Seal Requirements

9.6.1 Green Good to Stock Seal (DOC0552387 "Service Part Good to Stock Label")

All Good to Stock parts that are individually packaged (> \$20 unit cost) are required to have a green seal applied at all entry points (usually two places).

The terms "Good to Stock" and "Green Seal" are interchangeable.

9.6.1.1 Repair Suppliers

Upon completing a part's repair, and passing final tests, a Repair Supplier will complete appropriate information on the "Good to Stock" Package Seal (Green Seal). This is done prior to shipping the repaired part to the network for placement into inventory for order fulfillment.

9.6.1.2 <u>SwaP Suppliers</u>

Supplier Warranty Program, SwaP Supplier will ensure that the Production Control Identifier is printed in the GEHC barcode format and affixed to the "Good to Stock" Package Seal (Green Seal) in the appropriate location. This requires the use of the "Good to Stock" seal (Green Seal) in accordance with the minimums specified below.

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All Suppliers, (including Repair, Multivendor, Consumable)

Use the Good to Stock seal (Green Seal - DOC0552387) in accordance with the minimums specified below:

Requirements	Repair Supplier	SwaP Supplier	All Other Suppliers	Warehouse
Suppliers check off the Supplier Box Warehouse check off the Warehouse Box	х	х	х	x
Production Control Identifier (If applicable)	Х	Х		
Date	Х	Х		
Repair Supplier	Х			
Repaired By (Name/Number)	Х			
GEHC Part Number	Х			

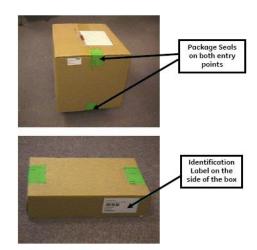
HOW TO SEAL A PACKAGE:







For consumable parts



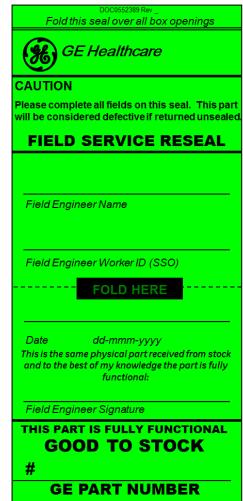
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9.6.2 Green FE Reseal (DOC0552389 "Service Part Field Service Return Label")

To be used as indicated by the return rule on the return label (as shown below)

• Field and Customer Returns of unused, unopened goods, and surplus items





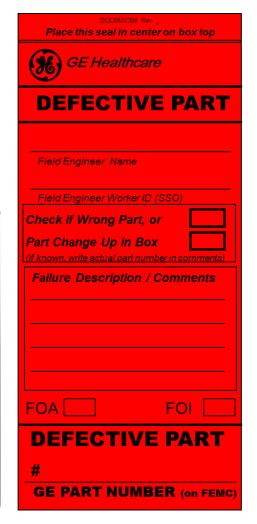
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9.6.3 Defective FE Reseal (DOC0552390 "Service Part Defective Part Return Label")

To be used as indicated by the return rule on the return label (as shown below)

- Defective Items which have been Debriefed
- Wrong Parts Received
- FOA/DOA Items
- FOA/DOI Items
- Change Up Returns of Defective Items

EEP WITH PACKAGE
Return Ref #: 49419773
Description : HARD DRIVE, FC-AL, 36.7GB, SEAGATE
GE Order Num : 10028432
System ID: 0853090317



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9.6.4 Recycling FE Reseal (DOC0552391 "Service Part Recycling Return Label")

To be used as indicated by the return rule on the return label (as shown below)

 ONLY USE WHEN INDICATED BY THE RETURN RULE. ALL items with Purple Seals are sent directly to recycling





9.7 Ordering Package Seals

When required, include the PLC's specified in the purchase agreement per GEHC Document **5215680GSP**, Supplier Product Locator Card Procedure. There are multiple suppliers that labels can be ordered from-two are listed below. Any label supplier can be used as long as it meets the requirements listed in the documents below.

- Good to Stock part number DOC0552387
- Field Service Reseal part number DOC0552389
- Defective Part part number DOC0552390
- Recycling part number DOC0552391

Marek

Email – <u>mailto:georders@marekgroup.com</u>, USA Phone Number – 262-549-8924 or 262-549-8900. Suppliers must provide to Marek Group Inc., their shipping address, shipping contact, phone number, and billing address for package seals. <u>Note:</u> <u>Marek Group Inc.</u> will direct bill Suppliers for all labels

DuraTech

DuraTech Industries

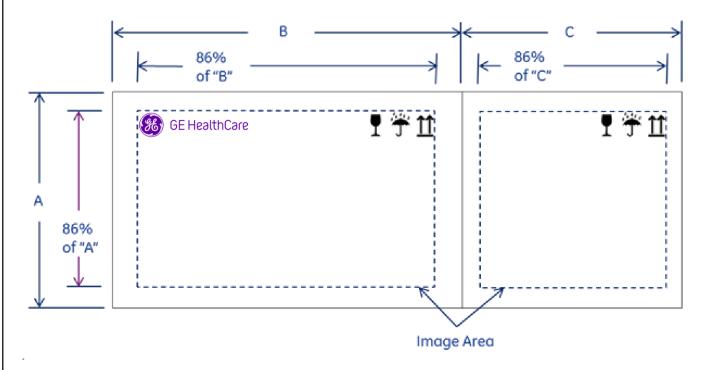
3216 Commerce St. LaCrosse, WI 54603 1-608-781-2570

DuraTech Industrial Components (Beijing) Co., Ltd.

No. 28, Yuhua Road, Airport Economic Core Zone Shunyi District Beijing China 101300

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10.0 Artwork Layout Guidelines



- 1. Graphics should fit into an image area that is 86% of the box panel dimensions.
- 2. Maintain a left margin with GE HealthCare text + monogram.
- 3. GEHC monogram/text to be 24% of height of image area.
- 4. Monogram should not be used by itself, must be to the left of "GE HealthCare" text.
- 5. Hazard symbols should be 2/3 the height of monogram and right aligned in uppermost image area.
- 6. GE HealthCare & monogram should be centered with height of symbols.
- 7. Use Master Artwork for correct proportions.

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11.0 Exhibit #11 – Size and Weight Limits for Distribution and Delivery

11.1 General

Arrangements can be made to transport products of almost any size and weight to any location in the world. However, exceeding specific size and weight limits reduces carrier selection flexibility and often results in increased transportation costs and slower delivery times.

The size and weight information supplied in this section is typical for global carriers. It is intended to act as a guide to avoid delivery delays and to help minimize costs. It should be used as a design and planning tool but should not be considered exact data for any one carrier or any one specific shipment. Contact the Logistics Specialist in your region for specific information and guidance.

11.2 Global Air Shipment

The key limitation factor for air shipment is height. For efficient shipment by air, packages and crates should be held to a maximum of 300cm (118") long X 226cm (89") wide X 206cm (81") tall. A more efficient and sometimes more economical height limit is 160cm (63"). This allows belly loading in all cargo and most passenger aircraft.

The overall height dimension can be increased to 241cm (95") for DC10 and 300cm (118") for 747 cargo aircraft. However, many large markets of the world, including much of Latin America and Asia do not have DC10 or 747 service, so products over 206cm (81") tall cannot be shipped by air to these locations. Products over 300cm (118") tall can NOT be shipped by air.

Air carriers are likely to tip over packages and crates that are over 206cm (81") tall to facilitate loading on smaller aircraft. It is also common practice for air carriers to tip over packages and crates that are over 160cm (63"), to facilitate lower deck loading on passenger and cargo aircraft.

There is no actual weight limitation for cargo aircraft. The limiting factor will be the capacities of available mechanical handling equipment to load and unload the aircraft and the weight limitations of air pallets used. See Section 11.2.2.1 for air pallet size and weight limitations.

11.2.1 Key Height Limits for Efficient Air Transport

Crate height is the key factor for efficient air transport. The following summarizes the key height dimensions that affect cost and cycle time for air transport:

- 1. 74 cm (29 Inches) Most efficient and economical air service.
- 2. **160 cm (63 Inches)** Still very good efficiency and economy.
- 3. **206 cm (81 Inches)** Point where problems and costs increase greatly.
- 4. **241 cm (95 Inches)** 747 cargo aircraft only possible carrier above this height
- 5. **300 cm (118 Inches)** Maximum height limit for air transport.

