A

Major Project Report

on

MEDICAL DEVICE PACKAGING

submitted in partial fulfilment of requirements for the award of the degree of

MASTER OF DESIGN

(Product Design)

By

KSHITIJ GUPTA

2K21/MDPD/06

under the supervision of

MR. PARTHA PRATIM DAS

(Assistant Professor)

DEPARTMENT OF DESIGN

DELHI TECHNOLOGICAL UNIVERSITY

(Formerly called Delhi College of Engineering)

Bawana Road, New Delhi – 110042

APRIL 2023

DEPARTMENT OF DESIGN

DELHI TECHNOLOGICAL UNIVERSITY

(Formerly called Delhi College of Engineering)

Bawana Road, New Delhi – 110042

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I, Kshitij Gupta, Roll No. 2K21/MDPD/06, am a student of MTDes (Product Design), with this declare that the project dissertation entitled "MEDICAL DEVICE PACKAGING" is submitted by me to the Department of Design, Delhi Technological University, New Delhi in partial fulfilment of the requirement for the award of the degree of Master of Design in Product Design. This original work has not been copied from any source without proper citation. This work has yet to form the basis for awarding any Degree, Diploma Associateship, Fellowship or other similar title or recognition.

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Date :

DEPARTMENT OF DESIGN

DELHI TECHNOLOGICAL UNIVERSITY

(Formerly called Delhi College of Engineering)

Bawana Road, New Delhi – 110042

CERTIFICATE

I hereby certify that the Project Dissertation titled "MEDICAL DEVICE PACKAGING ", which is submitted by Kshitij Gupta, Roll No. 2K21/MDPD/06, Department of Design, Delhi Technological University, New Delhi, in partial fulfilment of the requirement for the award of the degree of Master of Design, is a record of the project work carried out by the student under my supervision.

Signature:

Place: NEW DELHI

PARTHA PRATIM DAS

Date:

SUPERVISOR

Assistant Professor

ABSTRACT

This thesis report examines how Packaging Design is executed in the Medical Device industry. The discussion begins with discussion of Medical Technology in India, its advancement in the coming years. The report goes on to describe how Medical Device Packaging is regulated and what are the characteristics to be kept in mind while designing it. It converses the types, importance, examples, and applications of Medical Device Packaging and the regulatory and the quality standards to maintain, especially for sale in Europe and USA.

Furthermore, it displays my work on the packaging design and the sticker label design on an incontinence device of Consure Medical which was the Industrial Project for the 4th semester of my Master's Degree.

ACKNOWLEDGEMENT

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KSHITIJ GUPTA

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1.1 Medical Technology in India

There is an increasing need for reputable online healthcare solutions. The research found that 72% of internet users seek health-related information online. In response to these conclusions, research shows that the healthcare sector did add more workers globally in 2016 than any other sector. The healthcare sector has risen to the top globally regarding revenue and employment growth. Employment in the medical technology sector is growing rapidly due to the services offered and increased investment by public and private organisations. (1)

"In the next 25 years, the Indian medical device sector has the potential to become the world's manufacturing and innovation leader. By 2030, it might expand by 28% per year and reach US$ 50 billion. The Union Minister for Chemicals and Fertilisers and Health and Family Welfare, said this. The government is driving the nation's first-ever exhibition in collaboration with the country's medical device sector. (2)

According to estimates, India's medical device business is worth US$ 11 billion, and its share of the worldwide medical device market is 1.5%. With a CAGR of 10-12% over the previous ten years, the industry in India has experienced rapid expansion. (2)

1.2 Advancement of Medical Technology in India

The government is primarily responsible for fostering the conditions allowing India's medical technology industry to grow. The essential parties must work closely with the government to encourage government innovation.

The government and the sector that supports the medical technology industry have made several particular requests that have contributed to the long-term rise of biomedical engineering employment in India.

2 MEDICAL DEVICE PACKAGING

Medical Device Packaging is a vital aspect in transporting the medical devices safely and securely from the factory to the shelves. Packaging acts as a way of interaction between people, the environment, and each other. (3)

A medical device must be shielded by ensuring package integrity to avert physical damage, biological contamination, and other external disturbances. Commonly, appropriate packaging is needed for medical devices. The device's precise labelling and identification is the secondary reason. (3)

In the case of medical devices, the packaging becomes of paramount importance because the life of a fellow human being depends on the correct functioning and performance of the device, which could prove to be fatal. So as compared to other fields, the medical device's packaging becomes crucial and carries a sense of responsibility with it. (3)

2.1 Regulatory standards

Medical device manufacturers must adhere to guidelines on the design and development of their packaging, encompassing everything from quality control systems to labelling and traceability, to guarantee the safety and efficacy of their goods and correspond to end users' expectations. (4)

2.1.1 Sterile device packaging

The European Medical Devices Regulation 2017/745 (MDR) comprises overall protection and performance necessities (GSPRs) in Annex I related to contamination and microbial infection. These GPSRs include requirements associated with sterility. The In Vitro Diagnostic Medical Devices Regulation 2017/746 (IVDR) has parallel requirements to the MDR. (5)

Kindly refer to topic -1 in the appendices section to learn more about the sterilization requirements of the medical device packaging. As for this thesis report, we will focus primarily on non-sterile medical devices and their packaging.

2.1.2 Non sterile device packaging

Validations of medical device packaging show the durability and reliability of the packaging over time. Before a product is marketed, these validations must be completed per ISO standards and local, national, and/or international laws. (6)

Per the EU Medical Device Directive, packaging systems for non-sterile devices must maintain the product without degrading at the level of cleanliness required and, if the devices are to be sterilised before use, minimise the risk of microbial contamination. The packaging system must be suitable, considering the method of sterilisation suggested by the manufacturer. (6)

Each manufacturer is responsible for ensuring that device shipping and packing are made to prevent alterations or damage during normal handling, processing, storage, and distribution circumstances. (6)

Medical device packaging is validated using standard goods that have not undergone typical warehouse storage. For the initial investigation of the fingerprint seal, non-sterile samples are needed. It also incorporates several other significant packaging validation factors (i.e. validation of seal process, complete package seal integrity). (6)

This International Standard's dual objectives are to create harmonised industrial control criteria and define the test procedures for non-sterile medical device packaging. Physical test procedures are based on ISO 2233, ISO 4180, ASTM F1886 and ASTM-F 88, whereas test procedures for non-sterile package performance are based on ISTA Process and ASTM D 4169-16 methodology. (6)

Medical device packaging is outlined in MDR annex I, General Safety and Performance Requirements (GSPR). The requirements may be summed up as follows: (3)

The gadget must be packaged so its characteristics and performance won't be negatively impacted during storage and transportation.

The package shall maintain a sterile condition until the pack is broken.

Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the product.

Test the packaging system to ensure compliance with the requirements.

There isn't a set standard to adhere to for the packaging validation of non-sterile medical equipment. The maker must, nevertheless, adhere to GSPR requirements. As a result, it is

up to the manufacturer to choose the proper packaging for their medical equipment; it should not adversely affect the gadget's efficiency or functionality. The packaging must be enough to safeguard the equipment; for instance, if dropping the device may cause harm, the packaging must be appropriately cushioned and padded to prevent this damage. (3)

General Safety and Performance Requirements, or GSPRs, (7)

• Packaging techniques for non-sterile devices should protect the integrity and cleanliness of the product.

• The device shall be packaged so that its characteristics and performance should not be adversely affected during transit and storage.

The manufacturer must show that they satisfy the conditions mentioned above. And how they demonstrate is entirely up to them. Here are a few techniques we can recommend.

• Conduct the appropriate tests based on the risk assessment, such as vibration and drop tests, to show that the device's performance and attributes are not negatively impacted while transported or stored.

• A real-time or accelerated stability test.

• Take into account packing strategies used by like or equal devices on the market

• Pack the gadget, ship it with normal couriers to the haziest places, and then receive it back. (7)

2.2 Shipping requirements

SYS – 046 Packaging Validation Procedure - This procedure's goal is to guarantee that shipping and packing materials are created and assembled in a way that safeguards the product from contamination or damage when exposed to potential dangers during handling, processing, storage, and distribution. (8)

This packaging validation process is designed to maintain the integrity of sterile barriers and prevent product damage during transportation for sterile and non-sterile products. For package validation, the following tests should generally be assessed: (8)

- Seal Validation

- Package Integrity Testing
- Seal Strength Testing
- Shelf-Life Studies and Accelerated Aging (ASTM F1980)
- Transportation and Distribution Testing (ASTM D4169, ISTA1, 2, 3 series)

2.3 Labelling requirements

Globally uniform labelling regulations would benefit the maker, the user or patient, and the regulatory authorities. It is less expensive to achieve regulatory compliance and gives patients quicker access to breakthrough technology and therapies when jurisdictional distinctions are eliminated or reduced. (9)

To offer recommendations to manufacturers and regulatory agencies regarding the labelling of medical devices that fully informs the user of:

- The device's identity and intended use or purpose
- How it should be used, maintained, and stored
- Any remaining risks, warnings, or contraindications; while also promoting
- Labeling commensurate with the technical knowledge, experience, education, or training of intended users.
- The use of symbols
- The avoidance of country-specific prescriptive rules for labelling language, content, or label style or labelling that provide no value to users or patients

Label: Information is written, printed, or graphically shown on medical equipment. This phrase encompasses information presented on the packaging of each unit or the packaging of many devices where physical restrictions prohibit this from happening.

Labelling / information supplied by the manufacturer: Any written, printed, or graphic material attached to, included with, or connected to the identification, technical description, or usage of a medical device but does not have shipping documentation. Note: Under specific regional and national legislation, "labelling" is defined as "Information provided by the maker" (Source – ISO 13485)

Instructions for use: The manufacturer's clear intentions for the usage of a product, procedure, or service, as evidenced by the details, guidelines, and information they gave (Source – 21 CFR 801.4)

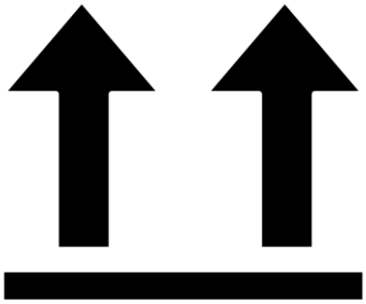
Medical device: Consult Information Paper About the Definition of the Word "Medical Device" (SG1/N029), a GHTF guideline document. (9)

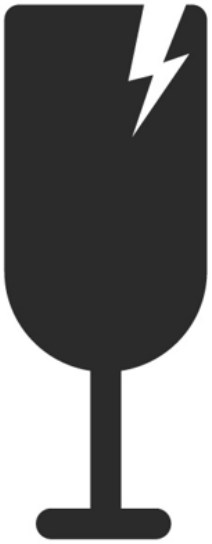
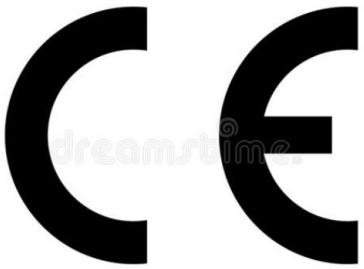
2.4 Graphic requirements

The devices intended to be used around the ICUs and the medical devices are expected to be calming and soothing with no sudden breaks or colours that alarm. The design language and the colours used are supposed to be easy on the eyes and not startle.

