COMMITMENT TO QUALITY

The “MONOZUKURI Way”. When quality becomes a customer-driven concept, quality includes meeting or exceeding our customers’ needs or expectations.

MONOZUKURI - Craftsmanship

The most important points that customers demand of our products are quality and reliability. At our factories, we have established the "MONOZUKURI Way" as a theme of action, and we are carrying out various initiatives to improve quality, and working to pass on the legacy of traditional Japanese manufacturing technology in a multi-faceted fashion.

Commitment to Quality

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The road to PHCbi Quality

In April 2018, Panasonic Healthcare Holdings Co., Ltd. changed its name to PHC Holdings Corporation, and our Biomedical Products are now marketed under our newly launched PHCbi brand.
The “bi” part of our new brand PHCbi is not only a shortened form of the word “biomedical” but also represents both our strength and philosophy as an abbreviation of “biomedical innovation.”

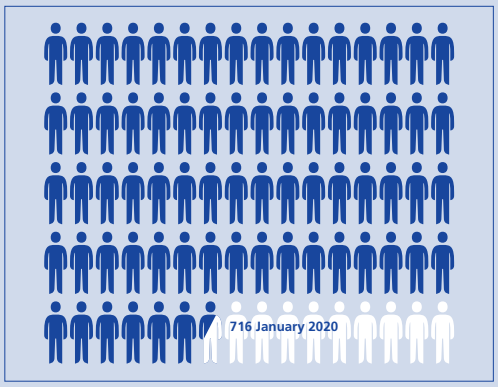
Since the launch of our first Pharmaceutical Refrigerator model in 1966, we have taken advantage of this technology to create exceptional products and services with a high degree of quality and reliability. We have worked to meet the expectations of customers in the medical and life science fields under both the Sanyo and Panasonic brands.

While the company and brand names may have changed, there are no key changes. As before, we will continue to provide our customers with high-quality products and top-class services.
In addition, we will continue to provide after-sales service and maintenance for our biomedical products previously sold under the Sanyo and Panasonic brands.

As of April 2018, the 686 PHC employees are engaged in the development, quality assurance, and production of products of PHCbi. Within the facility, we have many environmental testing laboratories, and these are used for stringent product screening with the aim of studying technology development and maintaining quality.

In addition, at the "MONOZUKURI-Dojo," whose purpose is to pass down the legacy of traditional technology, we are carrying out various kinds of training to improve skills such as brazing capillary tubes of Ultra-low Temperature Freezers, etc., requiring a high level of skill.

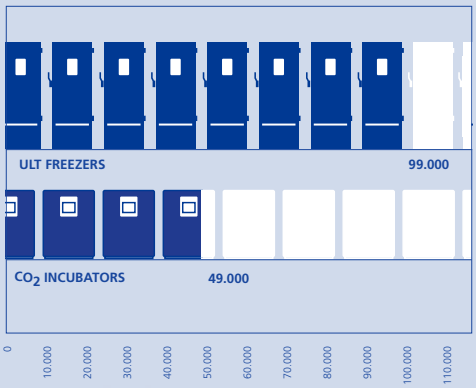
PHCbi in numbers



Number FTE

Number of factories

Number of our products operating worldwide

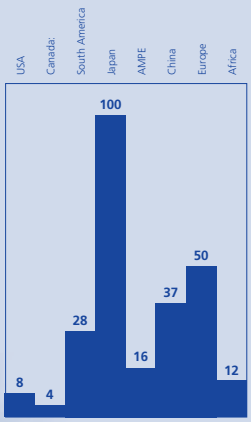


Number of sales countries

110

Number of sales offices

8



Number of distributors

Committed to Quality

Quality - It's a word that all are familiar with and one which many manufacturers claim to have or strive for. In the view of PHC, quality is a term that is ultimately defined by the customer. When quality becomes a customer-driven concept, quality includes meeting or exceeding our customers' needs or expectations. We focus on total quality which includes advanced processes and the culture of our organization. The result of our total quality initiatives involve many steps to provide our customers with superior value.





1

Understanding Customer Demands

Our vision of total quality involves many face-to-face visits to customers to directly hear what they have to say about using the equipment we have supplied.

2

Creating a New Product Concept

Developing Basic Technology

Developing a concept for a new product is very similar to the "basic research" processes in life sciences. Technical staff and engineers develop various basic and innovative technologies to realize the concept for a new product.