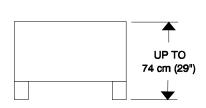
Hold "Total Shipping Heights" below each increasing dimension as product and package height allows.

<u>Note</u>: Aircraft door openings are actually 76.2cm (30"), 162.5cm (64"), 208.2cm (82"), 243.8cm (96") & 302.3cm (119") high. However, crates shall be 2.5 cm (1") less than the opening to allow for thickness of air pallets and other factors associated with aircraft loading.

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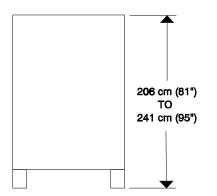
Key Height Limits for Air Transport



BELLY LOADING ALL PASSENGER AIRCRAFT FOR NEXT FLIGHT OUT EMERGENCY SERVICE

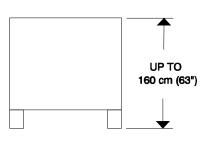
MAXIMUM EFFICIENCY, FLEXIBILITY AND LOWEST COST POTENTIAL

74 CM (29") APPLIES ONLY TO MD 80 AIRCRAFT (AFFECTS 6% OF TOTAL). ALL OTHERS, (94%) CAN USE 79 CM (31").



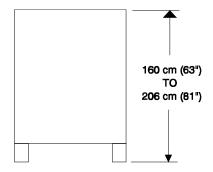
UPPER DECK LOADING ON DC-10 AND 747 CARGO AIRCRAFT ONLY

GREATLY REDUCED EFFICIENCY & FLEXIBILITY AT HIGHER COSTS. LIMITED SERVICE TO MOST DESTINATIONS, WITH NO SERVICE TO SOME DESTINATIONS, INCLUDING MUCH OF LATIN AMERICA AND MANY POINTS IN ASIA. EXPECT DELAYS



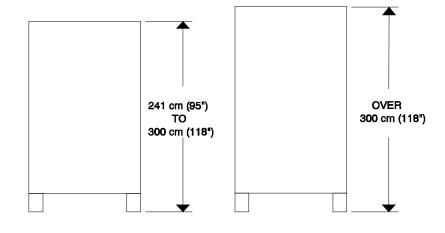
BELLY AND UPPER DECK LOADING ALL CARGO AIRCRAFT AND BELLY LOADING MOST PASSENGER AIRCRAFT

GOOD EFFICIENCY, FLEXIBILITY AND LOW COST POTENTIAL



UPPER DECK LOADING ON MOST CARGO AIRCRAFT

REDUCED EFFICIENCY AND FLEXIBILITY.
SERVICE LIMITED TO DESTINATIONS WITH
CARGO AIRCRAFT SERVICE. SOME
DELAYS CAN BE EXPECTED



VERY RESTRICTED, 747 CARGO ONLY POSSIBLE CARRIER CAN <u>NOT</u> SHIP AIR. MUST SHIP BY TRUCK OR OCEAN

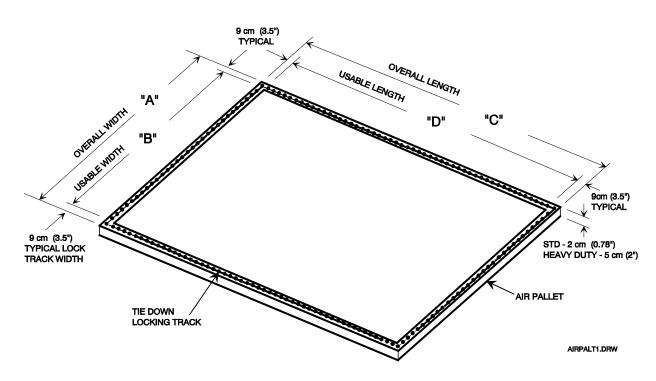
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11.2.2 Large Products on Air Pallets

Large products shipping by air will be secured to an air pallet by the airlines. Specific air pallet specifications and loading requirements are different for each airline. The following information is provided as a general guideline and all dimensions referenced are typical.

11.2.2.1 <u>Air Pallet Specifications</u>

Typical Air Pallet Specifications



Usable Air Pallet Load Area and Maximum Weight

PALLET TYPE	"A"	"B"	"C"	"D"	Max Weight
3 m (10') Pallet	243.8cm	226cm	317.5cm	300cm	6,668 kg
	(96")	(89.0")	(125")	(118.0")	(14,700 lbs.)
6 m (20') Pallet	243.8cm	226cm	605.8cm	588cm	10,795 kg
	(96")	(89.0")	(238.5")	(231.5")	(23,800 lbs.)

Air Pallet Loading Weight Distribution

PALLET TYPE	Max Pallet Loading
STD	1465kg/Sq. m (300 Lbs./Sq. Ft.)
2cm (0.78") Thick	
Heavy Duty	4882.7kg/Sq. m (1000 Lbs./Sq. Ft.)
5cm (2.0") Thick	

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11.2.2.2 Air Pallet Loading and Securement

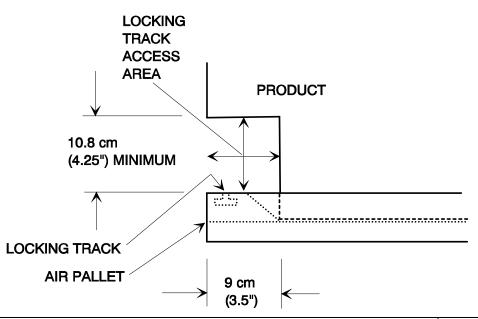
The air pallet will be locked to the floor of the aircraft cargo bay, so it is critical that the product(s) are adequately secured to the pallet to prevent all horizontal and vertical movement. The following are typical requirements of all airlines:

- 1. Product weight must be distributed as evenly as possible on the air pallet.
- 2. Products on wheels shall be blocked or supported in some manner to prevent rolling.
- 3. Large products must be secured both at the base and over the top.
- 4. Base straps are angled in opposite directions to eliminate all horizontal movement.
- 5. Top straps are used to eliminate vertical movement. Top straps can also be angled to help eliminate horizontal movement.
- 6. Tie-down straps are typically 5 cm (2") wide and are tensioned and secured with clamp type ratchet assemblies.
- 7. Tie-down straps are secured to the air pallet with devices that attach to a locking track on the edge of the air pallet.
- 8. Products must be positioned to allow access to the locking track along the edge of the air pallet.
- 9. Products on the pallet will be covered with plastic sheeting for moisture protection.
- 10. The number of base and top straps is dependent on the weight of the product(s) and varies by airline.
- 11. Most airlines require that a cargo net be applied over the load after the straps and plastic shroud are in position.
- 12. The cargo net is secured to the same locking track on the air pallet as the straps.
- 13. Straps and cargo nets are tensioned manually, so the tension forces applied to the product are totally dependent on the person doing the work.

11.2.2.3 <u>Air Pallet Locking Track Access</u>

Allow access to the locking track when positioning products on an air pallet. Products can be extended to the edge of the air pallet, if an access area is provided over the locking track.