2.4.1 Symbols

Symbol	Symbol title	Explanatory test
	Do not re-use	Identifies a medical technology that is only to be used once "Single-use" and "use only once" are synonyms for "do not re-use."
	Non-sterile	Represents a medical instrument that has not undergone decontamination
	Caution	Indicates that use caution when using the device or control close to where the symbol is located or that operator awareness of or action in the present circumstance is essential to prevent harmful effects
	Consult instructions for use Consult electronic instructions for use	Indicates that the user should review the use instructions. "Consult operating instructions" is a synonym for "Consult instructions for use"

	Unique Device Identifier	Indicates a carrier that has information on a particular device's identification
	Do not use if package is damaged and consult instructions for use	A medical device should not be used if the packaging has been tampered with or opened, and the user should refer to the directions for more details
	This way up	To demonstrate that the transit package is upright
	Keep dry	Indicates a medical device that needs to be protected from moisture. This symbol can also mean "Keep away from rain"

	Fragile	Indicates a medical instrument that, if not handled correctly, might break or be injured
	Medical Device	Reveals that the object is medical equipment NOTE The full definition of "medical device" for European usage is provided in EU Regulation 2017/745.[23] There may be different meanings in other jurisdictions
	CE Mark European Conformity	Indicates that the product has a permit to be sold in European nations
	Authorized European Representative	Identifies the European Union's authorised representative
	Catalogue or model number	It contains the manufacturer's catalogue number, allowing the gadget to be located

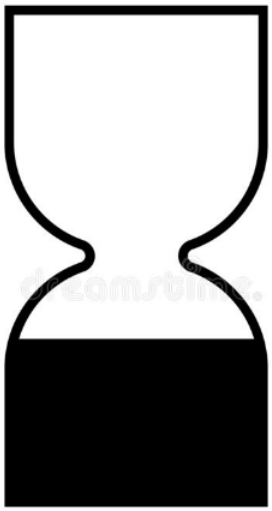
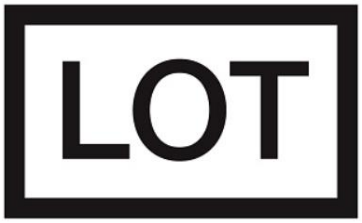
	Manufacturer	Shows the maker of the medicinal product The manufacturer's name and address must be displayed next to this mark, along with the symbol itself
	Use by Date	The time after which the medical gadget should no longer be utilised To signal that the medical equipment should not be used after the year, month, or day indicated, this symbol must be accompanied by a date The date must be represented using ISO 8601-1 format. The time must be placed close to the symbol
	Batch Code	It gives the batch code of the manufacturer so that the batch or lot may be recognised

Table 1: List of all the symbols used in Packaging (13)

2.5 Levels of Medical Device Packaging

There are many kinds of packaging materials and methods available.

2.5.1 Primary packaging

Primary packaging, often known as a consumer unit, is the packaging that comes into direct touch with the product itself. Primary packaging aims to confine, safeguard, and/or maintain the final good, notably against contamination. The completed product, such as a plastic pouch holding whole-grain cereal or the cardboard box carrying the bag of cereal, is contained in this initial layer. The end user or consumer is frequently the target audience for this kind of packaging. The items seem more enticing, are more accessible for

consumers to handle, and may be utilised to communicate with them by providing them with written product information. (10)

2.5.2 Secondary Packaging

The term "secondary packing" refers to anything that comes into touch with the primary pack; this might be a paper or cardboard box. (3)

This kind of packaging is used in addition to primary packaging to assemble a certain number of items into a stock-keeping unit or SKU. Combining smaller goods into a single pack makes it easier to handle them. This kind of packaging also offers additional protection to preserve the integrity of the primary packing. (11)

2.5.3 Tertiary Packaging

A carton box may be used as the secondary transit and bulk storage packaging technique.

With this packing, more SKUs may be transported from point A to point B in bigger groups (e.g., from a production facility to the point of sale). Products are treated as distribution units during this phase. Carrying large and/or heavy cargo securely and safely using this kind of packing is simpler. It thus makes handling, storing, and transporting things more manageable, in addition to assisting in damage prevention. (12)

3 PRIMARY PACKAGING

3.1 Packaging for Medical Devices used in ICU

3.1.1 Used by medical professionals

Central Venous Catheters

Thermoformed tray – primarily because of all the various parts and to keep these individual parts protected and separate. Low cost, in the lowest possible volume, makes it disposable and easy to open. In the back, Tyvek paper has been used for sterilization requirements.

Figure 1: Central Venous Catheter (24)

Figure 2: Central Venous Catheter Packaging (25)

Qora AEON

Figure 3: Qora AEON

It consists of a clamshell packaging which houses the components of the Qora AEON device, with the IFU attached on the back side of the lid.

3.1.2 Used by patients

Oximeter

Outermost contains a shrink wrap. A thin paper sheet for branding uncovers a relatively low-cost paperboard box without printing. Neatly folded box, not requiring any additional dunnage. The device itself is encased in a nice bag for protection, and because it is common for medical personnel to carry it, serving that purpose.

The second type of packaging for the same device includes just a paper box and contents arranged inside it as the shipment for such devices is significant, so they are neatly stacked together.

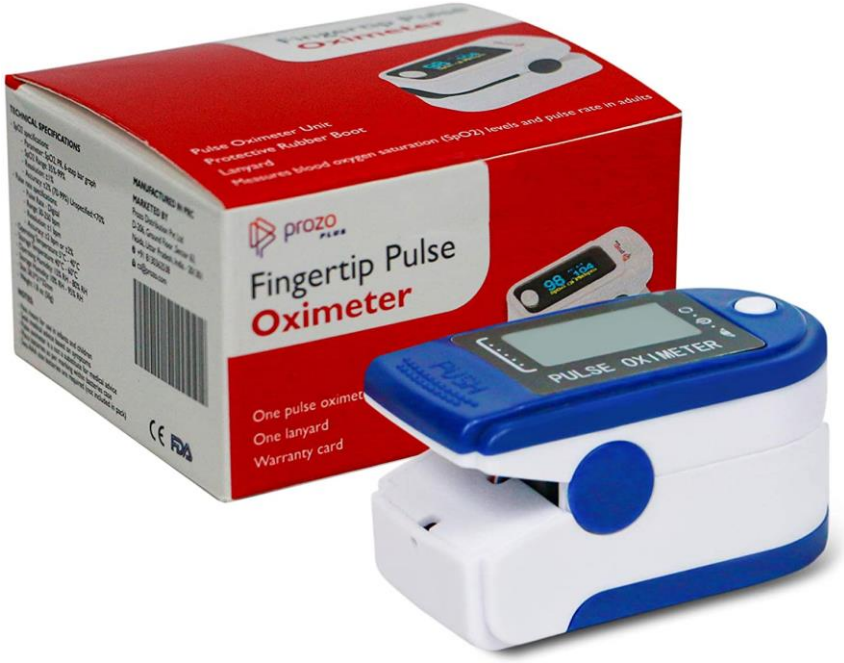


Figure 4: Oximeter (26)

Figure 5: Oximeter Packaging Layers (27)

Blood pressure cuff

Paperboard box with the components wrapped in bubble wrap and plastic sheets.

Figure 6: Blood Pressure Cuff Packaging (28)

Face mask

They are packed in a relatively good quality plastic pouch print with just the contents inside. No protection is needed due to the product type.

Figure 7: Face Mask (29)

3.1.3 Used by service engineers

Syringe pump

Figure 8: Syringe Pump Packaging (30)

Simple, functional packaging with minimal user experience and branding

Ventilator

Figure 9: Ventilator Packaging (31)

Packed in a recycled corrugated cardboard box with minimal printing, inside protected with air pillows on all sides and wrapped inside a plastic bag for scratch resistance and other safety.

Humidifier

Figure 10: Humidifier Packaging (32)

Inside a corrugated cardboard box is a well-kept bag with slots to keep everything from the machine to its IFU and various other attachments.

3.2 Options of Medical Device Packaging

3.2.1 Pouches

Pouches are inexpensive packaging solutions that enable high-volume production and short lead times, which means they are often only used for commodity goods. These "worker bees" in the medical field may be inexpensive, but they are helpful and practical. They can be moved about by stacking, tossing, flipping, and sling-shotting without much increasing the risk to the budget or supply chain. (14)

Best of all: Pouches may be combined and matched with various fabrics to suit any low-cost gadget.

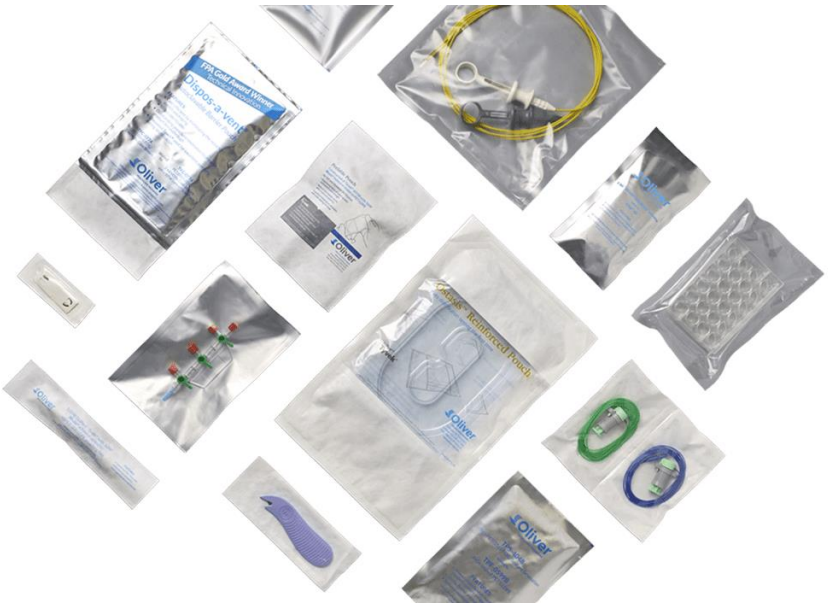


Figure 11: Pouches Examples

3.2.2 Laminations

Layers serve as our defence against unwanted forces; consider the protective layer that covers the sensitive surface of a new pair of sunglasses or a smartphone. We choose laminations to shield equipment from external threats in the medical packaging sector.

Laminations, which are included in the design of a medical pouch or bag, comprise two or more different films. Each film offers an additional layer of defence, such as corrosion, moisture, or UV protection, to mention a few.

This final combination gives what would otherwise be considered a piece of plastic a distinctive flair exclusive to the device's function and life cycle.

A stack of top-notch laminations has a further advantage in that most of the films are gas-impermeable, allowing them to be used as packaging for sterile goods. (14)

Figure 12: Lamination Examples

Die cut lids

The end user of the gadget must be able to open the box without disturbing the contents while undergoing treatment. The die-cut lid meets that problem.

The rugged design of this platform, which is frequently structured like a tray, enables a form that secures the object. Then, "clean peel" technologies guarantee a spotless, debris-free opening motion.

Due to their convenience and one-two punch, nurses and surgical workers choose die-cut lids as a favoured packaging choice (14)

Figure 13: Die cut lid

3.2.3 Thermoform trays

The next step is to produce a box that appropriately covers the medical gadget after spending numerous hours and money designing and manufacturing it. Thermoforming is a safe and economical packaging platform that can be created using high-speed equipment in modern, accredited Class 8 cleanrooms.