3

Creating a New Product Concept

Exterior/Interior Designs

As soon as engineering personnel begin developing a technological element, the design staff sets out to work on images.

4

Checking Local Legislation

We manufacture products for use in approximately 110 countries and regions around the world. Obviously, different laws and regulations apply, so we are always working to ensure our products conform to the laws and regulations of the individual locations

5

Design Review

Beyond determining specifications, evaluation criteria and achievement levels affecting

product quality such as reliability, durability and safety standards must be achieved in mass-production models.

6

Quality Assurance

Under PHC standards, quality actions required in new product development must clear three hurdles: AQ-0 approval for design completion, AQ-1 decision for shifting to mass production and AQ-2 decision for shipping mass-produced units.

7

Mass Production

The Gunma factory was established in 1959 as the Tokyo manufacturing site for Sanyo Electric Co., Ltd. It is a core facility housing the Product Technology Development & Design Department, Quality Assurance Department and Production Department.

8

Transportation
packaging design

Our product packaging is designed to fulfill various distribution challenges around the world. Using past accumulated lessons learned we focus on reducing and recycling materials to support environmental initiatives.

9

Installation

Product installations are often performed carefully by regional suppliers who are trained specialists. The path from facility entrance to the laboratory is measured and examined in advance to ensure precise, efficient installation. In some regions "white glove' service is also available to aid in installation and set-up.

10

Sales and After-Sales Service

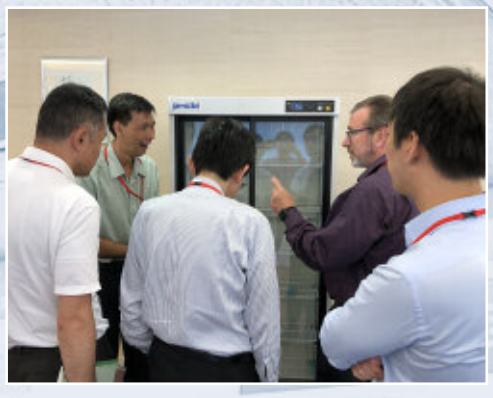
We always strive to learn more about our products. Before new products go into mass production at the factory, our sales personnel receives extensive knowledge about the products through intensive sales training

1 | Understanding Customer Demands

Our vision of total quality involves many face-to-face visits to customers to directly hear what they have to say about using the equipment we have supplied. How they feel about using the equipment as well as their opinions on how we can improve our products. improving it. Customer visits are typically conducted by sales, marketing and product planning department personnel. In many instances, technical personnel and design engineers also make customer visits as it helps them better understand customer needs and better disseminate utilize the information reported from the field. Furthermore, it provides an opportunity to directly gather product improvement ideas proposed by the customers.

Global Meetings

Product and marketing managers from around the world meet annually at the flagship factory in Gunma, Japan to present customer requirements from each region. Product planning, technical personnel and design engineers also attend to provide diverse points of view so that all participants can discuss the issues and customer needs together. Obviously, customer requirements for various global regions can vary widely. We hold many extended discussions to seek a direction for planning products that include each and every important aspect of customer requirements. We are also able to determine product concepts and target specifications based on in-depth discussions. During the global meetings, product development projects are approved for inclusion into mid- and long-term development plans (road maps). By making decisions through a diverse team approach, we are better able to meet the expectations of our customers.



2 | **Creating a New Product Concept** (Developing Basic Technology)

Developing a concept for a new product is very similar to the "basic research" processes in life sciences. Technical staff and engineers develop various basic and innovative technologies to realize the concept for a new product that will solve customers' issues and meet their requirements.

Teardown

Together, members from the technical department, engineers, product planning, marketing and sales departments form a dynamic team to tear down products. The tear down allows the team to verify and learn about specifications, the costs and quality of each component in our products as well as those of our competitors. We start creating basic technologies with a broad view so we do not simply depend on our own viewpoints.

The goal of each tear down can range from the scope of a complete platform, to a very small but very important key device. Various new specifications and functions to solve customer issues can originate from one individual's idea or from the ideas of several technicians and engineers. These new specifications and functions could result from ideas previously discussed or from something completely original.