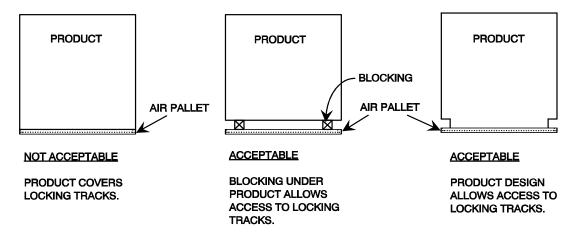
<u>Air Pallet Locking Track Access Requirements</u>



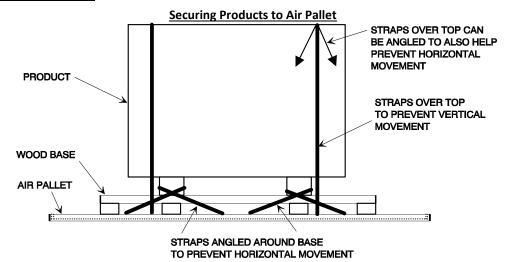
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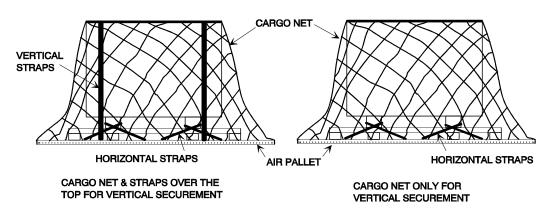
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Typical Air Pallet Locking Track Access Examples



11.2.2.4 Air Pallet Securement



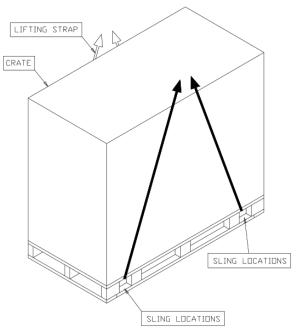


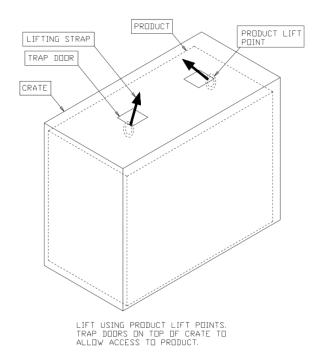
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11.2.2.5 Crane Lifting for Large Products

Crane Lifting Crated and Uncrated Products

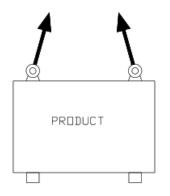
Crated Products

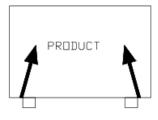


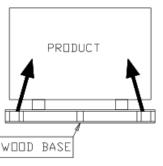


STRAPS MUST BE POSITIONED AT APPROVED LIFTING LOCATIONS

Uncrated Products







LIFT USING PRODUCT LIFT POINTS.

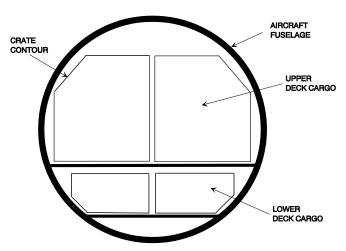
LIFTING WITH STRAPS UNDER PRODUCT SECURE PRODUCT
TO WOOD BASE AND
LIFT WITH STRAPS
UNDER WOOD BASE

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11.2.3 Matching Large Crates and Loads to Aircraft Contours

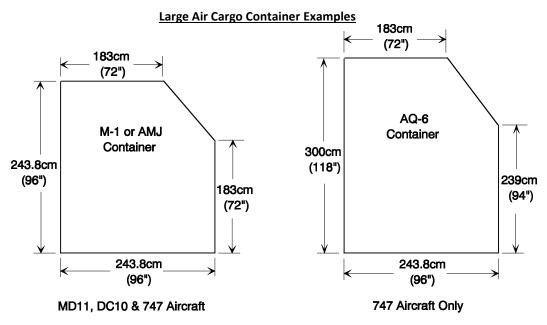
Due to the cylindrical shape of an aircraft fuselage, large crates and pallet loads with heights close to the maximum height limit often require a contour to match the aircraft. The following figure shows how contoured freight is positioned in upper and lower deck compartments.





The maximum dimensions and contour requirements for both upper and lower deck shipments vary greatly by carrier, aircraft type and position on the aircraft.

Air cargo containers provide good examples of maximum size and contour dimensions. The figure below provides typical examples of large cargo containers. Note: These should <u>not</u> be considered exact dimensions for any specific shipment. It is highly recommended that anyone with products in these size ranges, consult with your Logistics Department for specific information.



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11.3 Global OCEAN Shipment

11.3.1 General

Products shipping by ocean are typically loaded in Standard Containers (solid top & open top), Flat Rack Containers, and Non-containerized wood crates. Standard containers can be loaded below or on the deck of the vessel. Flat rack containers are typically loaded above deck. Non-containerized wood crates are almost always loaded above deck.

11.3.2 Containerized Shipments

11.3.2.1 Closed Container

- Most ocean shipments use standardized containers that are either 12.2m (40 ft) or 6.1m (20 ft) in length.
- Typical inside dimensions for a 12.2m (40 ft) container are 12 m (39 ft, 6 in) long X 2.3m (7 ft, 7 in) wide X 2.36m (7 ft, 9 in) high.
 - o There are also high cube containers that are 2.7m (8 ft, 10 in) high, but their availability is very limited.
- Typical inside dimensions for a 6.1 m (20 ft) container are 5.9m (19 ft, 4 in) long X 2.3m (7 ft, 7 in) wide X 2.36m (7 ft, 9 in) high.
 - High cube containers are not available in the 6.1m (20 ft) length.

11.3.2.2 Flat Rack Container

- A flat rack is an open, "U" shaped vehicle, with a bulkhead at each end. These containers are also, either 12.2 m (40 ft), or 6.1 m (20 ft) in length.
- Typical maximum product dimensions for a 12.2m (40 ft) container are 11.8m (38 ft, 9 in) X 2.148 m (7ft) X 2.095m (6 ft, 10.5 in).
- Typical maximum product dimensions for a 6.1m (20 ft) container are 5.7m (18 ft, 8.5 in) X 2.438m (8 ft) X 2.327m (7 ft, 7.5 in).
- The flat rack container is open on the sides and top, so the width and height of the product can be greater than the standard maximum dimensions. However, costs increase when the product size exceeds the standard maximum dimensions and cycle time may be affected.

11.3.2.3 <u>Non-containerized Shipments</u>

Products in wood crates that are too large for standard containers, or flat racks, can also be shipped by ocean through special arrangements with the forwarder/carrier. These shipments will require special handling and securement on the deck of the ocean vessel. This space is limited, so costs will be higher and cycle time may be affected.

11.3.2.4 Weight Limitations

- Weight limitations for closed containers are determined by the limitations of the surface movement in the exporting and importing countries.
- Weight limitations for flat rack containers are determined by the maximum payload allowed for the container during the ocean voyage. Products are typically transferred between flatbed trucks and the flat rack containers at the port, so highway transport limits do not apply.

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11.3.2.5 Typical Weight Limits for Closed Container Surface Movement in the United States

6.1m (20 ft.) Closed Container (Note: Average Container Weight = 2,041 kg (4500 lbs.))

	Maximum Gross Weight	Maximum Net Weight
- Standard Chassis	17,797 kg (39,235 lbs.)	15,755 kg (34,735 lbs.)
- Tri-axle Chassis	21,773 kg (48,000 lbs.)	19,732 kg (43,500 lbs.)

12.2m (40 ft.) Closed Container (Note: Average Container Weight = 3,856 kg (8500 lbs.))

	Maximum Gross Weight	<u>Maximum Net Weight</u>
- Standard Chassis	17,797 kg (39,235 lbs.)	13,941 kg (30,735 lbs.)
- Tri-axle Chassis	21,773 kg (48,000 lbs.)	17,917 kg (39,500 lbs.)

11.3.2.6 Typical weight limits for flat rack containers

6.1m (20 ft.) Flat Rack Container

- Average Container Weight = 2,330 kg (5,137 lbs.)
- Max Payload Weight = 21,670 kg (47,773 lbs.)

12.2m (40 ft.) Flat Rack Container

- Average Container Weight = 5,260 kg (11,596 lbs.)
- Max Payload Weight = 25,220 kg (55,600 lbs.)

11.4 Region & Country Specific Transport & Delivery Size and Weight Limits

11.4.1 GEHC-AMERICAS

11.4.1.1 Domestic Shipment (U.S.A. & Canada)

11.4.1.1.1 Van

Size limitations for U.S. Van shipments are 15.5 m (51ft) long X 2.5 m (98") wide X 2.8 m (110") tall. The typical weight limit is 18,000 kg (40,000 lb.). This is the weight limit of the Van but does not take into account weight limits of mechanical handling equipment used to load and unload the van.

11.4.1.1.2 Flatbed

The key size consideration for flatbed trailer shipment is a maximum width of 300cm (118"). The key weight consideration is 21,773kg (48,000 lbs.). Larger loads require special permits.