Thermoformed packaging is a popular choice among manufacturers of medical devices because of its excellent impact resistance, glass-clear transparency, and variety of design and barrier choices.

A robust thermoformed container is an excellent option for creating a high-value product. Although not the most affordable option, this one's level of security and associated peace of mind make up for the cost, even without considering its sterilisation powers. (14)

Figure 14: Thermoform Tray Example (33)

https://www.dordan.com/medical-trays-thermoformed-medical-trays

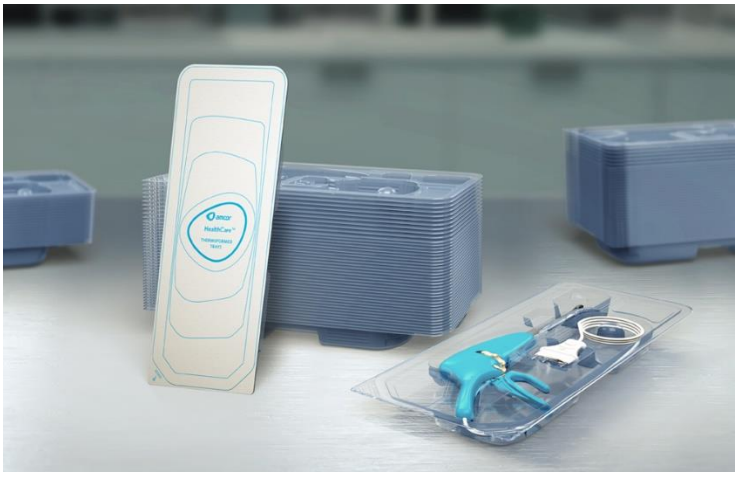


Figure 15: Thermoformed Trays (34)

https://www.amcor.com/insights/blogs/healthcare-packaging-thermoforming-trays

3.2.4 Paperboard boxes

Paperboard is a paper-based product that combines strength and lightness. It is simple to cut and shape to make unique buildings. These qualities make it perfect for use in customized packaging. It is created by pulping fibrous materials, such as scrap paper or wood, and then bleaching the resulting pulp. There are many grades of paperboard packaging, each appropriate for specific packaging needs. (15)

Figure 16: Paperboard Boxes (35)

3.3 Dunnage

Durable padding, known as "dunnage, " protects cargo during shipment. Dunnage can range from packing peanuts and bubble wrap to solid industrial polymers acting as cushions to keep objects in place. Dunnage will perform at its best when the proper box or poly bag complements it. Shippers shouldn't put a fragile item in a bubble mailer and call it a day, nor should they put a small thing in a big box and stuff dunnage. (17)

Why use Dunnage – (17)

Damage protection

When packages slide over a truck, ship, or train, dunnage protects them. Appropriately done dunnage may be inexpensive while protecting precious, delicate, and unsecured things.

Moisture protection

Moisture can damage goods depending on where they are being sent. Proper dunnage may shield expensive machinery like electronics from moisture when shipping.

Shock absorption

Products being delivered may move, drop, be compressed, or come into contact, which may cause shock and vibration. To prevent damage, dunnage is always used as a shock absorber.

3.4 Types of dunnage (17)

3.4.1 Bubble wrap

One of the most popular methods for shipping glass and other delicate items in bubble wrap. As long as the bubbles remain intact, they may be used repeatedly.

Figure 17: Bubble Wrap (36)

3.4.2 Kraft paper

It is recycled paper that is frequently crumpled and packaged. It's among the most popular sorts of dunnage since it's:

- Cheap
- Eco-friendly
- Reusable
- Extremely Efficient

Figure 18: Kraft Paper (37)

3.4.3 Foam

Electronics, medical equipment, delicate things, and fragile or pointy objects are frequently cushioned with foam. If you've ever bought a TV, you've pulled it out of the box with the foam dunnage on the side.

Figure 19: Foam (38)

3.4.4 Corrugated paper

Another widely used material for dunnage is corrugated paper. Due to its advanced design, the material can support a variety of weights, resist moisture, and offer ecological packaging solutions.

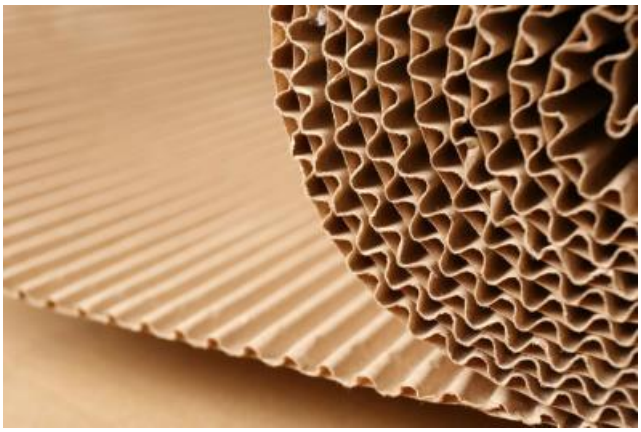


Figure 20: Corrugated Cardboard (39)

4 Sustainable packaging

4.1 What is sustainable packaging?

Figure 21: Sustainable Packaging (40)

Packaging with the smallest possible negative environmental impact is said to be sustainable. In other words, environmentally friendly packing materials produce the least pollution during manufacturing, production, transportation, disposal, and recycling processes. (16)

What is sustainable packaging made of?

Recyclable materials like PET or HDPE plastic, cardboard, and paper wrappings are all in environmentally friendly packaging. These materials can be shredded, pulped, melted down, and remoulded as raw material for a new packaging or other purposes, provided they have been adequately classified for recycling. However, unlike plastics, which deteriorate every time their polymer chains are broken (or melted), the cardboard will maintain the integrity of its qualities no matter how many times it is recycled before needing to be disposed of in a landfill or burned. (18)

Due to their similarities to plastic and ability to decompose in compost, other environmentally friendly materials, including PLA (starch) and cellulose-based polymers, are utilised for sustainable packaging. These biodegradable polymers may be shaped into flexible packaging, cutlery, and food service containers. Food packaging may also be done with compostable materials. These films work similarly to ordinary plastics thanks to technological advancements, but they are certified to decompose in compost because of their organic component safely. It is perfect for adequate, sustainable packaging because of its exceptional performance and environmental friendliness. (18)

4.2 Why should medical companies opt for sustainable packaging? (19)

Although the medical device industry has yet to change in this direction significantly, the worldwide market for sustainable packaging is expanding quickly. Before they can start setting - and achieving - some realistic targets, manufacturers must comprehend the overarching vision of sustainable packaging, according to Katherine O'Dea, a senior fellow at GreenBlue, and Art Gibson, vice president of environment, health, and safety at Baxter.

4.3 The Sustainable Packaging Coalition's definition

It comes down to eight essential elements. Packaging should be beneficial, safe, and healthy for people and communities throughout its life cycle. It should also meet market criteria for performance and cost. Packaging should be sourced, manufactured, transported, and recycled using renewable energy. It should maximise the use of renewable or recycled source materials. Packaging should be made from healthy materials in all likely end-of-life scenarios.

4.4 Current scenario of sustainable packaging in medical industry

Although Katherine O'Dea, a senior fellow at GreenBlue, points out that this is true in many industries, medical device businesses must start employing completely sustainable packaging. At this time, she observes, "It's challenging for any company to meet all the sustainability criteria." The crucial thing is for businesses to understand that this requires a holistic approach; the whole supply chain and lifetime must be considered.

Therefore, the first step for makers of medical devices is to comprehend the broad definition of sustainable packaging. Then, according to O'Dea, "they can set some priority goals and look at what is achievable for them shortly."

If they collaborate closely with their suppliers and completely comprehend the rules and performance standards, they could be allowed to use recycled content in a package.

Baxter, a business that tries to solve environmental challenges throughout the lifespan of its goods, has already started this process. According to Art Gibson, vice-president for environment, health, and safety at Baxter, "this ranges from sustainable design and bioethics during research and development, to efficient use of energy and materials during manufacturing and transport, to appropriate product advertising and promotion, and finally, responsible repair, refurbishment, and recycling at product end-of-life."

There are still many difficulties to be overcome, such as regulation. O'Dea highlights that "everything needs to be done in consort with the regulatory bodies." Companies must be aware of the rules and consult with the regulatory bodies to determine whether additional packaging is necessary for sterilisation and protection, for instance, or to guarantee the product's safety. The package design has to be innovated after that in collaboration with their suppliers. There may be another way to offer that additional layer of protection without adding more packing. (19)

4.5 What are bioplastics?

The word "bioplastic" does not just apply to polymers derived from natural, biodegradable or compostable ingredients. It refers to plastics made of plant and petroleum-based components that may or may not disintegrate and polymers made entirely of plant material that is not always biodegradable. (20)

Bioplastics are made from plants, biodegradable, or both.

When anything is referred to be "bio-based," it signifies that it was made, at least in part, from biomass (plants). Corn, sugarcane, tapioca, and other types of cellulose are a few examples of biomass utilised in bioplastics.

4.5.1 Types of bioplastics

Bioplastics are a group of goods with various qualities and use based on the raw ingredients and manufacturing processes used to create them. (20) At the moment, the bioplastic family may be split into three major categories:

Group 1 consists of plastics that are both biodegradable and biobased.

Group 2 consists of "drop-ins," or non-biodegradable polymers partially or entirely biobased.

Group 3 includes biodegradable plastics that are based on fossil fuels.

4.5.2 Group - 1

PLA

Sourcing

They may be produced using various organic materials, such as bacteria, plants, cellulose, protein, and chitin (the material found in prawn shells).

Properties and finish

PET and PLA have many of the same characteristics, and PLA polymers may be produced using the same processing equipment. Several finish options are available when printing with PLA, including matte, glossy, and silk. The sort of finish impacts the piece's colour, strength, longevity, and how feels to the touch.

Sustainability

The features do not hold for home composting, where it will behave like any other plastic material, although it is derived from plant-based ingredients and is thus appropriate for consumption by microorganisms. Its biodegradable nature provides a stepping stone but only under specified industrial settings in the industries.

Available vendors

We could not source reliable vendors for the PLA in India, and we found connections in the USA for the same material and in many different properties configurations.

Applications

Generally speaking, food packaging covers various industries, such as medical, textile, automotive, cosmetic, and domestic.

PHA

Sourcing

Recent discoveries have shown certain bacteria that can generate PHA from various carbon sources, such as waste effluents, plant oils, fatty acids, alkanes, and simple

carbohydrates. This considerably expands their marketability; for instance, employing waste products as a carbon source for the manufacturing of PHA would have the dual benefit of lowering the price of PHA and the cost of waste disposal.

Properties and finish

Inferior to other plastics in terms of both characteristics and quality, despite much research and development on producing PHA efficiently.

It is a food-grade plastic that is non-toxic.
Sustainability

PHA is fully biodegradable under the right conditions

Available vendors

We were not able to source vendors for the PHA in India.

Applications

It can be used for various purposes, including food packaging and medical implants.

