MEDLINE® CARELINE®
IMPROVING EFFICIENCY IMPROVING EFFICIENCY

Application Design Recommendations
User Manual

Contents

Introduction

The purpose of this document is to support salespersons when designing and developing applications powered by LINAK MEDLINE® & CARELINE® systems. The systems consist of LINAK products and can interface with third party equipment.

This document supports the OEM risk management process by informing about technology, principles and design characteristics in a LINAK system.

Definitions

CARELINE®	Together with MEDLINE, CARELINE represents one of the four LINAK market segments. CARELINE is covering bed applications for the healthcare market: homecare, nursing home and hospital.
MEDLINE®	Together with CARELINE, MEDLINE represents one of the four LINAK market segments. MEDLINE is covering all healthcare applications for the healthcare market, excluding beds for homecare, nursing homes and hospitals.
Control	The control that a user of the final application is using to change functions or move the application with. A control can be either analogue, Bluetooth® or OpenBus™, connected to an input on a control box.
Control box	A LINAK MEDLINE & CARELINE control box, typically named COxx, CAxx or CBxx.
Actuator or column	LINAK actuators and columns.
Accessories	Accessories refer to LINAK products like lights and weighing systems.
Digital services	Digital services are services connected to LCi or available in LINAK developed web services.
LCi™	LINAK Communication Interface.
OneConnect™	OneConnect is a part of LINAK digital services.
LCi Client	The LCi Client describes a product or component that connects to LCi.
User Manual	Describes how to use LINAK products. Newest version can be found at LINAK.com.

General

System and application design

LINAK designs and manufactures components that can be used in a combination to create a system that application manufacturers can use for their final medical product.

The application manufacturer and designer are always responsible for testing and verifying that the components delivered by LINAK meet the application requirements. As an example, this also includes forces, IP degree and movement etc.

The application manufacturer and designer are responsible for the application risk management and any mitigating actions needed.

This document is intended to serve as an input for the application design phase and to support LINAK salespersons when identifying and handling risks in applications.

This document does not replace the standard LINAK user manual and residual risk documentation, but must be seen as a recommendation and a natural supplementary.

Intended use and limitation

LINAK MEDLINE & CARELINE products and systems are intended to be used for healthcare products.

The systems are not intended to be used for distributing, transporting or monitoring vital signs and personal data.

IP degree

The IP degree on LINAK products is following standard IP ratings combined with unique LINAK versions of the IPX6 rating, for instance Washable and Washable DURA™. See user manual for specific descriptions.

The IP degree is guaranteed when a system is not moving and when products are mounted in accordance with the user manual.

Duty cycle

The duty cycle printed on the product label of for example actuators or control boxes must always be observed. If this is exceeded, there is a risk that the product becomes overheated and damaged. Unless otherwise specified on the label, the duty cycle is 10% or max. 2 minutes in use followed by 18 minutes not in use.

Risk Management

As a leading manufacturer of actuator systems for the healthcare industry, LINAK always performs evaluations of risks related to using LINAK components in final medical equipment.

The LINAK system handles most potential risks that can lead to unintended movement of an actuator system in case of error. The remaining residual risks, that must be evaluated and handled by the application manufacturer, are presented in generic documents divided into product groups: Actuators, Lifting Columns, Control Boxes, Controls, Accessories and Batteries.

These generic documents are named 'Disclosed information for safety and significant risks' and can be requested by contacting your usual LINAK sales contact.

Actuators and columns

Load

The nominal load stated on the actuator label is the dynamic load that the product is designed to lift/push/pull.

If this load has been exceeded either dynamic or static, the product is allowed to fail in a safe way.

Safety nut

Actuators can be fitted with a safety nut. This is an auxillary nut, moving with the main nut and supporting the load if the main nut breaks down.

When the safety nut is active, the actuator will continue to function but only in the specified direction of the safety nut.

An actuator with a safety nut fitted in push mode will only have the protection of the safety nut in a push application. Actuators with a safety nut in push mode will often be used for patient lifts and beds.

The safety nut fitted in push mode can be supplied with many different types of LINAK actuators (see the different actuator ordering examples).

Safety factor

The safety factor is stated in the data sheet. The safety factor is a static load.

Example of safety factor on an actuator with push 10,000 N/pull 2,000 N.