The next key size consideration is a maximum width of 365cm (144") and a maximum height of 365cm (144"). Larger loads are classified as "Super Loads," and require additional permits and escorts.

Larger and heavier loads can be transported, but due to the requirements for special permits and other transport restrictions, it will be at a much higher cost and slower cycle time.

11.4.1.2 <u>Domestic Delivery Limitations (U.S.A. & Canada)</u>

The recommended size limitations (which include clearances) for U.S. site deliveries that will fit most standard doorways and elevators are 259 cm (102") long X 105 cm (41.5") wide X 202 cm (79.5") tall. The most efficient size limitation that will fit all standard doorways and elevators is 236 cm (93") long X 90 cm (35.5") wide X 202 cm (79.5") tall. The maximum size limitation that will only fit the largest known doorways and elevators is 297 cm (117") long X 121 cm (47.5") wide X 212 cm (83.5") tall. Special handling and rigging will probably be required for delivery of these large products.

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The weight limitation for U.S. deliveries is determined by the elevator capacity.

11.4.1.3 Hospital/Clinic Facility Data (U.S.A. & Canada)

Note: The following data is typical for medical facilities in the U.S. It should not be considered exact data for any particular customer site. Percentages referenced are estimates.

11.4.1.3.1 Door Widths (Actual clear opening in door)

Standard – 106 cm (42") 80%

- 121 cm (48") 10%

Some clinics and older hospitals – 91 cm (36") to 106 cm (42") 10%

(Note: Subtract 1.3 cm (.5") from opening dimension for clearance to move through doorway)

11.4.1.3.2 Door Heights (Actual clear opening in door)

Standard - 203 cm (80") 90%

- 213 cm (84") 10%

(Note: Subtract 1.3 cm (.5") from opening dimension for clearance to move through doorway)

11.4.1.3.3 Corridors

Standard 152 cm (60") to 243 cm (96")

11.4.1.3.4 Elevator Door Heights (Actual clear opening in door)

Standard - 203 cm (80") 98%

- 213 cm (84") 2%

(Note: Subtract 1.3 cm (.5") from opening dimension for clearance to move through doorway)

11.4.1.3.5 Elevator Depths

Standard depths are – 243 cm (96") 10%

- 266 cm (105") 80%

- 304 cm (120") 10%

(Note: Subtract 7.6cm (3") from dimension for clearance to move product in elevator)

11.4.1.3.6 Elevator Weight Limit

Typically 2040 kg (4500 lb.)

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11.4.2 GEHC-EMEA

11.4.2.1 Domestic Shipment

11.4.2.1.1 Van

The typical size limitations for Van shipments in Europe are 240 cm (94.5") to 244 cm (96") wide X 250 cm (98.5") tall. The typical weight limit is 18,000 kg (40,000 lb.). This is the weight limit of the Van but does not take into account weight limits of mechanical handling equipment used to load and unload the Van.

11.4.2.1.2 Flatbed

The key size consideration for flatbed trailer shipment is a maximum width of 2.5m (98.4"). Larger loads require special permits and escorts.

11.4.2.2 <u>Domestic Delivery Limitations</u>

The recommended size limitations (which include clearances) for GEHC-E site deliveries that will fit most standard doorways and elevators are 236 cm (92.9") long X 120 cm (47.2") wide X 195 cm (76.8") tall. The maximum size limitation that will fit only the largest known doorways and elevators is 150 cm (59") wide X 212 cm (83.5") tall. Special handling and rigging will probably be required for delivery of these large products.

The weight limitation for GEHC-E deliveries is determined by the elevator capacity.

11.4.2.3 Hospital/Clinic Facility Data

Note: The following data is typical for medical facilities in EMEA. It should not be considered exact data for any particular customer site.

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	С	Door Width		с	Door Height		Corridor	Elevator Door Height	Elevator Depth	Depth		Elevator Weight Limit
Country	Private Clinic	Clinic	Hospital	Private Clinic	Clinic	Hospital	Standard	Majority	Private Clinic		Majority Clinics & Hospitals	Clinics &
France	90 cm (35.4")	120 cm (47.2")	140 cm (55.1")	202 cm (79.5")	202 cm (79.5")	212 cm (83.5")	150 cm (59") to 200 cm (78")	1.95m (76.8")	2.36 m (92.9")		2.36 m (92.9")	2.36 m (92.9") 1500kg (3307 lb) 1500kg (3307 lb)
Germany	90 cm (35.4")	120 cm (47.2")	120 cm (47.2") 198 cm (78")		198 cm (78")	198 cm (78")	170 cm (67") to 200 cm (78")	1.95m (76.8")	1.8 m (<i>7</i> 0.9")		2.36 m (92.9")	2.36 m (92.9") 1300kg (2866 lb) 1800 kg (4000 lb)
	82 cm (32")	82 cm (32")	82 cm (32")		202 cm (90")		700 cm (70 7")		25 50 102 01		2 26 m (02 0")	2 26 m (02 0")
UK	To 164 cm (64")	To 164 cm (64")	To 164 cm (64")	203 cm (80")	203 cm (80")	203 cm (80")	200 cm (78.7") 1.95m (76.8")		2.36 m (92.9")		2.36 m (92.9")	
Spain	90 cm (35.4")	_	_	202 cm (79.5")	202 cm (79.5")	212 cm (83.5")	150 cm (59") to 170 cm (67")	1.95m (76.8")	2.36 m (92.9")		2.36 m (92.9")	
Belgium	90 cm (35.4")	120 cm (47.2")	120 cm (47.2")	120 cm (47.2") 200 cm (78.7") 200 cm (78.7") 200 cm (78.7")	200 cm (78.7")	200 cm (78.7")	170 cm (67") to 200 cm (78")	200 cm (78.7") 2.36 m (92.9")	2.36 m (92.		9") 2.36 m (92.9")	
Turkey	90 cm (35.4")	120 cm (47.2")	140 cm (55.1")	120 cm (47.2") 140 cm (55.1") 202 cm (79.5") 202 cm (79.5") 212 cm (83.5")	202 cm (79.5")	212 cm (83.5")	170 cm (67") to 200 cm (78")	200 cm (78.7") 2.36 m (92.9")	2.36 m (92		2.36 m (92.9")	2.36 m (92.9")
Russia	110 cm (43.3)	120 cm (47.2")	120 cm (47.2") 198 cm (78")		198 cm (78")	202 cm (79.5")	180 cm (70.9") to 220 cm (86.6")	1.95m (76.8")	2.36 m (92.9")		2.36 m (92.9")	
Nigorio	120 cm (47.2")	120 cm (47.2")	120 cm (47.2")	202 cm (79 5")	200 cm (78 5") 212 cm (83 5")	71.7 cm (83 E")	170 cm (67")	1 95m (76 8")	25 m (92 g")		2 36 m (02 0")	
0	150 cm (59")	150 cm (59")	150 cm (59")			,	200 cm (78")					
Netherlands 90 cm (35.4")	90 cm (35.4")	110 cm (43.3") to	110 cm (43.3") to	110 cm (43.3") 200 cm (78.7") 200 cm (78.7") to to	200 cm (78.7") to	200 cm (78.7") to	240 cm (94.5") 1.95m (76.8")		2.36 m (92.9")		(92.9") 2.36 m (92.9")	
		47.2")	47.2")	86.6")	86.6")	220 cr						2400 kg
Switzerland	90 cm (35.4")		120 cm (47.2")	200 cm (78.7") 200 cm (78.7")	200 cm (78.7")	207 cm (81.5")	150 cm (59") to 250 cm (98.4")	1.95m (76.8")	210 cm (82.7" 2.36 m (92.9")	82.7") to 92.9")) to 210 cm (82.7") to 2.36 m (92.9")) to 210 cm (82.7") to 2.36 m (92.9")
	ì		Ì		ì		170 cm (67")					
Hungary	90 cm (35.4")	120 cm (47.2")	140 cm (55.1")	202 cm (79.5")	202 cm (79.5") 212 cm (83.5")	212 cm (83.5")	to 200 cm (78")	1.95m (76.8")	2.36 m (92.9")		.9") 2.36 m (92.9")	
Greece	80 cm (31.5")	110 cm (43.3")	120 cm (47.2")	205 cm (80.7")	205 cm (80.7")	$110\mathrm{cm}(43.3^{\circ})\Big 120\mathrm{cm}(47.2^{\circ})\Big 205\mathrm{cm}(80.7^{\circ})\Big 205\mathrm{cm}(80.7^{\circ})\Big 205\mathrm{cm}(80.7^{\circ})\Big 120\mathrm{cm}(47.2^{\circ})\Big 1.95\mathrm{m}(76.8^{\circ})\Big 1.35\mathrm{m}(53.2^{\circ})\Big 1.35$	120 cm (47.2")	1.95m (76.8")	1.35m (5		1.35m (53.2")	1.3

