

GUIDE

A structured and fast route to your medical equipment cart in 10 steps

INTRODUCTION

A structured and fast route to your medical equipment cart in 10 steps

In medical technology, configuring a reliable equipment cart is critical to the efficiency and safety of clinical workflows – and therefore to the overall market success of the medical system. This guide offers project managers a practical, structured approach to developing or configuring a medical cart that meets the highest quality standards. By following these steps, you increase project effectiveness, shorten your time-to-market, and strengthen the success of your overall system in clinical use.

Are you facing the challenge of developing a market-ready solution under tight time and budget constraints while aligning all stakeholders toward shared goals? This 10 steps plan leads you from the creation of your requirement specification to CE-compliant manufacturing and logistics. By following the precise recommendations, you will shorten your time-to-market and manage regulatory challenges in a structured way.

This guide serves as a blueprint for your project process. Individual requirements may vary, and framework conditions can be adapted accordingly.

1. Requirements Specification 3

2. Feasibility Assessment and Cart Concept 4

3. Pricing Information and Offer 6

4. Contractual Framework 7

5. Prototype Development 8

6. Quality Management 9

7. Product Release / Series Approval 10

8. Order Placement 11

9. Commissioning 12

10. After-Sales Support 13

1. REQUIREMENTS SPECIFICATION

The foundation for efficient and successful project execution

Goal: A complete and coordinated briefing document that forms the basis for a successful project and for the first concept proposal.

+ **Completeness:** The requirements specification gathers together all the information about the application area, product requirements, and regulatory framework, taking into account the needs of all stakeholders involved.
+ **Efficiency in decision-making:** It reduces internal coordination efforts, prevents unnecessary review loops, and enables faster decision-making.

A carefully completed requirements specification is the first step to starting your project with focus and direction. It provides transparency for everyone involved. . The medical device consultant reviews your requirements document and discusses any outstanding details with you. This ensures your project starts with perfectly aligned information for every subsequent phase.

Recommendation: Create a comprehensive requirements specification in coordination with all relevant stakeholders – this avoids later review loops and lays the foundation for a smooth project process.



2. FEASIBILITY ASSESSMENT AND CART CONCEPT

An implementation concept based on requirements, regulations, and economic efficiency

Goal: A concrete cart concept serving as a solid decision-making foundation.

Based on the requirements specification, the appropriate product development approach is defined. The following options should be considered:

+ **Modular:** fast and economical solution
+ **Hybrid:** customized adaptations combined with standard components
+ **Custom:** fully tailored product development
+ **Contract manufacturing:** turnkey solution from drawing to production

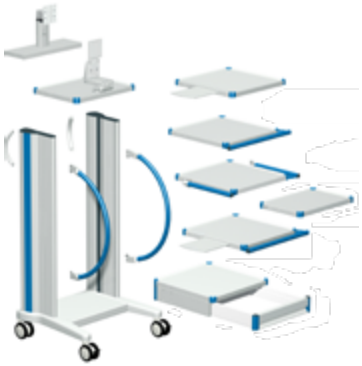
A concept-open approach considers technology, customization requirements, budget, timeline, and regulatory framework:

+ **Technical feasibility:** It ensures that the cart configuration can be implemented functionally.
+ **Budget implications:** The concept accounts for economic parameters and provides cost and resource transparency.
+ **Regulatory requirements:** It identifies relevant norms and documentation obligations early on, ensuring smooth certification.

The result is a detailed solution proposal developed in close collaboration with you. Regardless of the approach, the product concept is visualized through realistic renderings from multiple perspectives. This systematic process ensures a reliable basis for decision-making.

Recommendation: Define internally the desired level of customization for your medical cart and clarify whether your project requires a modular or fully tailored approach – this creates a clear foundation for the concept phase.

product solutions



MODULAR

Modular
product configuration

Modular
components



HYBRID

Functional and
visual adjustments



CUSTOM

Customized development
of product

Customer-specific
components



CONTRACT MANUFACTURING

Production based
on CAD data

Customer's medical
cart concept

Level of customization, costs and time-to-market

3. PRICING INFORMATION AND OFFER

The foundation for approvals and planning reliability

Goal: A reliable quotation that supports internal approvals and sets the direction for the next project phase.

+ **Budget indication:** An indicative price quote provides an early, non-binding estimate of unit costs, enabling internal alignment and potential conceptual adjustments.
+ **Solid decision-making and transparency:** The binding offer ensures transparency regarding project expenditures and allows for precise budget planning, including unit prices, quantity discounts, and optional service packages.
+ **Active budget control:** The offer helps identify and prevent potential price fluctuations early on.

The quotation is based precisely on the customer's requirements, incorporating all details and binding conditions. This ensures your budget is used efficiently and the project remains financially on track.

Recommendation: Define your planned quantities and additional service needs – such as integration or logistics services – early on to receive a tailored quotation with optimal conditions.



