

WHEN THE MEDICAL CART BECOMES A PROJECT AND COST RISK

Reflection Paper for Project Leaders

SEVEN RECURRING MINDSET PATTERNS AND THEIR IMPACT

Strategic Perspective

In many development and procurement projects, medical carts are considered a secondary component. The initial focus is on the medical device itself – on function, performance, regulatory approval, and time to market. The mobile carrier system often appears to be an accessory that can be selected or adapted at a later stage.

In practice, however, medical carts have a significant influence on usability, safety, and the overall perception of a system. Many of the associated risks do not arise from a lack of experience, but from project logic: clear responsibilities, parallel development streams, and the attempt to reduce complexity.

This document outlines seven recurring mindset patterns that repeatedly appear in projects involving medical carts. It addresses experienced product managers as well as project leaders and pursues a clear objective: to sharpen familiar assumptions, make implicit decisions visible, and enable structured reflection.

Mindset Pattern 1

"The cart is just an accessory – we'll take care of it later."

The medical cart is treated as a downstream component.

Context

This assumption is widespread in projects involving medical systems – and understandable. The primary focus is placed on the medical device itself. The cart is viewed as a secondary component.

Typical Assumption

The medical cart has no significant influence on the overall system and can be considered later.

What Happens in Practice

The cart is often the physical interface between user and medical technology. When addressed late in the project, many system-relevant parameters have already been defined.

Possible Consequences

+ Limited ergonomics
+ Additional coordination loops
+ Late-stage modifications with time and budget impact

Reflection Prompt for Project Leaders

At what stage in the project is the medical cart considered part of the system – and which decisions have already been made at that point?



Mindset Pattern 2
"Modularity automatically means flexibility."

Modularity is understood as a building-block principle –
not as system rchitecture.

Context

Modularity is a proven principle in medical technology. It promises adaptability, scalability, and product variety. It therefore seems logical to assume that individual modules or components can be combined independently.

In practice, this mindset often emerges when modularity is confused with interchangeability – especially in projects involving multiple suppliers or interfaces.

Typical Assumption

Individual components can be flexibly combined without fundamentally affecting the overall system.

What Happens in Practice

When modules from different origins are combined without systemic consideration, functional discontinuities arise. Mechanics, ergonomics, stability, and operating logic no longer integrate seamlessly.

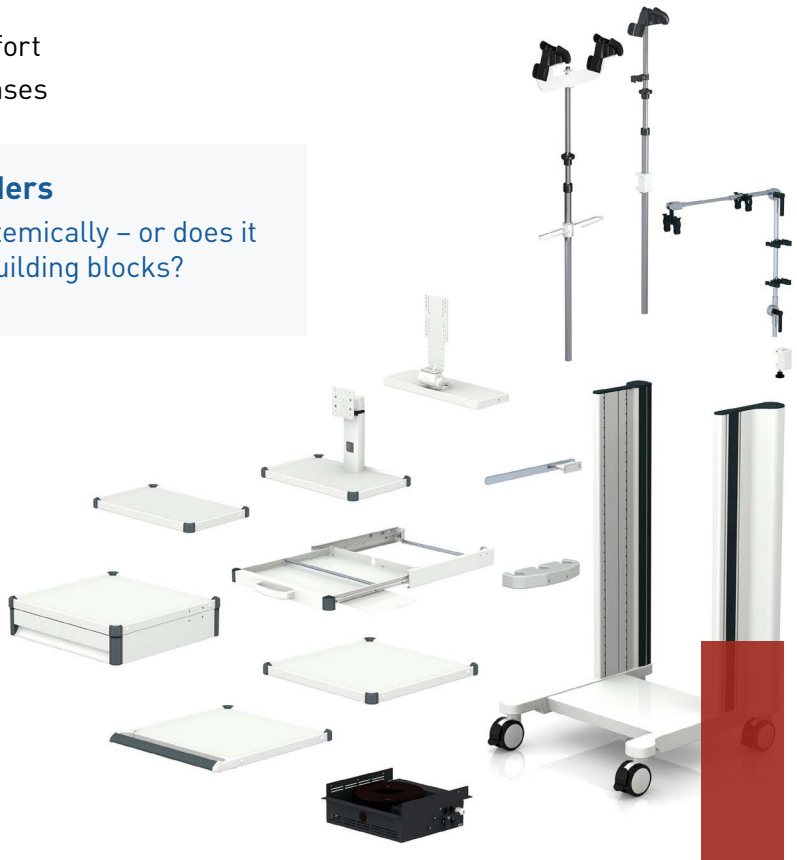
What appears reasonable at component level can create instability or increased validation effort at system level.