4.5.3 Group – 2

Examples: Bio-Polyethylene , bio-polypropylene and bio-polyethylene terephalate

PET

Properties and finish

- Good creep resistance; high stiffness; and high strength
- Good chemical resistance against acids
- Lightweight, moisture-resistant, and recyclable plastic used mostly for packaging.
- Low sliding friction and sliding wear. It is extremely durable and clear. (21)

Sustainability

Since PET is the most widely used plastic in the world and is used to make thermoforming trays, packaging materials, and plastic bottles, it is recyclable and may be used repeatedly. However, PET recycling requires a strong network of collection and separation points.

Available vendors

There are already relationships with suppliers of PET thermoforming sheets, making it simpler to obtain the material.

Applications

Screen printing, filters for sand and oil filtering, bracing wires for greenhouses and other agricultural applications, woven/knitting belts, filter fabric and other similar industrial purposes.

4.5.4 Group – 3

Examples: polybutyrate (PBAT) and polycaprolactone (PCL)

PBAT

Sourcing

The last category of bioplastics consists of novel, fossil-based polymers that are nonetheless biodegradable and include items like poly butyrate adipate terephthalate, also referred to as poly butyrate or PBAT. Due to their biodegradability and mechanical qualities, they are typically used with starch or other bioplastic materials to enhance the finished product's performance for a particular application. New bio-based or mostly bio-based versions are being developed, even though they are now manufactured as hybrids with petrochemical plastics.

Properties and finishes

It possesses several traits that low-density polyethene shares, including strong elasticity, fracture resistance, and flexibility. As a result, it may be used as a substitute in goods like bags, wraps, and another packaging. Due to its capacity to break down in compost within a few weeks, it is incredibly well suited to trash bags or throwaway packaging. Additionally, PBAT may be added to hard bioplastics to increase flexibility while preserving biodegradability.

Sustainability

Under ideal composting circumstances, it is entirely biodegradable.

Available vendors

Not found in India

Applications

Cutlery, grocery bags, trash bags, mulch film, etc.

4.6 Moulded pulp

Sourcing (22)

Our moulded pulp products are made from yearly renewable resources, such as bagasse, bamboo, wheat, straw, and mixtures of other grass fibres. We can also produce goods for corrugated paper drops and conventional wood fibres. All of the threads, as mentioned earlier, are recyclable, biodegradable, and sustainable.

Properties and finishes

- MPE may produce the thermoformed moulded pulp; if necessary, it can be laminated with bioplastic film.
- The temperature range for these components is -8 F to 350 F.
- Moulded pulp is a sustainable product for any medical use because it is also biodegradable.
- Because pulp can only cycle once, using it in a therapeutic setting also prevents the transmission of pathogens.

Sustainability

Additionally, in various configurations and typical applications, the qualities can occasionally change depending on the specifications and additives.

Available vendors

The vendors are available but they require high volume orders.

Applications

- Moulded pulp is used in several sustainable and biodegradable packaging solutions and medicinal items.
- Our kidney-shaped bowls, covered clamshells, and single-use washbasins may be sterilised in an autoclave.
- MPE also focuses on coated and laminated fibres to create goods impervious to alcohol, oil, and water.

5 CONSURE MEDICAL PACKAGING GUIDELINES

The current packaging in Consure Medical involves materials like Paperboards, plastic pouches and HIPS clamshell boxes.

The goals of the packaging at Consure Medical are –

1. Protect the packaging during its transport till it reaches the end consumer in its functioning and shape form and retains the legibility of the instructions preventing any concerns regarding their use.
2. The devices are primarily used by nurses in ICU and home-care scenarios and, in other cases, by the patients in their own houses, leading to the attribute that the packaging needs to be easy to open and allow quick access to the incontinence product as a function of packaging.

Consure Medical deals in non-sterile medical devices related to incontinence. Together with the nurses, the company has developed the industry's first complete portfolio of incontinence products.

5.1 Current Clamshell Packaging Material

5.1.1 HIPS (High Impact Poly Styrene)

Sourcing

Pure polystyrene is quite brittle and unsuitable for many purposes, it is mixed with other materials to form copolymers, such as rubber or polybutadiene. As a result, the plastic is greatly strengthened, pure polystyrene is converted to HIPS, and an extremely rigid material suitable for packaging applications is produced.

Properties and finishes

• Hard

• Rigid

• Translucent

• Strong resistance to impact

Sustainability

It does not disintegrate; it only occurs under particular industrial composting circumstances, and even then, dependent on the HIPS's standards and additives.

Available vendors

Consure Medical has a couple of vendors already sourcing them the HIPS material from which they source the clamshell packaging.

Already in contact with vendors around Okhla

Applications

- Consumer goods, including parts for toys, TVs and other audiovisual devices;
- Automotive industry: instrument panels and accessories, gas tanks
- Thermally produced sheets

5.2 Existing Packaging Methods

The following data has been gathered from a single device packaging of Consure Medical Technologies Inc. and hence, has been taken as a rough financial model for comparing different material costs.

S.No.	Component	Per Piece (Rs)
1	Packer box (fresh printing over white paper	42
2	Corrugated cardboard (3ply, single color printing over brown)	10
3	Paper inserts	12.5
4	Foam cut die piece	2
5	Sealing stickers (circular, small)	0.5
6	Shrink wrap (thin)	2
7	Clamshell tray (PET)	20
8	Clamshell tray (HIPS)	43
9	Clamshell lid (PET)	20
10	Clamshell lid (HIPS)	35
11	Paperboard (lid)	13
12	Paperboard (two side printed, lid)	16
13	Paper sleeve	12
14	Bubble wrap	10
15	Plastic sheet/ pouch	3
16	Sealing sticker (3 sided cover)	15

Table 2: Price of the packaging materials

5.3 Packaging dimensions currently in use

According to the terminology used in Consure currently,

A single device is referred to as a ‘each’

A packer box of the said devices is referred to as ‘box’

A shipper box containing the packer box is called ‘case’

An outer shipper box containing 3 of such shipper boxes is called ‘pack’

The dimensions of the ‘pack’ and ‘case’ are fixed which implies that box has to be designed to fit the maximum no. of boxes in each ‘case’ to maximize shipping volume.

‘Case’ dimensions

Length – 426mm

Width – 270mm

Height – 225mm

5.4 Brand guidelines

Logo

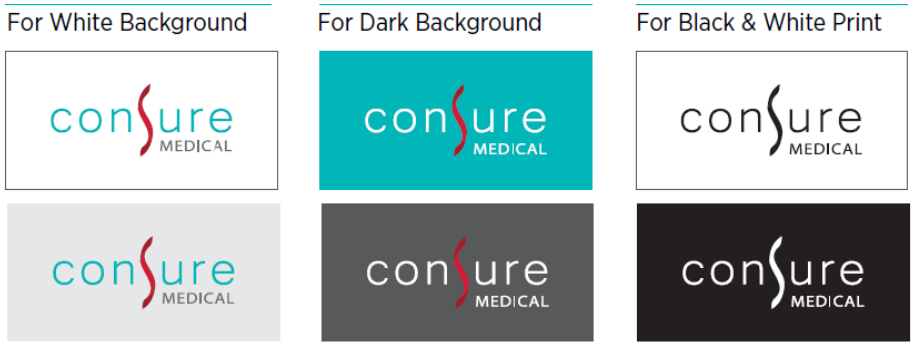


Figure 22: Consure Logo

Logo Placement, Clearspace and Size

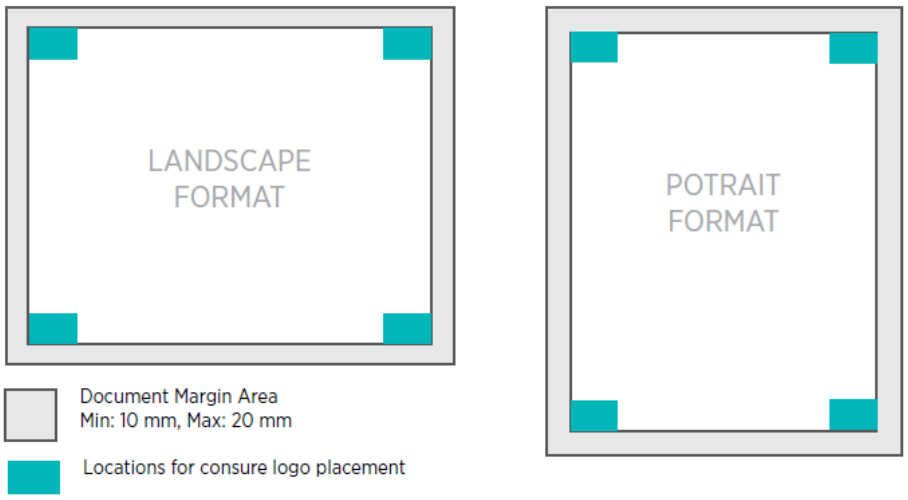


Figure 23: Logo Placement

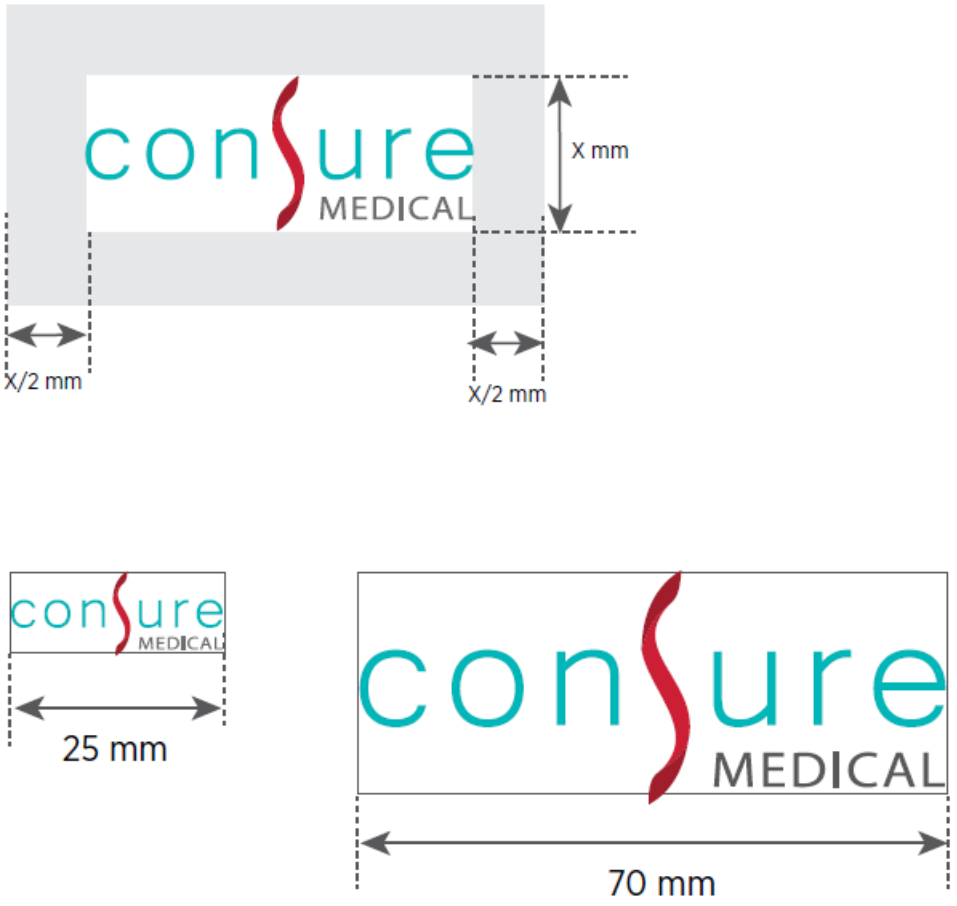


Figure 24: Logo Size

Any printed collateral should have margins of minimum 10 mm and maximum 20 mm on all sides. Consure logo should be placed aligned to the inner margins at any of the corners, as indicated above.