Sample offer with detailed item description



Sample quote with product drawing



Configuration example as part of the price information

4. CONTRACTUAL FRAMEWORK

Legal certainty for data protection, responsibilities, and goals

Goal: A legally secure foundation that fosters trust and transparent collaboration.

+ **Legal protection:** The contractual framework provides a reliable legal basis for data protection and project-related agreements.
+ **Clarity and structure:** Clearly defined objectives, milestones, and responsibilities promote transparency and structured project execution.
+ **Efficient collaboration:** Contracts such as the Quality Assurance Agreement (QAA) strengthen the partnership between OEM and supplier.

Before the project begins, the contractual framework is established to ensure structured implementation. This includes an NDA to protect sensitive data, development contracts, and clearly defined work scopes. At the customer's request, the NDA can be signed before any project information is exchanged. The Supplier Quality Agreement ensures smooth cooperation with sub-suppliers.

Recommendation: Clarify internally which legal and procedural frameworks apply to your organization and communicate them clearly to ensure a precise and efficient contract and project structure.



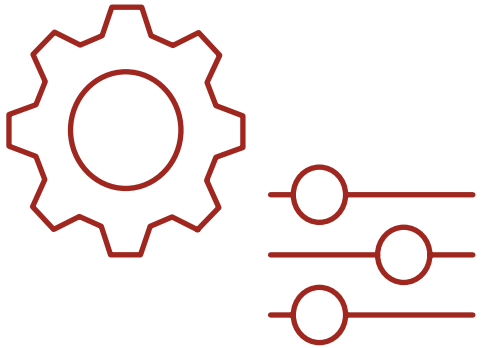
5. PROTOTYPE DEVELOPMENT

On-site presentation of the configuration and collaborative decision-making

Goal: Functional, qualitative, and visual evaluation of the prototype in the presence of all project stakeholders; verification of device integration, including cabling – thus enabling a full assessment of the overall system.

+ **Benchmark and optimization tool:** The prototype serves as a realistic model for fine-tuning the configuration and aligning potential adjustments.
+ **Collaborative decision-making:** All relevant stakeholders clarify open points on-site and approve the final setup.
+ **Preparation for (serial) production:** The prototype provides the starting signal for series production planning.

Within a defined framework, the medical cart is tested under real application conditions with original devices. All relevant project participants are involved in the review.



Recommended participants for the prototype review:

+ **Product Management / Marketing**
+ **Purchasing**
+ **Clinical Users / Biomedical Engineering**
+ **Technical Department / Design Engineering**
+ **Sales**
+ **Regulatory Affairs / Quality Management**
+ **Management**

Recommendation: Define clear decision criteria before the prototype review and ensure that all relevant departments actively participate – ideally including clinical users from the medical environment.

6. QUALITY MANAGEMENT

Guaranteed technical and regulatory compliance

Goal: Technical and regulatory assurance of the medical cart through structured processes, complete documentation, and compliance with all relevant standards for market approval.

+ **Early risk detection:** The medical device consultant identifies potential regulatory risks early and provides targeted advice.
+ **Documentation and evidence:** The quality management system ensures the availability of all required documents for international approvals – including records, evidence, and test protocols for product certification in the EU, USA, Asia, and other markets.
+ **Conformity assessment:** Testing according to DIN EN 60601-1 ensures that the cart meets medical device requirements.

A certified quality management system in accordance with DIN EN ISO 13485 provides the regulatory basis for CE conformity. The customer supplies the regulatory requirements for their target markets and receives corresponding documentation from the supplier.

Recommendation: Define your target markets early and ensure that partners familiar with local regulatory requirements support you – enabling documentation to be prepared in a precise and compliant manner.



7. PRODUCT RELEASE / SERIES APPROVAL

Verified, documented, and approved before production

Goal: Series approval or product release ensures the product has been verified, documented, and approved by the customer for production.

+ **Market readiness and safety:** The release is based on standard-compliant testing in accordance with DIN EN 60601-1 and a certified DIN EN ISO 13485 quality management system. This guarantees complete traceability and supports a safe market launch.
+ **Finalization of conformity:** All required certificates and documentation – such as CE declarations and ISO certificates – are finalized and validated.

The confirmation of conformity is the prerequisite for integrating the cart into a medical system. Testing is conducted step-by-step and fully documented according to DIN EN 60601-1. Stability tests are performed in the test lab with the fully assembled system. The customer provides the actual medical devices or simulated loads for testing.

Recommendation: Provide all medical devices that will later be assembled in the system for the testing process. This is the only way to conduct tests under real conditions and generate reliable test reports.



8. ORDER PLACEMENT

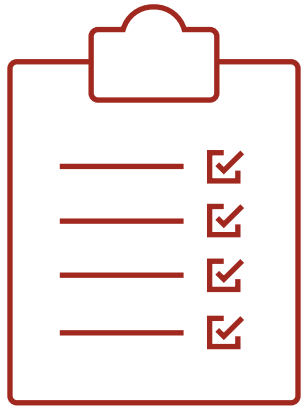
Binding order confirmation and fixed delivery date

Goal: Reliable budget planning and dependable delivery schedules based on system-supported production planning.