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11.4.3 GEHC-JAPAN

11.4.3.1 Domestic Shipment

Size limitations for truck shipments in Japan are as follows:

Type of Truck Crane Lift Truck	Weight Limit 4,000 kg (8,800lb.)	Floor Size 510cm X 208cm (200.8" X 81.9")	Door Opening Size Open Truck, No Door
Wing Truck	4,000 kg (8,800lb.)	620cm X 208cm (244" X 81.9")	Open Truck, No Door
Flat Bed Truck	10,000kg (22,000lb.)	930cm X 230cm (366.1" X 90.5")	Open Truck, No Door
Gate Truck	2,000 kg (4,400lb.)	480cm X 190cm (189" X 74.8")	180cm X 180cm (70.9" X 70.9")

11.4.3.2 <u>Domestic Delivery Limitations</u>

The recommended size limitations for Japan site deliveries that will fit most standard doorways and elevators are 250 cm (98.4") long X 115 cm (45.3") wide X 198 cm (78") tall. The most efficient size limitations that will fit older facilities in Japan are 250 cm (98.4") long X 85 cm (33.5") wide X 176 cm (69") tall. Special handling and rigging will probably be required for delivery of larger products to these older facilities.

The weight limitation for GEHC-YMS deliveries is determined by the elevator capacity.

11.4.3.3 Hospital/Clinic Facility Data

Note: The following data is typical for medical facilities in Japan. It should not be considered exact data for any particular customer site.

11.4.3.3.1 Door Widths

Entrance of Operation Room – 85 cm (33.5") Entrance of Scan Room – 115 cm (45.3")

11.4.3.3.2 Door Heights

Older Hospitals - 176 cm (69") 10% Newer Hospitals - 198 cm (78") 90%

11.4.3.3.3 Corridors

Small Hospital – 90 cm (35.5") Medium Hospital – 120 cm (47.25") Large Hospital – 250 cm (98.4")

11.4.3.3.4 Elevator Door Heights

Standard 210 cm (82.5")

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11.4.3.3.5 Elevator Door Widths

Standard 120 cm (47.25")

11.4.3.3.6 Elevator Depths

Standard depths are 250 cm (98.4")

11.4.3.3.7 Elevator Weight Limit

Typically 750 kg (1650 lb.) to 1000 kg (2200 lb.)

11.4.4 GEHC-China

11.4.4.1 Hospital/Clinic Facility Data

Note: The following data comes from limited information collected for facilities in China. It is not complete and is not exact data for any particular customer site.

11.4.4.1.1 Door Widths

Minimum – 90 cm (35.4") Maximum – 120 cm (47.2")

11.4.4.1.2 Elevator Door Widths

Minimum – 90cm (35.4") Maximum – 150cm (59") Most Common – 110cm (43.3)

11.4.4.1.3 Elevator Depths

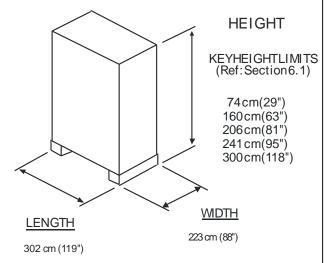
Minimum – 180cm (71") Maximum – 250cm (98.4")

11.5 Summary-Size & Weight Limitations for Efficient Handling & Distribution

<u>NOTE</u>: This data is typical for carriers and customer facilities worldwide. It is intended to act as a guide to help minimize costs and delays. It should not be considered exact data for any one shipment to any particular customer site. Percentages referenced indicate the estimated percentage of facilities with that size limitation. For example, the Width Limit of 105cm (41.5") shown as 80% for the Americas indicates that an estimated 80% of facilities in the Americas have a width limit of 105cm (41.5").

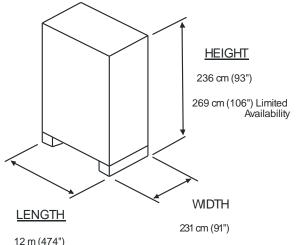
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WORLD WIDE AIR TRANSPORT



Limited by the capacities of available handling equipment.

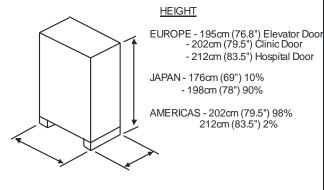
WORLD WIDE OCEAN TRANSPORT



12 m (474") & 5.9 m (232")

WEIGHT Limited by the capacities of available handling equipment.

CUSTOMER DELIVERY - BY POLE



LENGTH (Elevator Depths)

EUROPE - 236cm (92.9")

JAPAN - 250cm (98.4")

WEIGHT

EUROPE

AMERICAS - 236cm (93") 10% - 259cm (102") 80% - 297cm (117") 10%

AMERICAS-1,800kg (4,000 LBS)

-1,800kg (4,000 LBS)

-750kg(1,650LBS)30% -1,000kg(2,200LBS)70%

WIDTH

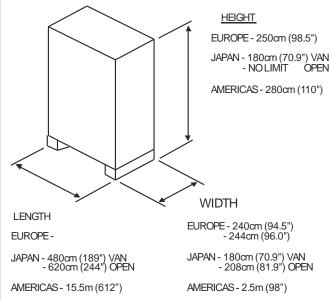
EUROPE - 90cm (35.4") Private - 120cm (47.2") Clinic - 140cm (55.1") Hospital

JAPAN - 85cm (33.5") 10% - 115cm (45") 90%

AMERICAS - 90cm (35.5") 10%

- 105cm (41.5") 80% - 121cm (47.5") 10%

TRUCK / VAN - BY POLE



WEIGHT

EUROPE -18,000kg (40,000 LBS) JAPAN -2,000kg (4,400 LBS) VAN -4,000kg (8,800 LBS) OPEN

AMERICAS - 18,000kg (40,000 LBS)

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12.0 Exhibit # 12 – GE HealthCare Packaging Optimization Best Practices GE Health care Packaging Optimization

Best Practices

Contain / Protect / Communicate / Comply	No damage / Product clearly identified / In compliance
2. Minimize size Size & Weinter	to product & pallet to package / Nest parts / No wasted space
Minimize size Size & Weight Drive Minimize weight	Minimize wood, use corrugated & foam where possible
4. Size to optimize carrier equipment	Plan for trucks, ocean containers, aircraft door openings
5. Size to optimize customer delivery	Plan for door openings, elevators, hallways
6. Minimize number of packages	One larger package < \$\$ than multiple smaller packages
7. Reuse when possible	Reduce scrap and replacement cost
8. Maximize package density	Carriers charge by size/volume for light weight packages***
9. Allow stacking (especially when under 200 cm (79") tall) Optimize carrier equipment & storage space
10. Reduce / Reuse / Recycle	al cost ↓ replacement cost ↓ scrap cost ↓ ecomagination ↑

Packaging Optimization Do's & Do Not's

Do

- 1. Insure package protects product from damage
- 2. Design package to match product size
- 3. Insure product clearly identified
- 4. Comply with all global regulations
- 5. Reuse existing packaging when possible
- 6. Nest oddly shaped items when possible
- 7. Design package to optimize carrier equipment







◆Packagesopt imize container

Nested products save space

Do Not

- 1. Use over-sized package and ship empty space
- Use over-sized pallets
- 3. Ship empty space filled with dunnage
- 4. Use wood if not necessary
- 5. Ship uneven pallet loads
- 6. Add unnecessary restrictions
 - (i.e. "Fragile", "This End Up" 11, "Do Not Stack")
- Wood crat e not necessary Wasted space







Pallet larger than package





Uneven pallet load



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13.0 Packaging Instructions for Common GEHC Parts

This guidance is intended for common parts shipped out by GEHC that may not have packaging defined.