Consure logo size should not go below 1 inch width and /or above 2.75 inch width.

Correct Logo Usage

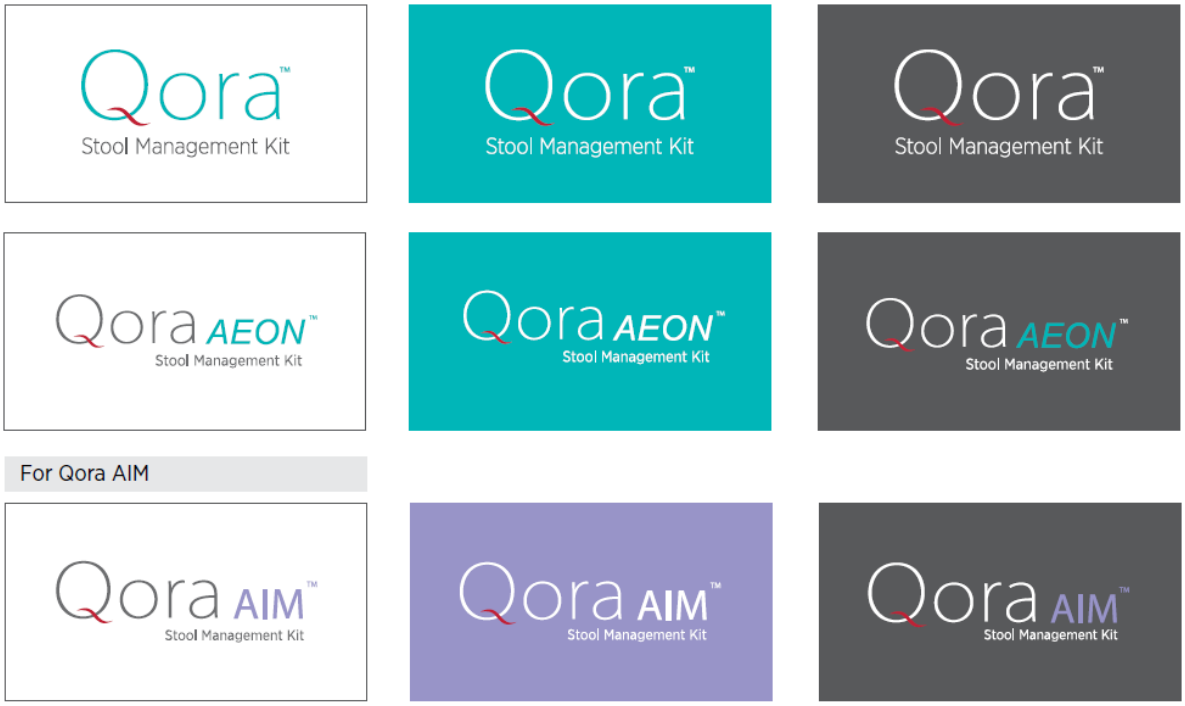


Figure 25: Correct Logo Usage

Incorrect Logo Usage

Figure 26: Incorrect Logo Usage

Consure or Qora logo should not be used in any way other than what is listed above. Logo placement should always be on flat uniform background with proper clearspace and size.

Brand Color System

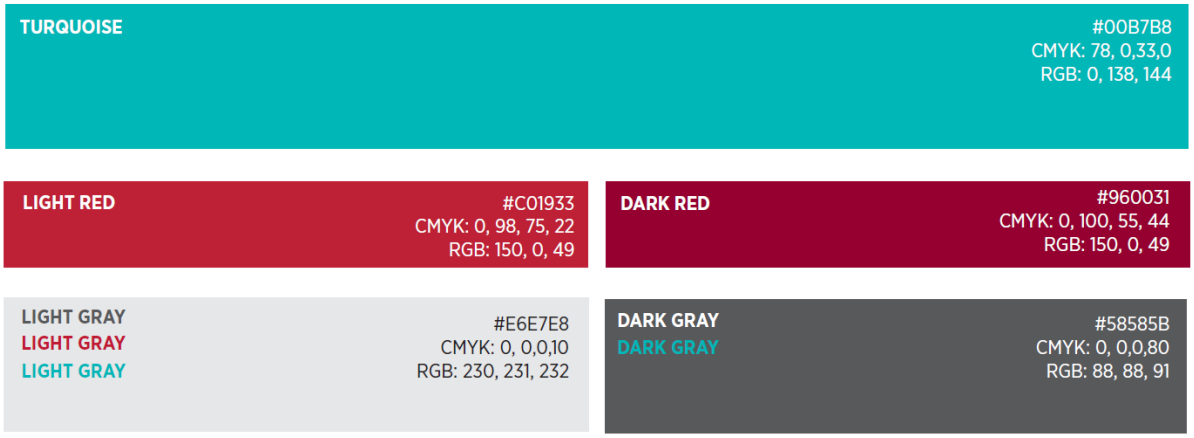


Figure 27: Brand Color System

Turquoise should be used to highlight Qora's features and advantages. Light Red/Dark Red should be used to highlight problems and disadvantages. Reds should never be used as background colours. Turquoise can be used in lighter shades and variable opacities.

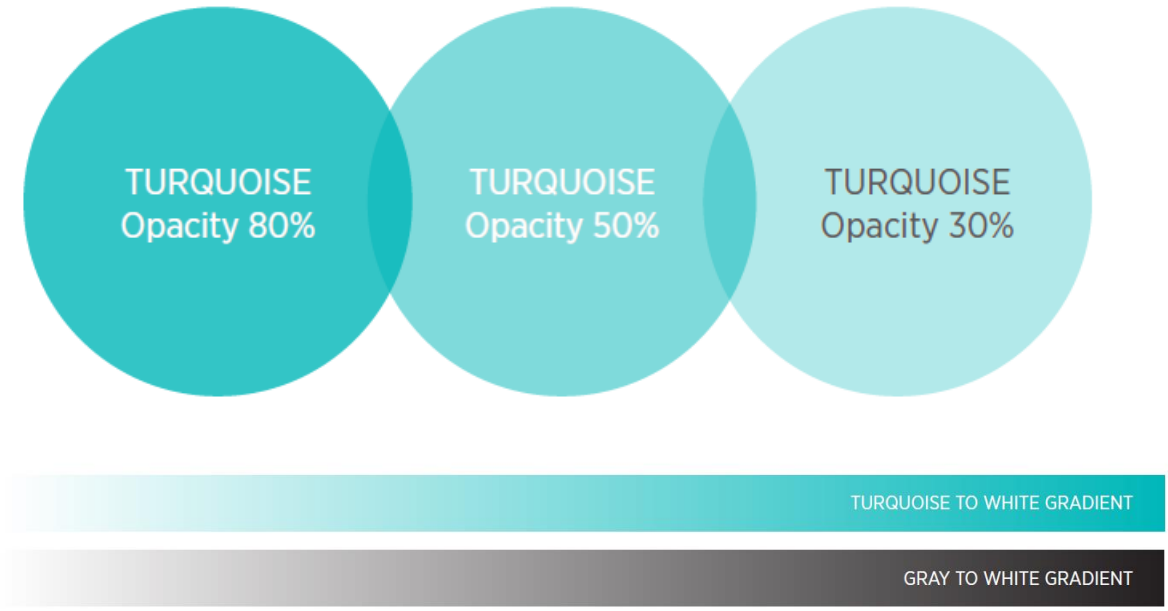


Figure 28: Consure Logo Color Scheme

Subtle gradients can be used in turquoise, gray or white for pictures, graphs and illustrations. Any consure document should use only these colours or their gardes for visual representation.

Typography

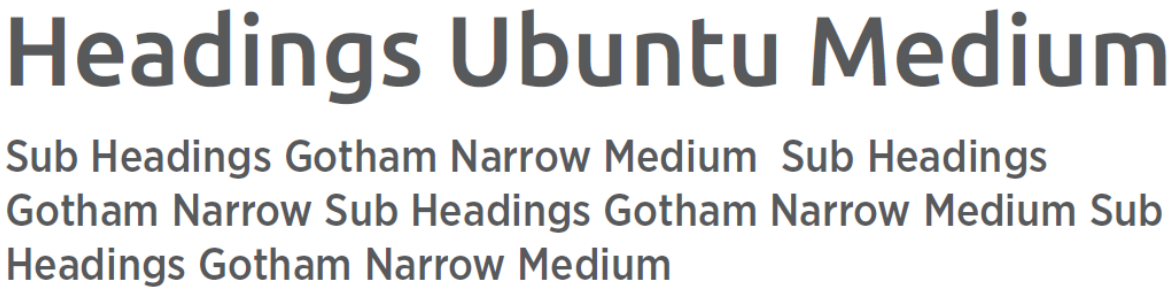


Figure 29: Consure Typography

1. Body text size can vary between 9 points to 14 points depending on the document size. Body text should align LEFT and not be indented beginning of paragraphs.

2. Text on dark backgrounds should always be white.

3. There should be enough contrast between background and text colour.

4. Footnotes and references should not go smaller than 6 points. References should always be in the bottom of the page, left aligned, with maximum text box width as 120 mm.

6 Qoramatic

Automated Stool Management

6.1 What is Stool management system?

Fecal diversion away from patient, rectal irrigation, stool sample collection

6.2 What is Automated stool management system?

Fecal diversion using negative pressure, rectal irrigation to help proper fecal diversion.

6.3 Importance of Packaging configuration for Nurses

Nursing time for controlling FI is three times as long when underpads are used. More than 23% of front-line healthcare professionals experienced psychological discomfort due to increased physical strain during the pandemic.

Nurses generally spend 60 minutes daily managing incontinence while wearing IBCs. A recent pandemic revealed an increased workload for nurses treating critically ill patients, donning PPE, etc.

This suggested that it was necessary to design the package to make it as straightforward as possible for the nurses to install the device. As a result, more time would be available for patient care, and less would be needed to set up the device.

6.4 Device specifications

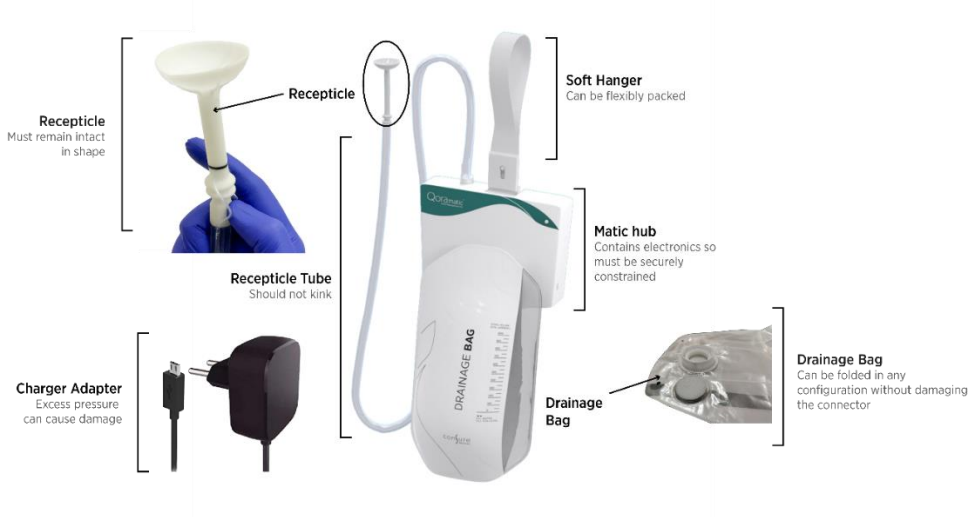


Figure 30: Device Specifications

It was important to understand the various components and understand the different constraints associated with them individually to keep in mind while packaging the components.