The ideas conceived by technicians and engineers are examined from both 2D and 3D perspectives. Initially, samples are created as non-functional prototypes; followed by handmade, fully functional models. By experimenting and verifying prototypes from various perspectives, issues are detected and improved upon. By repeating a trial and error process several times, what was initially just an idea is refined to become a device with specifications and functions that will bring the highest value to our customers.

Improving performance and specifications versus maintaining a product's exterior dimensions is a challenge that is often encountered. Achieving the planned performance and specifications is critical. However, reducing product footprints to a minimum without compromising performance also becomes an underlying goal.

3 | Creating a New Product Concept (Exterior/Interior Designs)

As soon as engineering personnel begin developing a technological element, the design staff sets out to work on images. These are initially basic sketches, but over time, as they are presented to engineering for examination in detail, the images are rendered in 2D and 3D.

Our design staff are able to utilize a wide scope of knowhow, tools and lessons learned accumulated over 50 years of product development. For example, deciding on the height of shelves in a refrigerator cabinet, the door opening/closing angles, positioning of operation panels and optimizing operation procedures. Should a user switch from using our former SANYO and Panasonic branded-products to PHCbi products, a learning curve is not needed at all and there is no confusion regarding operation.

Updating our Knowledge Base

When considering usability, we do not think at a micro level, but renew ideas taking a macro view of our research processes, scheduling and timeframes. Supplying quick and concise feedback to researchers using our products while enhancing usability helps us gain positive results.

Our designers are very attentive to the laboratory environment where our products are installed. No matter the level of excellence of product designs, they cannot be regarded as superior designs if they have a negative effect on a laboratory's atmosphere. This explains the recent color changes to our products and the legacy of elegant but robust designs we are known for.

Ideas examined in 2D and 3D are then reflected in a prototype product that is then subject to further examination; followed by various stages of improvement with the prototypes being operated and closely observed. Designers continue to refine the designs based on various evaluations from different personnel and feedback from verification results of basic technologies.


-80℃
-85℃

4 | Checking Local Legislation

We manufacture products for use in approximately 110 countries and regions around the world. Obviously, different laws and regulations apply, so we are always working to ensure our products conform to the laws and regulations of the individual locations.

Various pharmaceutical, safety, and environmental regulations around the world affect our product designs to ensure that we meet prevailing regulatory guidelines. At the same time, we also ensure that our manufacturing standards meet global initiatives for reduced carbon footprint.

- Japan - Pharmaceutical Affairs Law regulating the manufacturing, importation, and sale of drugs and medical devices, Electrical Appliance and Material Safety Law.
- USA - Federal Food, Drug, and Cosmetic Act (FDCA), recognition standards of the Nationally Recognized Testing Laboratories (NRTL). Significant New Alternatives Policy (SNAP),
- Europe - Medical Device Directive (MDD), Restriction of Hazardous Substances (RoHS directive), Waste Electrical and Electronic Equipment (WEEE directive), F-Gas Regulations and other directives.

- China - Food and Drug Administration codes (CFDA).

Laws and regulations are constantly changing and in order to stay up-to-speed with existing regulations worldwide, our Legislative Division is always monitoring changes. Although designing and manufacturing products for a global market means that we need to design for the most strict of those standards, the end result is that our customers receive the most robust and environmentally friendly products.

5 | Design Review

Beyond determining specifications, evaluation criteria and achievement levels affecting product quality such as reliability, durability and safety standards must be achieved in mass-production models. Conventional model quality issue data is also shared among the design team. Verification processes for mass production are conducted repeatedly. Detailed goals toward mass production are reached by checking applicable laws and regulations for each country and assessing prevailing environmental measures and confirming costs.

Hand-made engineering samples (ESs) undergo various performance/quality verification steps such as thermal conduction analysis, acceleration testing, durability and vibration testing, providing the team with points to be improved upon for mass production.

The compressors on the refrigerated engineering samples are removed after running in extreme environments for an extended period of time so that wear patterns of the main components can be verified in detail.

If the design team is not satisfied that the product meets our high quality standards, another engineering sample is created and verified through the aforementioned process. This process will be repeated until our strict quality standards are met. This extreme process can delay the appearance of our products into a rapidly changing market, however we believe that quality cannot be compromised.

"ESs" are also used to clarify requirements for factory mass production teams to assess the readiness of manufacturing equipment, jig tooling, construction methods and related matters in planning form a new process flow. By planning, quality issues are less likely to appear during actual mass production.