Safety factor test:

1 hour with static load (incl. safety factor)

- Actuator fully extracted
- No collapse is allowed, but drifting inwards/outwards is accepted

Safety factor test is 1 x 1 hour.
Actuator fully extracted.
Static constant load.
No collapse allowed, inward movement is acceptable.

Voltage

LINAK actuators and columns are usually available as 24 V or 33 V versions. In some cases, also as 12 V versions.

For LINAK control boxes and systems, the product data sheet tells which version to use. Never use 12 V motors for LINAK control boxes.

Spline

An actuator with this feature is only capable of pushing, not pulling, i.e. when the piston rod is extending. This is a safety feature which in a bed frame (e.g. foot rest) will prevent injury should a limb get caught between moving parts as the actuator is retracting.

Spline types

Mechanical splines:

When the actuator is pushing, the spindle nut is fully engaged in the piston rod and the actuator will push with full force. If the actuator tries to pull then the spindle nut will disengage from the piston rod. Therefore, the piston rod cannot pull with any force.

The actuator positions of LA31, LA28, LA30 and LA32 cannot be trusted when the mechanical spline has been activated, as these spindles are not guided in the inner tube.

The mechanical spline will drop to the position of the nut carrying the piston rod. As example this means that if an obstacle is hit and the mechanical spline is activated and the user continues to drive inwards, the part of the application that has been blocked by the obstacle will drop to the spindle nut position when the obstacle is removed.

Ratchet spline:

The ratchet spline is also a mechanical type of spline, but with that benefit that it will not drop when an obstacle is removed.

If the ratchet spline is combined with Hall feedback, then this must be considered when designing software.

Ratched spline combined with a software-controlled control box enable IRS™ functionality that can be programmed to a selected functionality when ratchet spline is active.

Electrical spline:

The electrical spline feature shuts off power to the motor when the pull force activates a microswitch built into the product.

Push to pull movement

If repeated dynamic push-to-pull movements are essential for the application, perform tests to validate the performance, and contact your LINAK contact person for support.

Quick Release with damper

Selected quick release (QR) actuators can be equipped with an internal damper mechanism. The damper inside the actuator provides a slower lowering speed compared to the normal QR lowering speed.

When the QR is activated, with the existence of a certain amount of push load, the spindle rotation speed will engage the damper mechanism and will start a slower lowering. The speed of the activated damper will be load dependent and the damper is only acting as an extra friction when QR-lowering is activated.

Self-locking

Self-locking is an expression for the ability of actuators or lifting columns to stop and hold the rated load on the product label. Self-locking applies for both push and pull.

To obtain the specified self-locking ability, the actuator must be connected to a LINAK control box, as LINAK control boxes are designed to short-circuit the motor terminals of the actuator or column for minimum 20 seconds after the actuator movement stops.

When stopping the actuator or column, it is allowed that the column or actuator moves 'one spindle pitch' before self-locking is obtained.

Mounting

Mounting of actuators and columns must always be in accordance with user manual and data sheet.

Always pay attention to allowed sideload, bending moment, alignment etc.

Flammability

Consider flammability requirements for the application. Data sheets for LINAK products state the UL94 flammability class.

Feedback

Feedback types

When designing applications, where the position of the applications or parts within the application are considered critical, the robustness of the different feedback types must be considered. There are several examples of this listed below, but the OEM is always responsible for these considerations when designing an application and handling the application risk management:

- It can be inconvenient or even harmful if the application can move to a position where the user is squeezed or situated in a position that is not natural for a human body.
- Mechanical collision can occur or the application can even collide with the floor, chairs or a windowsill.

General

Overload of actuators can cause drifting. If the actuator drifts due to overload or other external forces, the control box will not be able to detect the change in most cases as the control box will not be powered and monitoring the feedback signal. This applies for systems with relative positioning.

Replacing actuators and columns with feedback should be followed by an initialisation of the replaced part.

Position accuracy should be considered to be 'one spindle pitch', e.g. LA40

with 4 mm spindle pitch = 4 mm accuracy.

Missing feedback pulses from Hall feedback will result in a 'balance error'. This can have different causes. As an example, defective cables between control box and actuator/column or defective electronics can cause a balance error. This error will cause the system to enter 'position lost state'.

Digital Hall

Relative positioning

The difference between single Hall and dual Hall is that dual Hall includes the direction. With single Hall, the control box counts pulses in the expected movement direction of the actuator or column.

Digital Hall is pure positioning feedback to the control box.

Broken cables etc. can cause an inaccurate position as the control box cannot detect the difference between error and end stop, causing the channel to initialise.