Matic hub –

Contains electronics, should have adequate protection in case of physical manoeuvring. The connector is protruding so design accordingly.

Adapter –

Needs standard fall and bump absorption to prevent the electronics from getting damaged. The wire for the adapter can be folded and altered accordingly.

Receptacle tube –

Contains receptacle which enters the rectum canal, meaning that the receptable shape has to be intact and needs to be kept without folding it.

The tube should be kept without kinks so that it does not hamper its use and should be protected in packaging using inserts and in a standardised manner.

Drainage bag –

Can be folded and kept in any configuration and folding without damaging the connector piece.

6.5 Existing Packaging

Figure 31: Existing Packaging, Packer Box

It consists of a packer box in which the components are arranged using foam and folded paper inserts.

Based on the no. of orders, the ongoing DFM and testing of the device had to be shipped in batches which implied that the quantity of the device shipped was small. This meant we needed easy-to-produce and transport packaging, leading to the packer box. Moving forward, the number of devices shipped was projected to be high, requiring a change of material from the paperboard packer box.

Figure 32: Packaging Arrangement-1

Figure 33: Packaging Arrangement-2

6.6 Steps involved in the current unboxing of the Qoramatic device packaging

1. After opening the box take out the IFU
2. Take out the drainage bag and unfold it
3. Take out the matic hub and make the connection with the drainage bag securely
4. Using the soft hanger on the matic hub, position the matic hub to the side of the bed
5. Remove the adapter from box and connect to power
6. Now connect the receptacle to the matic hub and to the patient rectal canal.

6.7 Problem Areas

1. The matic hub connector was protruding whereas the rest of the components of the packaging were occupying a low volume relatively

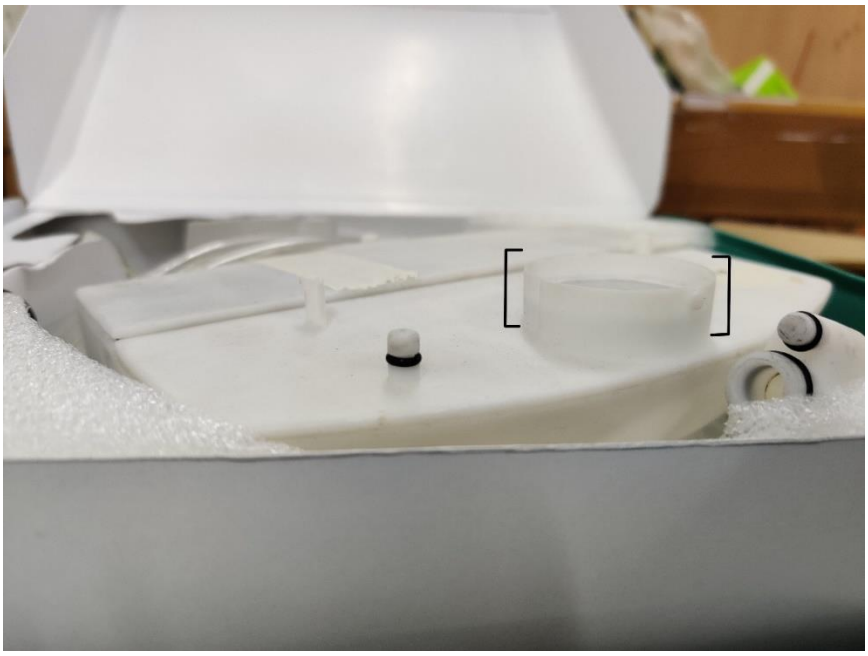


Figure 34: Matic Hub

As highlighted in the image

2. Material of the packaging was currently paperboard, which was easy to assemble and manufacture but relatively costly compared to the plastic counterparts available in the form of thermoforming plastics.

Figure 35: Material Selection

https://bpkc.com/packaging-supplies-the-complete-guide/

3. Existing paper inserts hold the components in place but don't provide the best rigidity to hold the receptacle tube in place

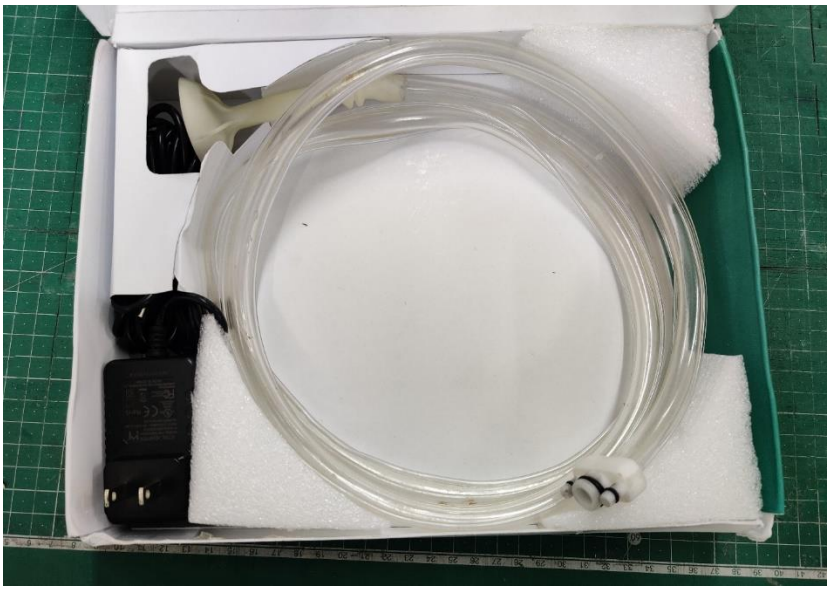


Figure 36: Packer Box Problem

4. The biggest challenge while arranging the components is the placement of the receptacle tube which is a thick PVC tube with 11mm OD and has to be kept securely and the receptacle head has to be kept undisturbed and without stress acting on it for it to maintain its shape and integrity.

6.8 Objective

Based on the product and packaging research of the Qoramatic Device, the following characteristics were defined for designing the packaging.

Designing a packaging with the following characteristics-

1. Cost effective packaging
2. Minimum Volume Footprint
3. Protection and safety of the Product and all individual components
4. Good user experience
5. Premium medical flagship product

6.9 Volumetric arrangements

I began my process by arranging the components in a number of ways to understand the volume acquired by each part and its effect on the space available for packaging.

Tall box arrangement –

Figure 37: Tall Box Arrangement

Figure 38: Tall Box Arrangement, Exploded View

Matic hub on the bottom, then the charger adapter with the receptacle tube and on top of that the drainage bag.

Problems –

1. The width of the box, does not bode well in the B10 box, which leads to no increment in the number of boxes for shipping.

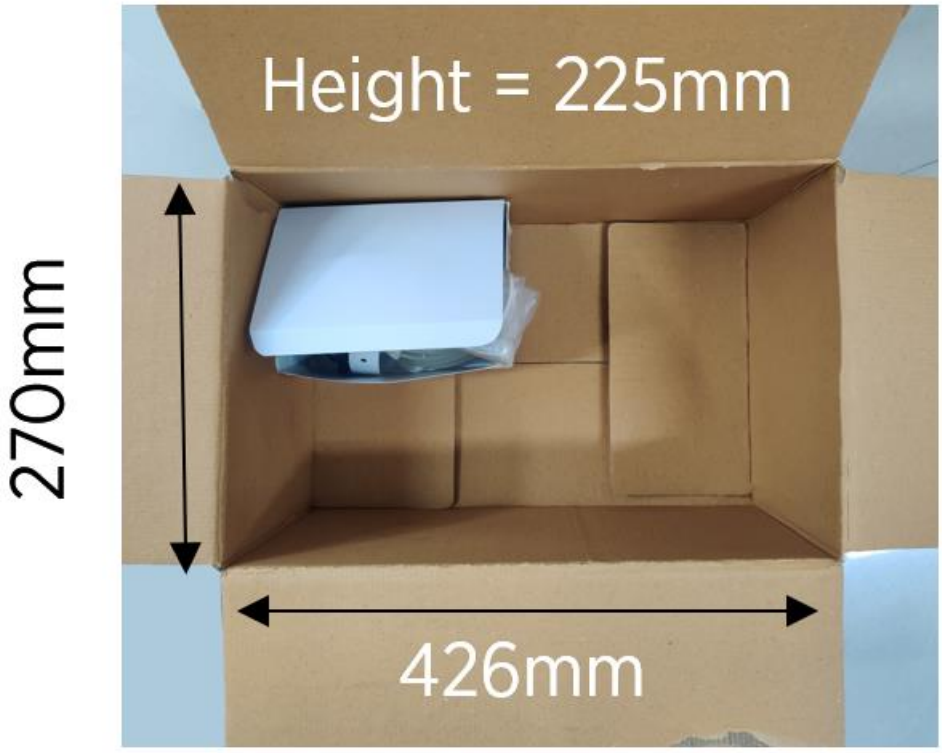


Figure 39: Tall Box Arrangement, Shipping Box

2. Moreover, when the items are arranged on top of each other without any space saving, the components need dunnage to prevent scratches and damaging.

Slim box arrangement –

Figure 40: Slim Box Arrangement

Figure 41: Slim Box Arrangement-1

Figure 42: Slim Box Arrangement-2

Problems –

1. The current box optimally covers all the components neatly but the matic hub connector protruding still poses a problem and restricts the number of boxes in the shipment due to this fact.
2. Other arrangements tried on CAD promise a different configuration without increase in the shipping volume so does not make sense.

Figure 43: Slim Box Arrangement, Shipper Box

6.10 Prototyping

The following prototype was made with a cardboard all around and PU foam cutout as inserts.

6.11 Proposed packaging

Since there is a particular component that is leading to the rise in height of the overall packaging and restricting the number of units to be shipped as well, I thought of a method wherein the protruded part could be the only part sticking out of the packaging and the base of the packaging can have a cavity to adjust the protrusion in. As shown in the diagram, the method can increase the amount of boxes that can be shipped, and simultaneously such packaging designs are possible to execute in the clamshell style of packaging.