In parallel to the development of the engineering standards, our software development team decides on systems design, determines user interface specifications, and conducts repeating basic operational and comprehensive control testing.

The entire development strategy culminates concludes in completing the DR (design review) process where new product specifications are finalized, production of PR (Pilot Run) models on mass production are performed. Once again, product designs, manufacturing processes and software controls are verified.

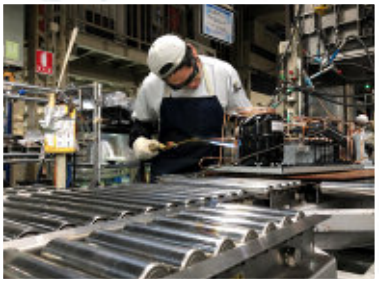
6 | Quality Assurance

Under PHC standards, quality actions required in new product development must clear three hurdles: AQ-0 approval for design completion, AQ-1 decision for shifting to mass production and AQ-2 decision for shipping mass-produced units.
In order to clear the a hurdle and move on to the next, all product quality issues must be addressed, otherwise the process will not continue.

Delaying solutions until the later stages is strictly prohibited.
The pre-production model manufactured using actual production facilities is subject to various verification and review processes. It is conducted mainly by the Quality Assurance department and performed with a customer's point of view. The verification process is conducted in the dedicated laboratory laboratories of the Quality Assurance department. The process to verify product readiness is wide-ranging, including temperature control status, safety, reliability, basic operation and product usability.

Next, the PP model must also undergo a drop test in our test room to verify reliability. For example, the recently launched MDF-DU702VH (VIP ECO) that has undergone drop testing for extended periods and is still being verified; no abnormalities have been found. If one should appear, the cause of the failures will be integrated into improvements in the manufacturing process.

Finally, checking and evaluating a product means exanimating its basic operations and functions from a customer's perspective. For example, a pre-production model's performance is verified referring to the instruction manual utilizing non-technical staff from various departments without a direct connection to the product. This process helps ensure our manuals are easy to understand and potential misuse of the product is minimized.



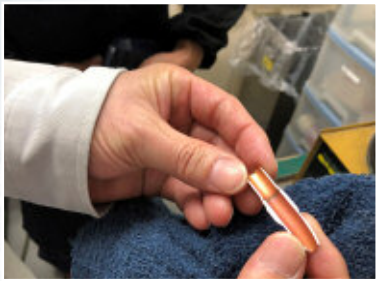

NOTICE
-56.9

Bringing a new product to market is not the only goal of the Quality Assurance department.

If a product already installed in a customer's laboratory is performing optimally, determining the cause and rectifying it is a very important task for us.

If, after delivery to a customer, the performance is not optimal, we register the information on our BMQS system (Biomedical Product Quality System). The system allows global teams in sales, quality assurance, customer service, technology, production, marketing and other areas access and share information. Causes for each issue are discussed and analyzed so that necessary countermeasures can be quickly implemented.
In rare instances where products become repeatedly problematic, the product in question is returned to the factory for disassembly and analysis to discover the root cause of the issue. The root cause is corrected with the goal of ensuring that the same problem does not reoccur and is added to our extensive catalogue of lessons learned. Furthermore, changes are made to production to enhance overall product quality and that so any solution is implemented to other products where possible.

Based on information gathered from our markets, we incorporate all of the lessons learned from the beginning of our product development and cross-organizational activities to avoid reintroduction of any quality issue we have encountered over our 50+ year history.
One example of our extreme total quality focus was initiated several years ago, to deal with an industry wide challenge; the long-standing "refrigerant gas leakage" issue. This issue was particularly problematic as it would often appear until when refrigeration products were several years old and starting to slowly warm-up. The "Gas Leakage Restraint Project", implemented by cross-organizational personnel, aimed at resolving this long standing issue and involved members from the quality assurance, manufacturing, and technology departments. The project examined and clarified gas leakage causes as well as enhance welding condition methods, work standardization, and testing precision. Their efforts resulted in the industry's most advanced method of preventing causes of refrigerant leaks. This ground breaking project resulted in reducing the potential for refrigerant leakage even in products where symptoms would not occur until well into the future and increased overall product quality significantly.