+ **Planning reliability:** The binding order confirmation, including a fixed delivery date, allows for precise scheduling of the system rollout to the OEM's end customers.
+ **Legal and logistical assurance:** Framework agreements and forecasts secure the supply chain and enable reduced delivery times, which can be further shortened through stockholding.
+ **Trust and reliability:** Transparent processes foster dependable collaboration and guarantee on-time delivery with verified quality.

After product release, the order is placed and confirmed with a binding delivery date. This confirmation is based on the documented series approval, ensuring compliance with all legal, technical, and logistical requirements. It provides the foundation for the OEM's downstream market launch activities and ensures certainty across all departments and effective stakeholder management.

Recommendation: Plan your quantity requirements proactively and align all subsequent steps and resources with the confirmed delivery schedule – ensuring on-time delivery to your customers and smooth project execution.



9. COMMISSIONING

Seamless device integration and on-site implementation

Goal: Smooth commissioning at the end user's site without delays and with minimal effort.

+ **Immediate operational readiness:** The carts are prepared so that users only need to position and connect their medical devices.
+ **OEM support:** Typically, an OEM representative supervises the on-site commissioning, instructs the clinical staff, and approves the complete system.
+ **Efficient integration:** Clear instructions, safety notes, and a well-thought-out device setup enable fast integration into the existing system environment.
+ **Supplier support:** The cart manufacturer can facilitate commissioning through preconfigured and prewired carts – an option best considered during the concept and series release phases.

Commissioning takes place at the end user's site – under real conditions. A well-prepared cart minimizes OEM workload and ensures a safe, efficient system handover. This reduces training time, conserves resources, and increases satisfaction for all stakeholders.

Recommendation: Ensure your carts are as preconfigured and well-documented as possible. Assess early whether prewired or preassembled cart systems from your supplier could further speed up commissioning. Verify whether your supplier can support you as a system integrator in maintaining DIN EN 60601-1 compliance for the overall system.



10. AFTER-SALES SUPPORT

Personal and proactive service beyond the scope of the project

Goal: Long-term satisfaction among all stakeholders through process optimization and proactive planning of follow-up deliveries.

+ **Continuous support:** A dedicated contact person remains available after commissioning for technical questions, forecasting, and subsequent projects.
+ **Process optimization:** Experienced medical device consultants support the ongoing optimization of the product configuration and internal processes, for example through integration or logistics services.

Project responsibility does not end with delivery. The dedicated contact person continues to accompany the project beyond commissioning, fostering a partnership that ensures stability, efficiency, and long-term success.

Recommendation: Make active use of after-sales support. Through regular exchange with your contact person, you can identify optimization potential early and enable shorter delivery times for repeat orders.



Template for the Requirements Specification (1/3)

Application and Project Environment

Project name

Medical application area

☐ Clinical area ☐ OR ☐ Ward ☐ Outpatient environment

Intended use

Target markets (countries, regions)

Device Integration

Quantity

Type / designation

Dimensions (W × H × D, data sheets, or 3D drawings)

Position on the cart

Weight

☐ Gas cylinders ☐ Camera heads ☐ Endoscopes

Accessories

Other

Monitors

Manufacturer, model

Dimensions (W × H × D, data sheets, or 3D drawings)

Weight

Interface (e.g. VESA, custom)

Monitor support arm specifications

Position on the cart

Template for the Requirements Specification (2/3)

Electrification

Power (VA) ☐ 660W ☐ 1200W ☐ 1600W ☐ 2000W

☐ Maximum load ☐ Continuous load

Isolating transformer

Supply voltage by market region (115 V USA/Canada, 240 V EU, 100 V Japan)

Insulation monitor for leakage current monitoring

☐ Yes ☐ No

Power strip inside the column

Grounding concept

Protective conductor concept

Number and type of outlets

Central on/off switch

☐ Yes, quantity ☐ No

POAG connections

Commercial Framework

Target price of your overall system

Target price of iTD medical cart

Annual quantities

Delivery call-offs throughout the year

Lead times

Project start and desired first delivery

Template for the Requirements Specification (3/3)

Differentiation and Design

Base color

Accent colors

Branding (logo/CI guidelines)

Specific design wishes

Service Options

Pre-assembly: cabling, material logistics

Device integration and warehouse logistics

System integration and direct distribution

Customization

Regulatory Affairs

Market-specific requirements

Standards and norms by target market

Documentation and traceability requirements

Confirmation, declaration, and assessment of conformity

Approval prerequisites

Special regulatory requirements for target markets

TRUSTED EXPERTISE IN MEDICAL TECHNOLOGY

Headquarter

Jahnstrasse 1
84347 Pfarrkirchen
Germany
+49 89 61 44 25-0
sales@itd-cart.com
www.itd-cart.com