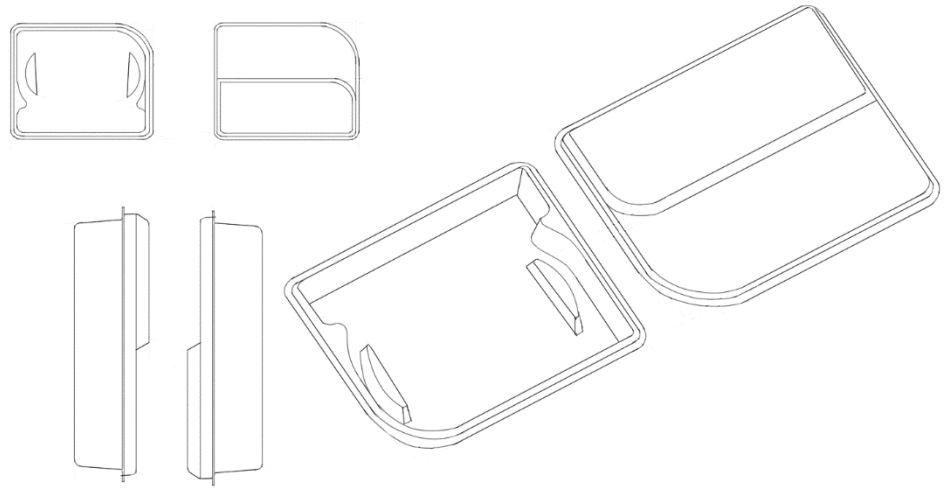


Figure 44: Proposed Packaging

6.12 Solution

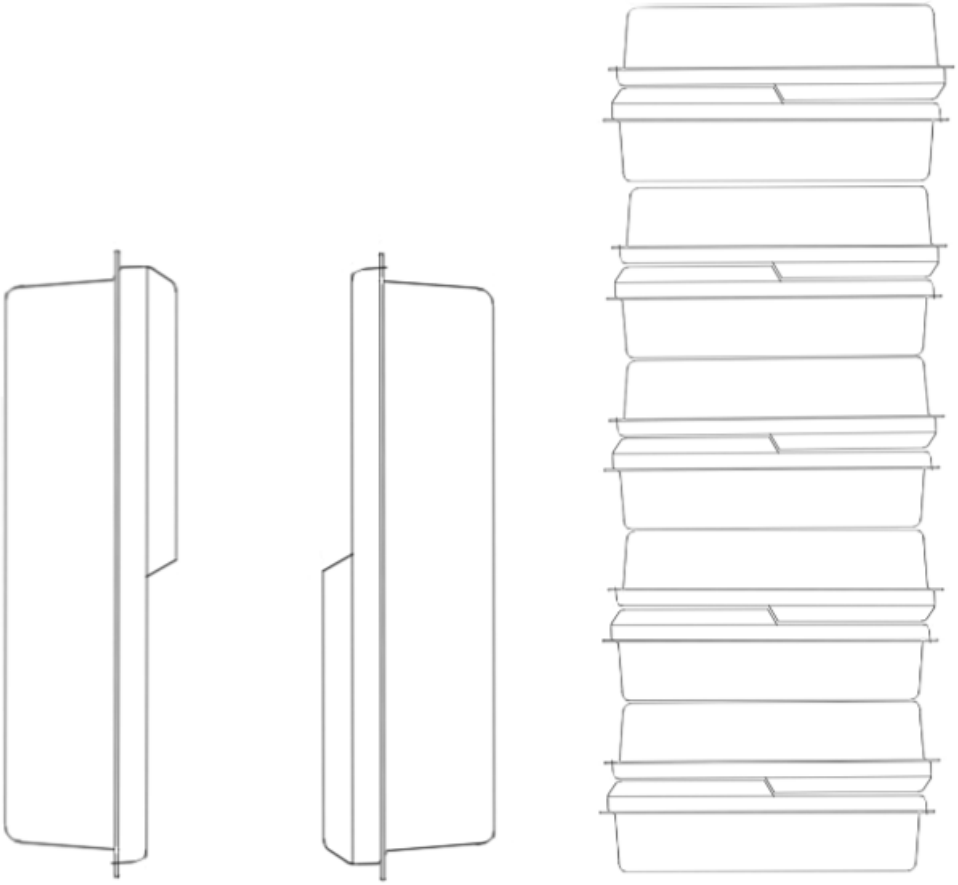


Figure 45: Stacking Solution

Figure 46: Clamshell, Shipper box

Protruding the clamshell lid on the lower side can allow us to save enough space on the total arrangement of the boxes to increase the packaging volume by 25%

6.13 Arrangement

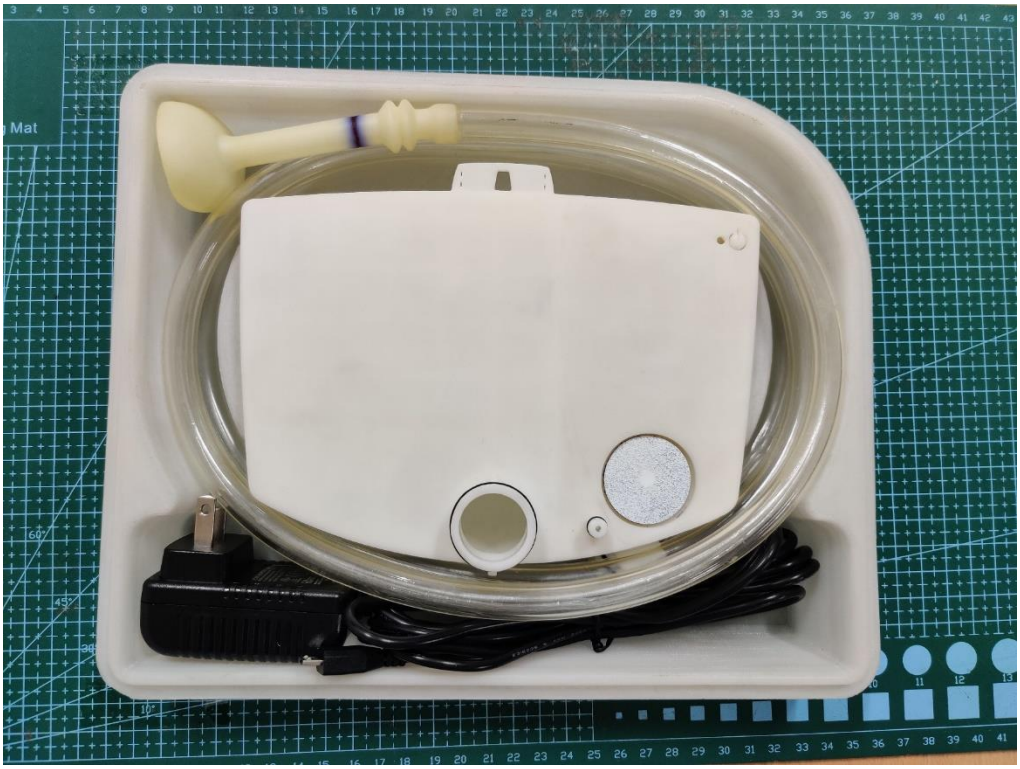


Figure 47: Proposed Arrangement

6.13.1 Type of packaging

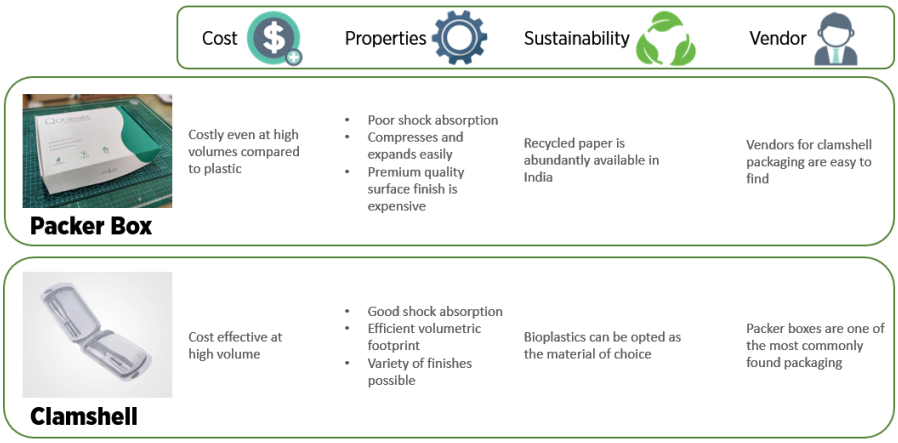


Figure 48: Packaging Method

6.13.2 Proposed Material

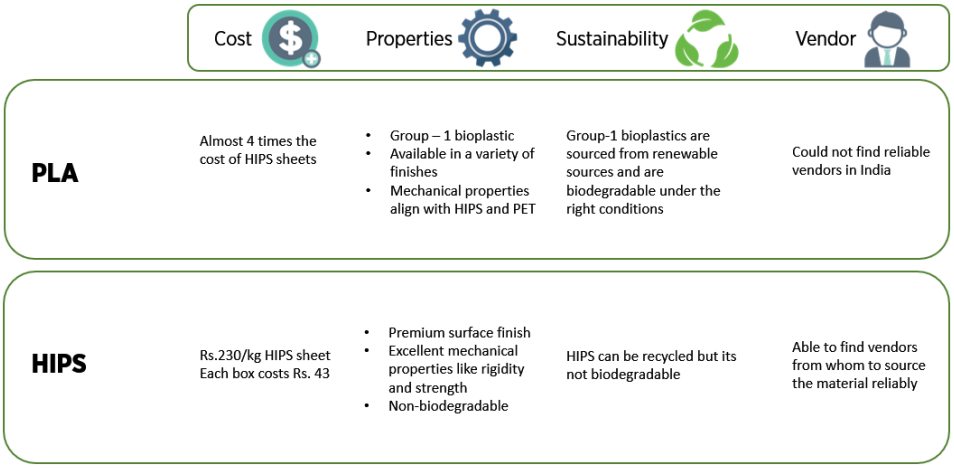


Figure 49: Packaging Material

6.14 Renders

Figure 50: Final Renders

6.15 Sticker Label Design

For the device, the instruction stickers on the front and back included with all the regulatory requirements and the legal requirements were to be designed.

6.15.1 Existing Sticker labels

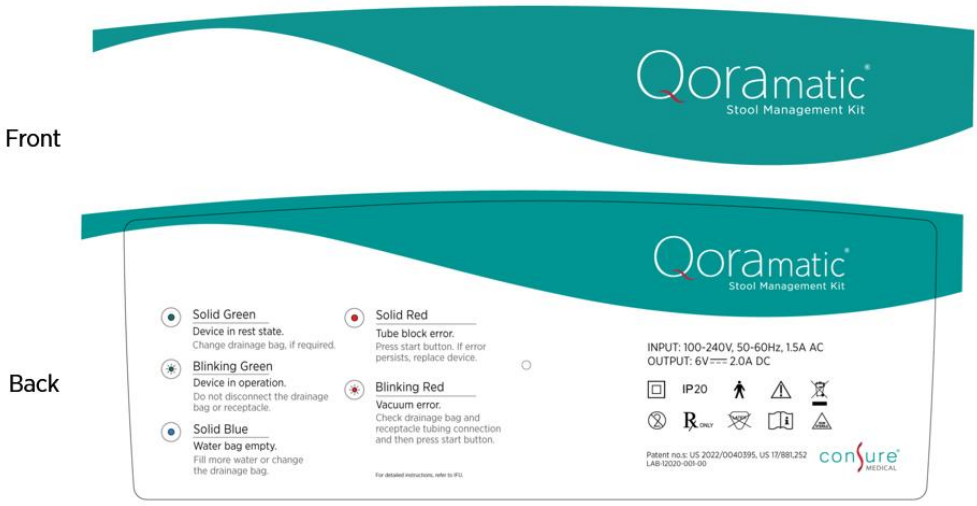


Figure 51: Existing Sticker Label

Figure 52: Sticker Label Render

6.15.2 Brief

- Needed the sticker to cover the right half of the device to hide the electronics arrangement
- Aid the user to navigate easily through the indications of the device for various light indications
- The graphics of the sticker should be a part of the Consure Design language.