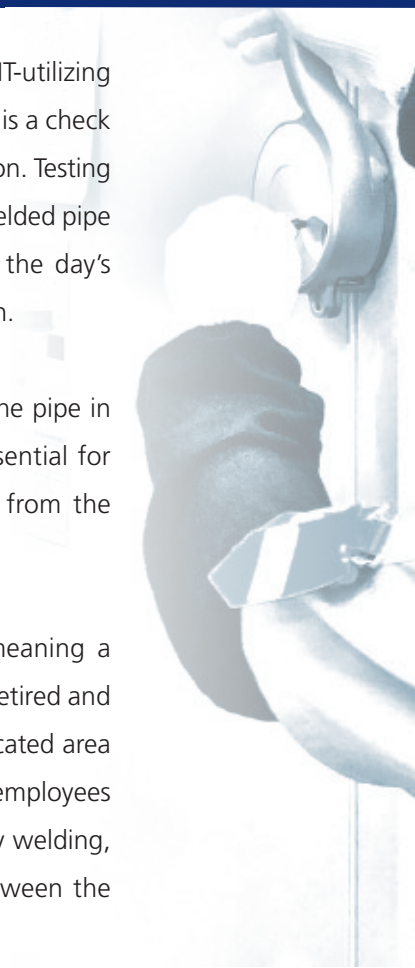


7 | Mass Production

The Gunma factory was established in 1959 as the Tokyo manufacturing site for Sanyo Electric Co., Ltd. It is a core facility housing the Product Technology Development & Design Department, Quality Assurance Department and Production Department.

The motto of the factory, "Monozukuri Way" consists of five keywords: "Customer First", "Quality is Lifeline", "On-site, On-product" (meaning the best way of understanding a situation is to be where the action is)", "Challenge to change" and "Making products involves training personnel." All employees at the factory share this motto and are involved with daily production, keeping total quality in mind at all times. All personnel continue to refine their skills and undergo continuous training to address various challenges that could occur on any given day. The culture of our manufacturing facility is such that stakeholders look forward to improving product quality and overall productivity as members of small, agile quality driven teams.

Factory personnel take pride in nurturing the PHCbi brand.



The factory can be characterized as a hybrid, composed of handmade production and IT-utilizing process assembly lines. During the "hand-made" stage such as capillary welding, there is a check of the workers' physical and mental state of mind before commencing the day's production. Testing the high skill requirement of the capillary welding process is performed by cutting the welded pipe vertically and verifying the welded section for integrity. Workers on the roster for the day's production must pass the test to meet the highest standards before starting production.

A capillary welding inspection process includes checking the physical appearance of the pipe in addition to leakage testing. Accumulated experience has shown that this step is essential for product quality control. Pipes that do not satisfy appearance quality are removed from the production line.

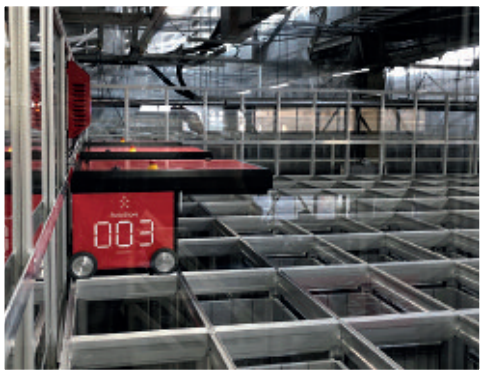
Beyond daily compliance testing, "Monozukuri-Dojo" is an additional resource, meaning a "practice hall for manufacturing". This facility's purpose in the factory is to encourage retired and experienced workers to pass on the "handmade" processes and techniques. This dedicated area allows veteran workers to mentor and coach their accumulated knowhow to younger employees who will be supporting the factory in the years ahead. Topics covered include capillary welding, manufacturing processes and many other areas which help transfer knowledge between the generations.


PHCbi

The Gunma factory along with its traditional "handmade" process is also further advancing IoT possibilities. Every ultra-low freezer we produce must pass a rigorous tests including the "compressor vacuum integrity", "refrigerant charge amount" and "final temperature pulldown inspection". Status settings in the production processes are all digitally measured with data gathered by serial number and utilized for traceability in the case a quality issue should occur. We don't just test a sample during a production run, every single freezer must meet quality standards. Outliers are addressed immediately and data is used to continually optimize quality.

Robotic processes that automatically select and pick up components based on production data and are currently utilized to raise productivity. This process was brought on-line as of April 2019.