13.1 Circuit Board Packaging Instructions

Electronic boards must be packaged individually. The packaging comprises two parts:

- a. Sealed conductive antistatic bag ensuring protection of the board from electrostatic discharge (ESD). Only conductive antistatic bags made of multiple-layer film of polyethylene, polyester, carbon and/or a metallic layer are authorized. These bags must have a part ID label on the outside, or be translucent, so the board can be identified without opening the bag. The bag must be closed using a tamper-proof label. This provides a guarantee that the true faraday cage has been created around the board and the board is protected against static electricity.
- b. <u>Sealed corrugated fiberboard box, with markings to identify its contents, to insure mechanical protection of</u> the board. It is recommended that a **tube and slide** type package be used.
 - The slide includes foam or other cushioning material.
 - The **tube** forms the outer shell of the package. It is the less expensive part of the package and is easy to replace when it becomes damaged or covered with prior shipment labels.
 - External dimensions of the package shall be at least 38mm (1.5") greater than those of the part packaged. The package must however, hold the part firmly.
 - The case is preferably pre-printed. The package carries the mandatory marking labels. Closure of the box must provide a guarantee to the user against all risk of opening.
 - The corrugated box used to deliver parts to the Global Parts must be clean and free of handwritten markings or labels other than that indicating the part number, the board origin and the package seal. This is essential to prevent errors of identification or distribution.
 - For repairable parts, the name of the repair or manufacturing center technician in charge of the final test, and the test date must be indicated either on the board or on the antistatic bag label.

13.2 Cable Packaging Instructions

Individually packaged in a bag with connectors bubble wrapped. The bags shall be labeled.

13.3 Power Supplier / Transformers Packaging Instructions

- Flexible foam shall be used to protect the units.
- Adequate protection shall be utilized to protect heavy parts during transport.

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14.0 Trial Shipment Testing Instructions

A typical trial shipment validation test involves:

- 1. Shipper communicates information on the new or redesigned packaging to the receiver.
- 2. Receiver provides comments and general feedback to the shipper.
- 3. Shipper & receiver work together to select an Order and agree on timing of the shipment.
- 4. Shipper prepares the shipment and ships the new or redesigned package.
- 5. Shipper provides receiver with shipment information, including AWB No. (air shipment) or PRO No. (truck shipment) and estimated date of arrival.
- 6. Receiver inspects the shipment on arrival and may follow it through the delivery process, if necessary.
- 7. Receiver provides feedback in the form of written comments, photographs, video, or whatever is necessary to communicate any problems or concerns.
- 8. If no problems, the receiver gives shipper approval to implement the change on future shipments.
- If there are problems, shipper makes necessary changes and initiates another trial shipment, or if the problems are very serious, the proposed new or redesigned packaging may be cancelled.
- 10. When the trial is complete, shipper collects all written correspondence on the trial, especially feedback from receiver and adds to the project file. This information will then act as the validation for the package.

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15.0 General Reference Documents and Specifications

The following references provide very detailed design specifications, material selection criteria, and other information that applies to these packaging guidelines, but are beyond the scope of this document:

15.1 Package Design Specifications

Japanese Industrial Standard (JIS)

JIS Z 1403 - Wooden Framed Boxes for Export Packing

Covers – Detailed design specifications and material selection guidelines for wooden framed boxes for contents of 500 kg (1100 lbs.) or more

General Electric CGR - Packaging Guide

Reference No. 90082, 2/1/91

Covers – General package and material selection and design procedures

U.S. Department Of Agriculture

Handbook No. 252 – Wood Crate Design Manual

Covers – Detailed design specifications and material selection guidelines for wooden framed crates

U.S. Federal Specification

PPP-B-621 - Boxes, Wood, Nailed and Lock-Corner

Covers – Detailed design specifications and material selection guidelines for wood boxes

15.2 General Industry Data

NOTE: This information is provided as a reference only. It covers the global distribution system and is not limited to the GE HealthCare distribution system.

Approximate Fragility of Typical Packaged Products

Extreme	ly Fragi	le
---------	----------	----

Aircraft altimeters, Winchester hard disc drives----- 15 – 25 G's

Very Delicate

Medical diagnostic apparatus, x-ray equipment----- 25 – 40 G's

Delicate

Computer display terminals and printers, electric typewriters ----- 40 – 60 G's

Moderately Delicate

Stereos and television receivers, floppy disc drives ----- 60 – 85 G's

Moderately Rugged

Major appliances and furniture ------85 – 115 G's

Rugged

Table saws, sewing machines, machine tools ------ 115 G's & up

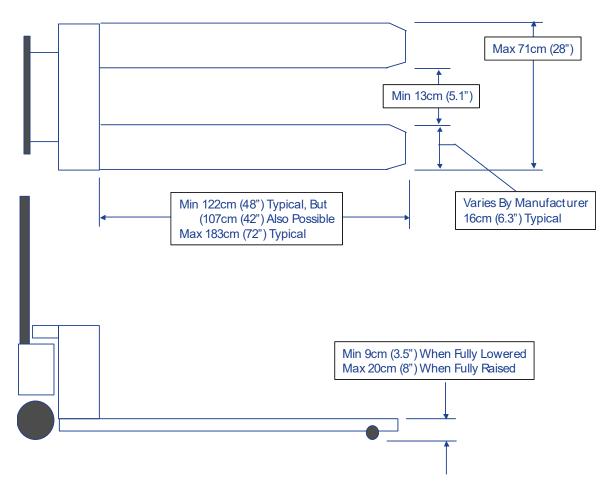
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15.3 Typical Pallet Truck Specifications

Other dimensions are possible, but these represent global standards from the major pallet truck manufacturers.

Typical Pallet Truck Specifications



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15.4 REACH Reference Information

15.4.1 Articles

"Article means any object which during production is given a special shape, surface or design which determines its function to a greater degree than its chemical composition (REACH, Article 3(3)).

The function of packaging is containment and as such the shape, surface, design or a combination of these elements is normally of greater significance than the chemical composition of the packaging material used. Therefore, most packaging is considered an article under REACH. Producers and importers of articles in the EU generally are subject to two key requirements under REACH:

- Registration of substances intended to be released from articles if the total amount of the substance released exceeds 1 tonne/year.
- Notification to ECHA of candidate list substance present above a concentration of 0.1 % weight by weight if the total amount of candidate list substance in the articles > 1 tonne/year.

In addition, anyone shipping a product in the EU in packaging that contains a candidate list substance above a concentration of 0.1% must provide this information with the shipment along with safe use information. (Article 33)

Due to these requirements, packaging manufacturers need to know/identify what chemicals are in their products, the quantity, and if the substances(s) are for intended release.

If they are not importers of record when buying products in the EU, those who buy substances/preparations/articles contained in packaging are known as "downstream users" under REACH.

A downstream user should contact his suppliers (of packaging or articles/products contained within packaging) and confirm that actors in his supply chain have complied with REACH.

A downstream user of packaging should request information on whether the packaging contains candidate list substances in order to comply with the requirements of Article 33 of REACH.

15.4.2 Intended Release

Both the condition of intended release AND reasonably foreseeable conditions of use must be met before registration of the substances in an article, in this case, packaging, would be required (under Article 7(1) of REACH).

Regarding packaging (as articles) it is not normally the situation that substances are intentionally released from the packaging material in order to fulfill the function of the packaging i.e. containment, and so registration is not required.

Finally substances (in packaging) which are/can be released as a result of wear/tear, due to accidents, or degeneration/aging are not considered (under REACH) as intentional releases, in particular, considering that such types of releases are not necessary or required as an essential part of contributing to the function of the packaging material i.e. containment.

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15.4.3 General Guidance on Packaging (considered as articles under REACH)

Questions to consider and help decide your role under REACH with respect to packaging material.