6.15.3 Sticker Forms

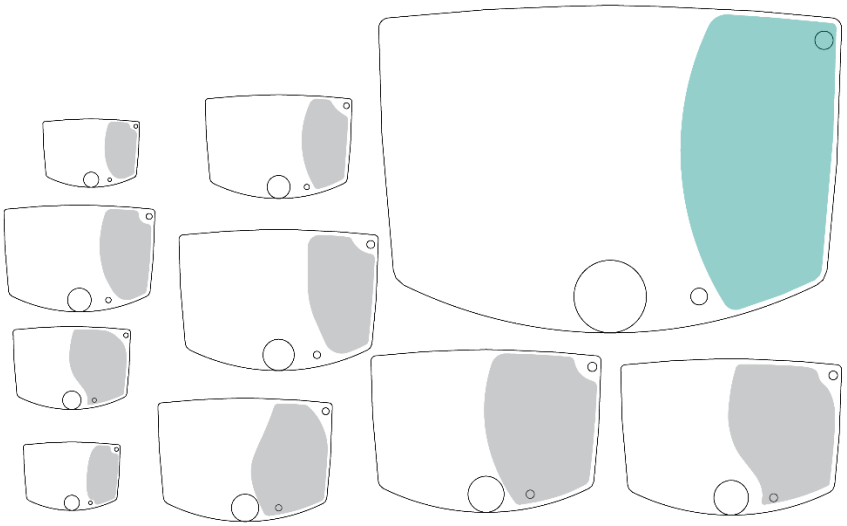


Figure 53: Sticker Forms

6.15.4 Front Layout

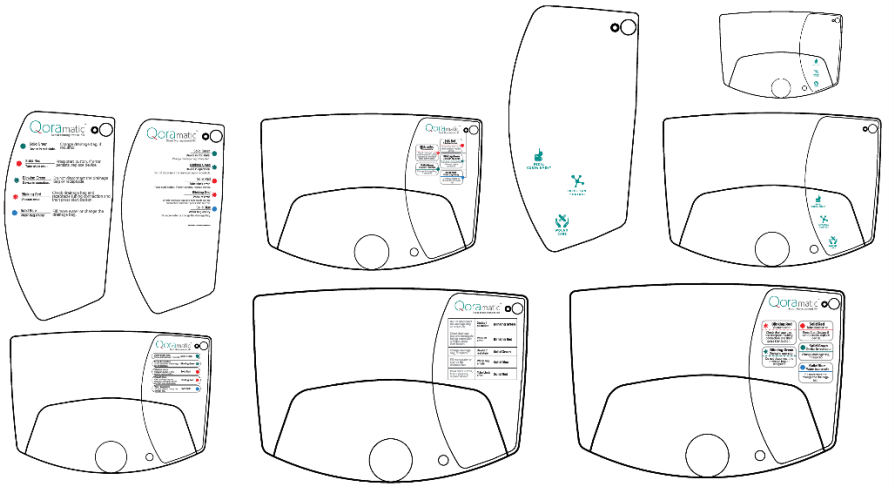


Figure 54: Front Layout

6.15.5 Back Layout

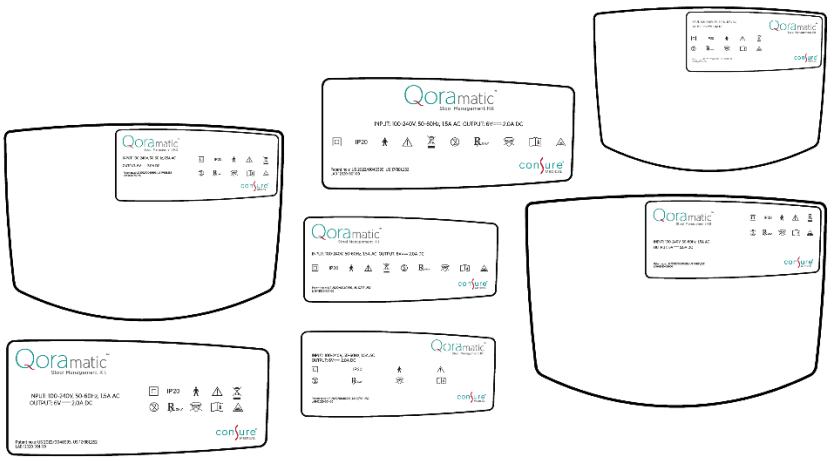


Figure 55: Back Layout

6.15.6 Graphics

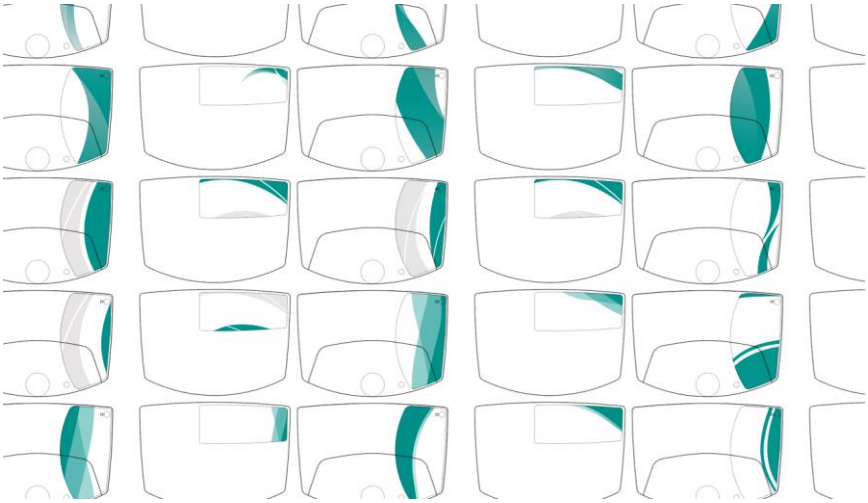


Figure 56: Graphics

6.15.7 Final Design

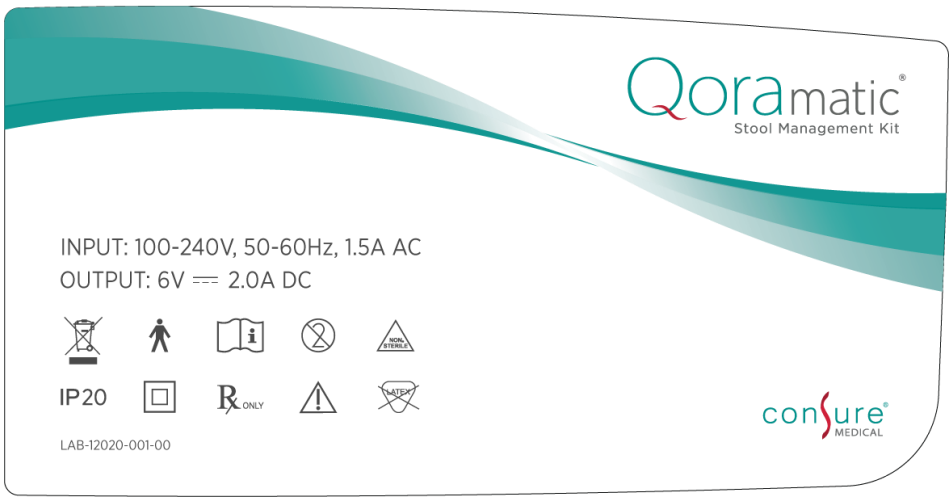


Figure 57: Back Final Design

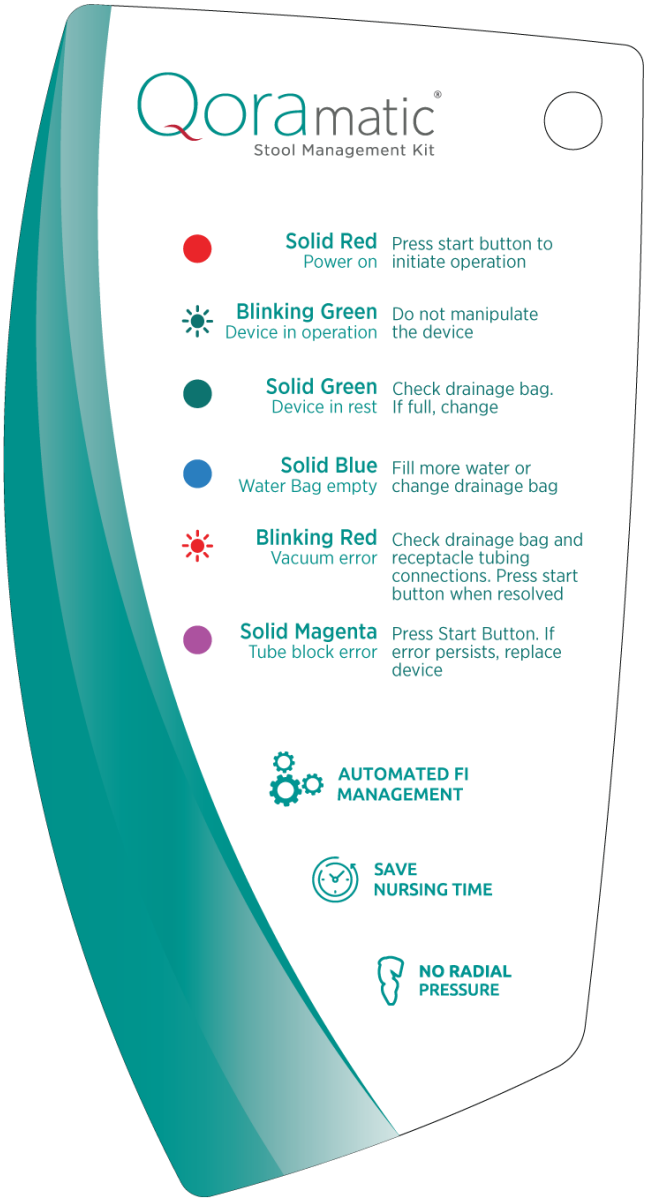


Figure 58: Front Final Design

Figure 59: Final Render

Figure 60: Final Render-2

7 Appendices

Medical Device Packaging - EU / FDA Standards (3)

- EN ISO 11607-1 Addressing packaging materials, sterile barrier system
- EN ISO 11607-2 Addressing validation of packaging processes
- BS EN 868-2 Packaging for terminally sterilized medical devices. Sterilization wrap. Requirements and test methods
- ASTM D3330 Package Strength Testing by Peel Adhesion Testing
- ASTM F88 Package Strength Testing by Seal Peel Testing
- ASTM F1140 Package Strength Testing by Burst Testing
- ASTM F2054 Standard Test Method for Burst Testing of Flexible Package Seals Using Internal Air Pressurization Within Restraining Plates
- Package Integrity (ASTM F2096: Bubble Test)
- Seal Integrity (ASTM F1886: Visual Inspection, ASTM 1929: Dye Test)
- Seal Strength (ASTM F88: Peel Test, ASTM F1140: Burst Test)
- Standards related to non-sterile medical device packaging (23)

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9 List of publication of candidates works

1. **Liquid Cooled Battery Thermal Management System for 3S2P Li-Ion Battery Configuration**

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