Dual Hall encoded

Relative positioning

Same dual Hall principle as dual Hall digital, but one of the feedback signals also contains information about end stop status.

More robust than digital Hall. An unplugged or broken cable will be detected immediately, not causing false initialisation.

Potentiometer

Absolute positioning

A potentiometer is changing resistance depending on the actuator or column position. The change in resistance is used for calculating the position. Usually chosen due to absolute positioning.

Lower accuracy than dual Hall feedback. To be tested and verified in the application.

Normally used in combination with Quick Release to keep the correct position when the actuator is moved unpowered.

End stop principles

Power switch

Stand-alone end stop system integrated in the actuator. If power switch is combined with dual Hall digital, the control box detects end stop when both Hall signals are missing or not changing.

End stop is usually detected when end stop is reached. The following cases will be seen as end stop: broken cable, unplugged cable or e-spline.

It will cause wrong positioning if the triggered end stop is the end stop used for initialisation as the channel will initialise not being at end stop.

Power switch end stop is remembered until power-down. After power-down, the movement needs to be reactivated to detect the end stop.

Signal switch

Signal sent to the LINAK control box.

The control box stops the actuator movement.

Encoded

The voltage level on feedback signals indicates if end stop is reached, and the LINAK control box stops the actuator movement.

If an actuator or a column is not connected, and the channel is activated, this will cause fatal error.

Control boxes and hand controls

Analogue

Analogue control boxes are ideal for applications where a limited number of accessories is needed and where there is no need for software functions and/or feedback.

Analogue systems are controlled with analogue controls. Analogue controls are controlling which channels are activated, and the control box will run the actuators if the required movement is possible with respect to available power, half-bridge technology or movement limitations.

Consider the risk of a moving application into positions that are not wanted. This must be done both with one or more keys activated.

Analogue control boxes do not have any actuator-specific current cut-off.

OpenBus

OpenBus™ control boxes are software-controlled systems with high customisation possibilities.

If multiple OpenBus controls are connected to the system, the control box cannot differ which OpenBus control the commands origin from. The OpenBus control box simply reacts on the command received.

If two buttons are activated, causing an illegal key combination, the movement stops, and when one of the keys is released, the function operated by remaining activated key will continue.

Invalid OpenBus commands or combinations hereof will result in a stop of the function and/or movement.

Power consumption on OpenBus network: 200 mA on both 8 V and 40 V supply is available. This is usually no challenge, but for large systems with multiple OpenBus controls, accessories, weighing solutions etc. the LINAK sales support must be involved to perform the power calculation.

Analogue controls are an absolute no go for OpenBus systems as they will cause failure and damage to the system.

For OpenBus and LCi™ power calculations, please see calculation template in Chapter 4.

Always consider voltage drop in larger systems with long OpenBus cables and many connections. If in doubt, contact your usual LINAK contact person.

Bluetooth

LINAK Bluetooth® is optional or included in most control boxes.

Bluetooth has several functions in a LINAK system. It can be used for Bluetooth controls, time counting and is enabling LCi as interface.

Control boxes and Bluetooth controls can be paired by using direct paring. See User Manual.

A control box software can be programmed to only accept the application manufacturers custom LINAK Bluetooth controls. In this way, the application manufacturer can control which Bluetooth controls that can be paired and used for controlling and moving the system. This can be beneficial for both commercial aspects, but also for the application designer in relation to the application risk management.

LINAK does not limit the Bluetooth range. LINAK Bluetooth controls are designed to transmit with full power. This is due to the lack of foreseeing local wireless noise environments and to ensure that the Bluetooth control will be able to connect and control the system. This needs to be considered in the application design, and potential actions must be taken by the application designer to mitigate potential identified risks.

Bluetooth controls can transmit to the LINAK control box if they have low battery. The application designer can decide in the control box software whether and how this shall be used in the application.

SMPS and power management

Most LINAK control boxes are either powered by Switch Mode Power Supply (SMPS), 120 V - 240 V or battery-powered. Often a combination hereof is used, either having the battery as backup battery or as main power source.

Batteries used in LINAK systems must be LINAK batteries. LINAK system power management can be divided into two:

actuator power management and system power management.

Actuator power management

Is available in software-controlled control boxes. It is used to get the maximum power out of the available SMPS or battery power to get the optimal split between lifting power and speed.