Additionally, we are introducing a system that allows all factory personnel to conduct real-time checks via their computers focused on personnel engaged in a particular process, the hours expended spend and the production volume achieved. The new tracking process allows us to further define productivity and quality goals to catch issues in the early stages before they enter finished products.



8 | Transportation (packaging design)

Our product packaging is designed to fulfill various distribution challenges around the world. Using past accumulated lessons learned we focus on reducing and recycling materials to support environmental initiatives.

Packaging design starts immediately following product specification approval.

Prototype packaging is used with an actual product and verified through drop, vibration, and compression testing. The packaging design is not just designed for strength integrity, but includes crushable zones to absorb potential impact on the products while in transit.

Furthermore, workability during the unpacking stage at the final destination is required. 2D/3D simulations are repeated on a trial and error basis. Unpacking ease and speed at the installation site is also considered.

Packaging design personnel make customer visits to confirm the physical constraints for the installation at the customer's facility by the supplier with the actual procedures employed. The onsite unpacking procedure is compared to the unpacking procedure developed by packaging design personnel and provides valuable and useful information for further improvements.

Additionally, packaging design personnel visit recycling plants to see how the used packaging materials are processed allowing us to make use of the information for the next packaging design.

9 | Installation

Product installations are often performed carefully by regional suppliers who are trained specialists. The path from facility entrance to the laboratory is measured and examined in advance to ensure precise, efficient installation. In some regions "white glove' service is also available to aid in installation and set-up.

When deciding on the three dimensions of products, designers must keep in mind door dimensions for the lab entrance, elevator size, installation space in the lab, and, of course average height of lab personnel actually using the products. They must be able to address these issues anywhere in the world.

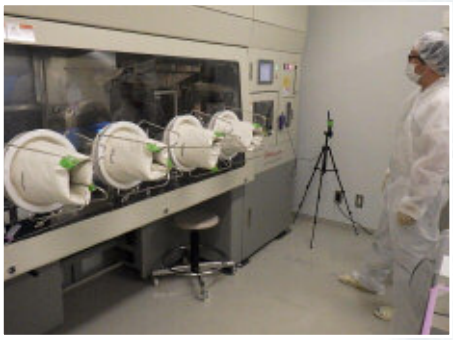
No matter how high the performance level of a product may be, products that do not meet sizing or aesthetic requirements cannot truly represent our brand. Product designers select product colors consulting with laboratories. Product engineers work closely with laboratories and researchers to determine the optimal size for a product. The opinions available from each region's supplier is also a part of the entire process. Together with our suppliers we form a collaborative team that functions to provide an optimal customer experience.

10 | Sales and After-Sales Service

We always strive to learn more about our products. Before new products go into mass production at the factory, our sales personnel receives extensive knowledge about the products through intensive sales training. During the training, we learn all about the features of our new products and the differences between ours and competitive products. If you would like to know about products of other companies, just ask us!

Sales people are not only our company employees. Many dealers and distributors around the world who handle life sciences equipment are very important partners for us. We listen to what they have to say as well as what the customers tell us.

Please contact us if there is ever an issue with our equipment. A service engineer trained in our medical equipment will visit you as soon as possible. Our support service team will respond to all your inquiries, ranging from everyday repair correspondence to professional validation of your equipment.



Our technical support service teams receive extensive training at regularly scheduled intervals. Technical support Service staff from around the world attend the annual training sessions at the Gunma factory. They learn about correct product maintenance and are trained to perform other important procedures such as exchanging and filling refrigerants using state-of-the-art processes and procedures.

Sales teams possess expert-level knowledge on cell culture solutions such as our Cell Processing Center (CPC), Cell Processing Work Station (CPWS), as well as proper maintenance procedures for delicate equipment and sophisticated facilities. The dedicated special support team for cell culture facilities is able to respond to cases requiring extremely high precision, such as validating an entire facility and adjustments to equipment.

When important research results are announced in the life sciences field and become newsworthy topics, you can take it for granted that our facilities, equipment and sales/maintenance team are almost always playing an active role.

Sales people and support teams are always happy to listen to their customers. Any ideas you may have which can help us improve our products are genuinely welcome.


PHCbi
PHCbi
PHCbi
-80°C
TwinGuard


-80c
VIP ECO
Natural Refrigerants

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