1. Do you manufacture packaging material?

If yes:

- a) What substances, if any, do you use in this manufacturing process?
- b) What quantity of substances do you use?
- c) Where do you source your chemicals i.e. EU or as an importer from non-EU?
- d) Are these chemicals being registered by your supplier(s)?
- e) <u>Do you import (from outside the EU) more than 1 ton per year of these chemicals for your manufacturing process?</u>
- 2. Do you buy packaging materials from:
- (a) EU manufacturer? then you are a downstream user of packaging (i.e. an article under REACH) and need to contact your supplier to find out what substances are contained within the packaging, are they being registered, can they be intentionally released from the packaging material?
- (b) Non-EU manufacturer? Then you are an importer of an article and need to find out what substances are contained within the packaging, the quantity of the substance(s) and can they be released intentionally from the packaging, or, has the non- EU manufacturer appointed an Only Representative in which case your role is reduced to that of a Downstream User.
- 3. Do you use substances/preparations/articles at your workplace or in your work activity, which are contained/supplied to you in packaging?

Then you are a downstream user who should contact the supplier to find out what substances are contained in the packaging, what quantity of substance per packaging unit and whether the substances in question can be intentionally released?

Those involved in the manufacturing of packaging do not in themselves manufacture chemicals but, as many packaging manufacturers use chemicals during the process of manufacturing their product, they should be aware of how they may have obligations under the REACH Regulation (EC) No. 1907/2006. Remember you are not required to register articles under REACH but they need to know if the substances within/used in the article are subject to the requirements under REACH.

Examples of the materials and substances used in packaging include: paper, metal, inks, adhesives, glass, coatings, plastics, board, foil, drums, etc.

In other words, manufacturers of packaging may use chemicals such as inks, adhesives, coatings etc. This can be as an importer if obtaining the chemicals/substances from non-EU source or as a downstream if the source is based within the EU.

Packaging should be assessed independently of the object (substance, preparation and/or article) it contains. Whether the packaging is a carton, box, plastic wrapping, bottle or tin can, it is considered an article under the meaning of REACH and as such therefore the packaging is not part of the substance/preparation or article it contains. It should be noted that there can be various layers of packaging e.g. a plastic wrapper that is then placed inside a box, whereby each layer of packaging is an independent article and so must be considered separately.

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15.5 List of Symbols, Abbreviations, Definitions, Acronyms

Active Label

A label that undergoes a physical change indicating that a specific action has taken place (i.e., Tiltwatch Labels, Humidity Indicators, etc.)

<u>ATC</u>

Advanced Technology Center – part of the HealthCare, Imaging Technology Organization.

Consolidation Packaging

Any packaging applied by GEHC manufacturing, suppliers, distribution centers, or 3rd party shipping facilities used to consolidate multiple finished goods together, or any packaging added in addition to standard finished good packaging. This is packaging that is secondary or tertiary, not the individual packaging around a finished good or part. This packaging is used to combine multiple parts together, and/or can be added to facilitate handling. Examples: A pallet added to ship 3 finished good products (already in boxes). A box and void-fill packaging to combine 2 finished good items (already in boxes). A pallet, straps, and stretch wrap added to a large finished good (already in a box) to facilitate easier handling. Lean carts are considered consolidation packaging.

Controlled Ocean Container Shipment

A shipment where the ocean container is loaded in a controlled environment, either by the shipper or their agent, and is not broken until it arrives at the final destination, where it is unloaded in a controlled environment by the receiving pole or their agent.

Finished-Good Packaging

See Primary Packaging definition.

Finished Good Product

Product that can be used on a manufacturing production line, but is more typically shipped direct or reshipped, without any repackaging, to customers as a complete system or component of a system. Sourced by GEHC Global Manufacturing Operation.

GEHC

GE HealthCare

Good Receiving Point

The country of destination and all phases included in the distribution routing are expected to have good, safe handling and transportation systems to move the product from the point of entry to the final customer site.

HCS

Healthcare Systems

Individual Pack

Products packaged with a quantity of one item (part number) in one package.

Individual Package

A product that is packaged and labeled in the final packaging configuration which will allow it to be shipped directly to the final customer with no repackaging. The package is labeled correctly with all required documentation on the outside of the package, to prevent the need to open the package when received by a GEHC distribution facility.

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Individual Pack, Single Trip Containers

Products packaged with a quantity of one item (part number) in one package. The package is not designed for reuse.

Individual Pack, Double Trip Containers

Products packaged with a quantity of one item (part number) in one package. The package must be designed to protect the product for the initial shipment to the end user, and also, the return shipment of the same or a similar product to the supplier.

Large Product

Products weighing greater than 1000 kg (2200 lbs) that typically require special packing and handling considerations.

Line Use Product

Product being shipped to a GEHC manufacturing facility, specifically for use on a manufacturing line. Not intended for reshipment to a GEHC customer. Sourced by GEHC Global Manufacturing Operation.

Medium Product

Products weighing greater than 32 kg (70 lbs), but less than or equal to 1000 kg (2200 lbs), that usually require mechanical handling. These products usually ship in a crate or large box with wood runners and must provide access for fork trucks, hand trucks, or other mechanical handling equipment.

Milk Run

A closed loop trucking process that moves GEHC products and components between Suppliers and GEHC Manufacturing facilities and Distribution Centers

Minimum Pack

When a product ships with very little protective packaging. The package usually consists of a light wrapping of plastic film, cushioned paper, bubble wrap, or other similar material, with some means of handling provided. The product can have built-in wheels, built-in fork openings, be attached to a shipping dolly, or be secured to a wood base.

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Multi-Pack

Products packaged with more than one item (all the same part number) in one package.

Multi-Pack, Single Trip Containers

Products packaged with more than one item (all the same part number) in one package. The package is not designed for reuse.

Overpack

Any packaging that is secondary or tertiary packaging, not applied directly around the product or component. It is packaging that is used to facilitate consolidation and handling. It is used ad-hoc and is not standard. An example of this would be a <u>pallet</u> used to combine multiple Finished-Good boxes. Another example would be the <u>pallet, large box, and void-fill air pillows</u> used to combine and brace multiple small Finished Good boxes into a shippable container.

Overpack is generally applied by GEHC manufacturing facilities, supplier facilities who drop-ship, GEHC distribution centers, and 3rd-party distribution centers.

Packaging

All products made of any materials of any nature to be used for the containment, protection, handling, delivery and presentation of goods, from raw materials to processed goods, from the producer to the user or the consumer. Non-returnable items used for the same purpose shall also be considered to constitute packaging. Packaging consists only of:

- (a) sales packaging or primary packaging, i.e., packaging conceived so as to constitute a sales unit to the final user or consumer at the point of purchase;
- **(b)** grouped packaging or secondary packaging, i.e., packaging conceived so as to constitute at the point of purchase a grouping of a certain number of sales units, whether the latter is sold as such to the final user or consumer or whether it serves only as a means to replenish the shelves at the point of sale; it can be removed from the product without affecting its characteristics;
- **(c) transport packaging or tertiary packaging,** i.e., packaging conceived so as to facilitate handling and transport of a number of sales units or grouped packages in order to prevent physical handling and transport damage. Transport packaging does not include road, rail, ship and air containers, etc.

Passive Label

A label that provides written information only (i.e., "Fragile", "Handle with Care", "This End Up", etc.)

Poor Receiving Point

The country of destination, or any phase included in the distribution routing, is known or is expected to have a rough, unsafe handling and/or transportation system to move the product from the point of entry to the final customer site, requiring extra protection from the product's packaging.

Primary packaging or Finished-Good Packaging

Any packaging placed directly around the product being shipped. This type of packaging is generally standard and used every time the part is shipped. An example of this would be a monitor shipped in a **box with foam endcaps** and plastic bag. All these packaging components would be considered the primary packaging.

GEHC manufacturing facilities apply Primary packaging for Make Parts and occasionally Buy Parts. Suppliers apply primary packaging to Buy Parts, which is often re-used to ship to the customer.

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Processed Wood

Wood based material constructed using glue, heat, and pressure, or any combination thereof. Plywood, particleboard, and corrugated fiberboard are examples of processed wood.

Secondary packaging

Any packaging that combines multiple primary packaging containers, generally containing multiples of the same primary packaging. For example, a **bulk box** coming from a supplier that has 10 primary packaging boxes containing cables. Multiple secondary packaging boxes may then be placed into a larger tertiary crate or box to facilitate shipment and handling.

Service Part

Product shipped to customers for repair or replacement of existing systems. Sourced by GEHC Global Service Parts Organization.