Where high lifting capacity is needed, the actuator power management will reduce the voltage and increase the current to lift the high load.

System power management

Is used to balance the power available for actuators, power for third party devices and battery charging.

The priority is the following:

By default, the accessories have the highest priority.

Battery charging is of second priority.

Actuator and column operation have the lowest priority.

The priority is not 'either/or', but shows that power can be limited for actuator or column movement, if constant power is drawn from the system by other devices.

Power request safety concept

The LINAK system technology platform includes a unique safety concept consisting of two separate circuits - data and power request. Both data and power request need to be active to run a function. This reduces the risk of unintended movement to an extremely low level, increasing the safety of the application.

The power request safety is approved by UL in accordance with IEC60601-1 and applies to the entire LINAK system with all products. When an application manufacturer uses own controls to operate the LINAK system, either through analogue converters (like ABL, ACK, AOC etc.) or through system control by means of LCi, then the manufacturer must evaluate the risk in their application risk management and the potential need for applying standards like IEC62304 and similar.

Full and half bridge solutions

Full bridge control boxes can control all channels independently in all directions at the same time.

Half bridge control boxes have limitations between pairs of channels. The pairs of channels can only move in the same direction when operated simultaneously.

Means Of Protection

Medical devices must incorporate one or more Means Of Protection (MOPs) to isolate patients and operators from the risks of electrical shock. A MOP can be safety insulation, protective earth, a defined insulation distance or other protective impedance. These can be used in various combinations.

As of IEC/EN 60601-1 3rd edition, the standard differentiates between the risk to patients and the risk to operators: Means Of Patient Protection (MOPP) and Means Of Operator Protection (MOOP). The main difference between one MOOP and one MOPP is primarily the permissible creepage and clearance distance. Both requirements are satisfied using basic insulation. It is up to the medical device manufacturer to decide whether the equipment only requires MOP for the operator (MOOP) or whether the more stringent patient levels are required (MOPP).

If the manufacturer decides MOOP is enough, he will have to back up his reasoning with a risk asessment as per ISO 14971 which examines how likely it is that a patient will come into contact with the equipment.

Insulation class, class 1 and class 2

Many COXX control boxes have a fuse in the mains connection in both PE and N.

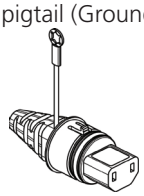
COXX control boxes have 2 Means Of Patient Protection (MOPP) in the power supply.

Class 1

Class 1 applications, using Class 2 control boxes, must be equipped with a pigtail mains cable. Otherwise, use a control box with internal protective earth. The earth connector of this control box must be connected to the frame.

Example:

IEC60320-1 C17
with 330 mm
pigtail (Ground)



Maximum 200 mΩ between mains plug PE and all application parts, if the application power supply cord is non-detachable. The LINAK power cord is non-detachable when mounted in the control box with a locking ring.

Class 2

To obtain Class 2, simply just use a LINAK power supply cord without pigtail.

MOPP class of products

If products with 1 or 2 MOPP are combined in a system, the system will fulfill the MOPP requirements. If products with 'no MOPP' are used in the system, the following simplified rules can be used:

- it must be the only 'no MOPP' in the system and the resulting touch current must be below 100 µA in normal condition or
- it must be the only 'no MOP' actuator in a system where all other actuators are minimum 2 MOPP or
- the OEM must be able to mitigate the risk that an operator or a patient can be in contact with two 'no MOPP' actuators at the same time (this can be mitigated by covers, distance etc.) in his risk management.

2 MOPP:

- LA31, LA40, BL1, LA23, LA20, LC1

1 MOPP:

- LA34 (reinforced composite version C and D), LA27, LA44, LC3 (for version with mains through contact LINAK), LA24

No MOPP:

- LA28, LA30, LA42

Electrostatic discharge

1. Handling and mounting of ESDS devices

- Handling of sensitive components only takes place in an ESD Protected Area (EPA) under protected and controlled conditions.
- Wrist straps and/or conductive footwear (personal grounding) are always used when handling ESDS devices.
- Sensitive devices are protected outside the EPA by the use of ESD protective packaging.

2. Responsibility LINAK/Customer

- ESDS devices must under no circumstances, during transport, storage, handling, production or mounting in an aplication, be exposed to harmfull ESD.
- LINAK can only guarantee the lifetime of ESDS devices if they are handled in the same way from production at LINAK A/S until they are mounted in the manufacturers application. It is therefore important that the ESDS devices are not removed from the ESD protected packaging before they are within the EPA area at the customers premises.