Possible Consequences

+ Unstable configurations
+ Additional testing and coordination effort
+ Limited scalability in later project phases

Reflection Prompt for Project Leaders

Is modularity in the project defined systemically – or does it only result from combining individual building blocks?



Mindset Pattern 3
"Regulatory standards only apply to the medical device."

The regulatory system boundary is defined too narrowly.

Context

Regulatory requirements are understandably associated primarily with the medical device itself. The cart is often perceived as passive accessory.

However, this perspective becomes insufficient once multiple components operate together in a clinical environment.

Typical Assumption

As long as the medical device is compliant, the cart is regulatorily secondary.

What Happens in Practice

Once carts, support arms, or mounting systems become part of the application system – especially in customized configurations – the regulatory system boundary shifts.

This shift is often recognized late, after design or integration decisions have already been made.

Possible Consequences

+ Retrospective and potentially costly testing
+ Additional documentation effort
+ Project delays or postponed market entry

Reflection Prompt for Project Leaders

Is it clearly defined in the project which components are regulatorily part of the system – and from which point onward?


F-017
Version 012

Technical Report
TR 029-2022

Client: ITD GmbH, Lilienthalstraße 19, 85579 Neubiberg

Order code: Mr. Hager – Director Global Engineering

Location of tests: ITD GmbH - Test laboratory, 84381 Johanniskirchen

Date of tests: 14.07.2022

Revision of the test: 001

Language of the original report: English

Standard sections:

Subject of evaluation: Are shown in blue — PT.0291.000 base – die casting

Standard basis: PT.0291.000 base – die casting from Touch Point Medical (Supplier: Superior Die Cast LLC) DIN EN 60601-1 (VDE 0750-1) Medical electrical equipment- Part 1: General requirements for basic safety and essential performance IEC 60601-1:2005 + Cor.:2006 + Cor.:2007 + Cor. 2010 + A1:2012; German Version EN 60601-1:2006 + A1:2013.

Task of the appraisal: Proof of conformity to the above mentioned standard.

Summarizing result: The tested bases safely fulfil the required 6-fold safety.

Reference to risk analysis: The application of risk management to medical de... According to EN ISO 14971:2022 has been ... includes the requirements of IEC 60601-1 fr... section 9.8 Mechanical hazards due to supp... under 9.8.1 General.

Test Engineer: Christian Kerscher, Quality Management & R.A.

Signature and date:

Review approval: Gerhard Burneder, Dipl. Ing., Director Quality & R.A.

Signature and date: 22.07.202...

This Technical Report may only be reproduced in its full version. It contains the result of a unique examination of the produ... for inspection and does not represent a generally applicable evaluation of characteristics from the running production or s... requirements of EN 60601-1 are discussed in the risk management file of the respective product. If the report is translated int... a reference to the translation must be made. The original version of this test report, inclusive of signatures, will be stored in the ... office in Johanniskirchen.

Printed copy is not subject to change management.

Mindset Pattern 4
„Design is secondary as long as the function works.“

Design is considered functionally – not systemically.

Context

Functionality understandably takes priority in technical projects. Design is often viewed as a downstream discipline. In clinical environments, however, this separation is insufficient.

Typical Assumption

The design of the cart is secondary as long as the function is fulfilled.

What Happens in Practice

In daily clinical use, the cart often shapes the first impression of the entire system. It is visible, present, and part of perceived quality – independent of the technical performance of the device.

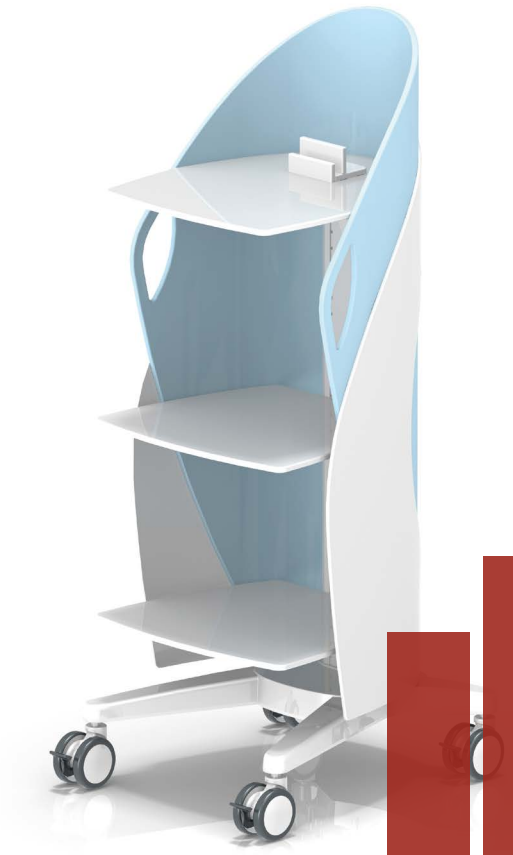
Here, design is not decorative. It structures, guides, and builds trust.