Raw Wood

Basic wood boards and lumber that have been cut from the wood of the original tree.

"Repairable" or "Exchange Part"

A part that is repaired by a GEHC repair source, or a repair supplier, for placement into the parts network. The part is repaired on a return and exchange program; a rebuilt part is sent to a Field Engineer, and the defective part (RG) is returned for credit, to be rebuilt.

Reusable/Returnable Containers

Containers specifically designed to be returned to the supplier for reuse. Applies to containers designed for both single and multiple items.

"RG" (Returned Good)

A defective Service Part returned from the field.

Small Products

Products weighing 16 kg (35 lbs.) or less that can usually be packed and handled manually by one person. A means for mechanical handling may be provided for convenience, but is not required. Usually shipped in wood or corrugated boxes and often consolidated with other small packages in a larger wood or corrugated box for shippent. Often shipped using overnight carriers where rough handling conditions can be expected.

Solid Wood & Non-manufactured Wood

Wood that has not been processed or changed from its natural state. Lumber and boards are an example of solid wood. (Note: In this document, Solid Wood and Non-Manufactured Wood are used interchangeably.)

Specialty Packaging

Packaging designed and engineered for a specific part. These requirements will be defined on the part drawing or purchase specification and take precedence over the general requirements of this guideline.

Tertiary packaging

Any packaging that is not primary or secondary packaging, and which facilitates the protection, handling, and transportation of more than one secondary or primary packages in order to group everything into unit loads during transit.

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Transport Packaging

Packaging conceived, so as to facilitate handling and transport of a number of sales units or grouped packaging in order to prevent physical handling and transport damage. Transport packaging does not include road, rail, ship, or air containers.

VCI

Vapor Corrosion Inhibitors

WVTR

Water vapor transmission rate

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16.0 Labeling/Packing List Examples

16.1 Typical Export Packing List Example

GE Healthcare

ORG CTM

Ship To

GE MEDICAL SYSTEMS ITALIA SPA
C/O MIT SAPETRANS
VIA DELL'ARTIGIANATO 12
CARUGATE, 20061
Italy

Ship From:

GEMS CT Manufacturing GEMS CT Manufacturing 3000 North Grandview Blvd Waukesha, WI 53188 United States Packing Slip

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Checked By:

Requested Date:

08-JUN-2007

Approved By:

Waybill:

Customer PO#:

See Below

Packing Slip: Ship Method: 5407514

Carrier:

carrier:

Delivery Name: 9517773

Item Number	Description	Order # / Line #	Qty Shp	Cnt#
B7864TS	GT 1700 TABLE	1237420	1	2,6
		1.1		
	Customer P0:2691674.5			
B7864JP	VCT OPTION KEY	1237420	1	5
		2.1		
	Customer P0:2691674.5			
B7864JG	VCT GANTRY	1237420	1	1,3,6
		3.1		
	Customer PO:2691674.5	**		
B7864JD	VOL.SHIP COLLECTOR	1237420	1	5,5,5,5
		4.1		
	Customer PO:2691674.5			
B7858LC	LCD MONITOR_2PC/KIT	1237420	1 .	3,3
		5.1		
	Customer PO:2691674.5			
B72352CA	NGPDU-4 FOR VCT	1237420	1	4
		6.1		
	Customer PO:2691674.5			
B7864HS	VCT TECHPUB/OS/SW(SM RM)	1237420	1	5
		7.1		
	Customer PO:2691674.5			
B7864MC	VCT CONSOLE (8200)	1237420	1	3,3,3
		8.1		
(eg)	Customer PO:2691674.5			
(09)				

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16.2 Typical Supplier Packing List Example

Supplier ABC

12345 Main St. Anywhere, USA 54321 (111) 222-3333 PACKING SLIP FORMAT AND LAYOUT IS NOT CRITICAL.

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Packing List #: 111111

ASN / Shipment #: 222222

Ship Date: 01/02/01

ASN / Shipment # must be <u>clearly</u> labeled as "ASN / Shipment #"

Supplier Order #: 333333
Customer Order/PO#:3000123450001
Order Date: 01/01/01
Ship Method: FEDEX
FOB: Origin

Include Modality (XR, MR, etc.) in Ship-To Address

SHIP TO: G.E. Healthcare

X-Ray Manufacturing 3000 N. Grandview Blvd.

Waukesha, WI 53188

United States

G.E. Healthcare PO Box 60560

Fort Meyers, FL 33906

United States

Line #	Quantity	U/M	Part / Catalog #
	Shipped	U/M	Description
1	10	EA	2304313 Bracket

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Appendix A Example/Reference Documents

The "Industry Standards and Documents" (Section A.1) or "Other GEHC Standards and Documents" (Section A.2) referenced in this document are to provide background information or to identify the source of the statements. Since referenced documents may provide information on multiple subjects, only the subject(s) referenced in the body of this document are considered relevant.

This document is based on the standards and documents listed below. All standards and documents are subject to revision. Reference the appropriate source for the latest version.

A.1 Industry Standards and Documents

Reference	Description
69/493/EEC	European Economic Community Directive on Crystal Glass
94/62/EC	European Packaging Directive – Packaging and Packaging Waste
97/129/EC	European Packaging Directive – Packaging Markings
(EC) 1272/2008	Classification, Labeling, and Packaging of Substances and Mixtures
(EC) 1907/2006	Regulation of the European Union regarding Registration, Evaluation, Authorization and Restriction of Chemicals
2009/251/EC	Dimethylfumarate (DMF) Testing
ANSI/AAMI/ISO 11607-1	Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems, and Packaging Systems
ANSI/AAMI/ISO 11607-2	Packaging for Terminally Sterilized Medical Devices – Part 2: Validation Requirements for Forming, Sealing, and Assembly Processes
ASTM D4169	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM 5582	Standard Test Method for Determining Formaldehyde Levels from Wood Products Using a Desiccator
EN13427	Packaging - Requirements for the use of European Standards in the Field of Packaging and Packaging Waste
EN13428	Packaging - Requirements Specific to Manufacturing and Composition - Prevention by Source Reduction
EN13429	Packaging - Reuse
EN13430	Packaging - Requirements for Packaging Recoverable by Material Recycling
GB 18455-2001	People's Republic of China National Standard - Packaging Recycling Marks
HANDBOOK 252	US Dept. of Agriculture – Wood Crate Design Manual
ISO 780	Packaging – Pictorial Marking for Handling of Goods
ISO 1043	Plastics – Symbols and Abbreviated Terms
ISO 11469	Plastics – Generic Identification and Marking of Plastics Products
ISO 7000	Graphic Symbols for Use on Equipment
ISPM 15	Regulation of Wood Packaging Material in International Trade
JIS Z 1403	Construction of Wooden Framed Boxes for Packing
MIL B 131 H	Barrier Materials, Water Vapor Proof, Grease Proof, Flexible, Heat-sealable
PPP-B-621	Federal Specification: Boxes, Wood, Nailed, and Lock Corner
UL 60601-1	U.S. National Standard for Safety Testing Electrical Medical Devices

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A.2 Other GEHC Standards and Documents

Reference	Description
46-316745	Mechanical Environment Test Standard
2252595PRE	Thermal Environment Test Guideline
5215680GSP	Supplier Product Locator Card Procedure
5396068GSP	GEHC REACH Requirements for Suppliers to GEHC Legal Entities
DOC0041803	2013740-149 CP-1035 China Product and Package Label Requirements
DOC0062044	China Labeling and Language Requirements and Procedure
DOC0269245	GEHC China RoHS Labeling and Conformity Assessment Requirements
DOC0359234	AME Lab Environmental Testing Template
DOC0552387	Service Part Good to Stock Label
DOC0552389	Service Part Field Service Return Label
DOC0552390	Service Part Defective Part Return Label
DOC0552391	Service Part Recycling Return Label
DOC1060518	GEHC Venezuela Labeling Requirement
DOC1141717	GEHC Packaging Req. Document for EU Directive 94/62/EC
DOC1220258	GEHC Functional Req. for Compliance with EU Directive 94/62/EC and Amendments
DOC0841496	Global Labeling Content Requirement

END OF DOCUMENT	

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