Possible Consequences

+ Inconsistent appearance
+ Lower perceived value
+ Weaker differentiation in the market

Reflection Prompt for Project Leaders

Is design understood as an integral part of system impact – or merely as an outer shell?



Mindset Pattern 5
„Cable management is mainly about tidiness.“

Cables are treated as a detail – not as a usability topic.

Context

Cables are often regarded as a necessary detail that can be “tidied up” at the end of a project. In clinical reality, however, they play a much more significant role.

Typical Assumption

Nicely routed cables are primarily an aesthetic issue.

What Happens in Practice

Cables affect hygiene, safety, and usability. They are pulled, overlooked, cleaned, or repurposed – often under time pressure and in confined spaces.

What is not systematically planned becomes a risk in daily use.

Possible Consequences

+ Tripping and tension hazards
+ Difficult cleaning procedures
+ Increased risk of damage

Reflection Prompt for Project Leaders

Is cable management considered a safety and usability topic within the project – or just a final detail?



Mindset Pattern 6
„Unit price is the most important cost factor.“

Economic evaluation is reduced to purchase price.

Context

Unit price is measurable, comparable, and easy to evaluate in procurement. It therefore carries significant weight in early decisions. However, this perspective neglects the system context.

Typical Assumption

A low-cost cart reduces the overall cost of the system.

What Happens in Practice

The cart is part of a broader system with recurring costs: integration, logistics, service, customization, and scaling.

These costs do not occur once – they accompany the system throughout its lifecycle.

Possible Consequences

+ Higher total cost of ownership
+ Limited reusability
+ Reduced economic efficiency during scaling

Reflection Prompt for Project Leaders

Is the cart evaluated as an individual purchase price – or as part of overall system cost?



Mindset Pattern 7
„Clinical use is self-explanatory.“

Clinical use is implicitly assumed.

Context

Many decisions are made from a technical perspective. Clinical use is often implicitly considered. Real-world hospital environments, however, are more complex.

Typical Assumption

Users will intuitively understand the system and adapt to it.

What Happens in Practice

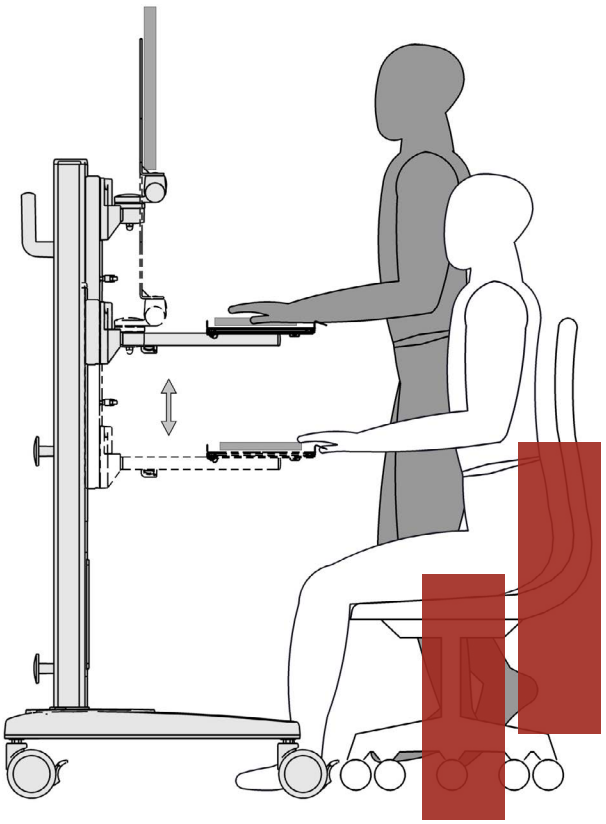
Clinical workflows are time-critical, highly variable, and operate under significant pressure. Systems not designed around real usage are bypassed or used inefficiently.

Possible Consequences

+ Workarounds in daily practice
+ Reduced acceptance
+ Limited benefit despite technical quality

Reflection Prompt for Project Leaders

How well are real usage scenarios and physical interaction truly understood – beyond assumptions?



Conclusion

The mindset patterns described rarely result from lack of knowledge. Rather, they emerge from complex project structures, time pressure, and functional division of responsibilities.

Precisely for this reason, it is worthwhile to consciously question these assumptions early. Not to fundamentally rethink projects, but to make system-relevant decisions at the right time – before their consequences become visible in field operation, audits, or during scaling.

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This orientation paper is based on experiences from numerous medical cart projects with Medtech OEMs.

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Expert talk »
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