EMC responsibilities

(in relation to a LINAK actuator system)

LINAK verifies the EMC performance of individual LINAK products and approves them individually. The LINAK products can be combined with various systems. LINAK also verifies the EMC system performance and the EMC performance on commonly used combinations.

LINAK holds certificates according to the applicable standards for the individual product and provides the customer, who is building the application and who is incorporating these products into systems (systems with control box, actuators, cables, batteries etc.) with these certificates. EMC testing of LINAK products in generic LINAK systems does however not correspond to a specific application environment which differs from the generic testing made. There will be differences which can affect the EMC performance in the specific target application.

The customer is responsible for qualifying and approving the complete application including the LINAK system.

Regulatory

LINAK products, being components to be incorporated by a manufacturer [definition: IEC 60601-1 ed.3.1, cl. 3.55] into Medical Electrical Equipment [definition: IEC 60601-1 ed.3.1, cl. 3.63], are tested in relation to EMC phenomena according to the Collateral Standard IEC 60601-1-2 ed. 4.1.

IEC 60601-1-2 ed. 4.1 sets forth the requirements for the electromagnetic compatibility of Medical Electrical Equipment, ensuring that devices operate safely and effectively within their intended environments. Compliance with this standard is essential to minimise electromagnetic interference and maintain the integrity and performance of Medical Devices.

Furthermore, IEC 60601- 1-2 ed. 4.1 states:

'*This collateral standard recognizes that the Manufacturer has the responsibility to design and perform Verification of Medical Electrical Equipment and Medical Electrical Systems to meet the requirements of this Collateral Standard and to disclose information to the Responsible Organization or Operator so that the Medical Electrical System will remain safe throughout its Expected Service Life.*'

Qualification process of a new application

The qualification process of a new application usually takes place in a cooperation between the customer and LINAK. LINAK provides the relevant support, competence and documentation needed for the customers' overall development plan and test plan for the specific application. The driving force of the qualification process is the customer who has the ultimate application responsibility (MDS).

The customer identifies and specifies the needed testing based on many different parameters (experience, risk management, requirements from standards etc.). In many cases, the customer is establishing and verifying tests early in the project to ensure that the approval process has a low risk of failing when tested in the approval institute. This is also recommended in the user manual on the LINAK.com homepage.
The customer chooses which tests to identify and when these need to be performed in the project to reduce the risk of failure in the approval process also including the EMC testing.

Battery and Power Communication Port

PCP compatibility

The Power Communication Port (PCP) is designed to meet the increased demand for additional channels, power to third party devices and battery operation.

No power can be drawn from the PCP network without agreement from LINAK or by using a LINAK product for third party power, for example a USB charger.

The connections and cable lengths of the PCP network must be kept to a minimum to avoid voltage and power loss in cables and connections, as this can cause unwanted system shutdown or slow speed of actuators and columns. If any questions, contact LINAK sales support for review of the system wiring.

Battery port/ no PCP

No communication between connected devices.

Products like CO53 and CB6SMK2 combined with BA18.

PCP 1.0 (analogue)

PCP 1.0 (analogue) is an analogue power interface between a control box and battery. It is only a power signal that tells if for instance a battery is connected. There is no data exchange happening.

Products like CA30, CA40 combined with BA16, BA19.

PCP 2.0 (digital)

PCP 2.0 (digital) is a digital channel between multiple devices such as control boxes and batteries. With PCP 2.0 it is possible to exchange data between devices where you will be able to receive information about for instance device status details (e.g. BA22) or use the channel to operate an actuator (LA42).

Products like CO61MK2, CA63 combined with BA19, BA22. Also compatible with PCP 2.0 products like LA42, PJ2.

Batteries in general

User manual and data sheet must be carefully read and observed when handling and using batteries in an application.

Lithium batteries

See special considerations in the LINAK User Manual.

Charging

For lithium batteries, the LINAK system only charges the battery to full if the battery level is below 80%. This to avoid increased wear and increase the lifetime on the lithium cells inside the battery.

Designed vs rated capacity

It is important to understand the difference between designed and rated battery capacity.

Rated capacity: refers to the capacity stated on the product label. The rated capacity represents the capacity that can be discharged from the battery if neither power management nor battery monitor system was active.

Designed capacity: refers to the capacity that can be used for movement and operation of the manufacturer application. The designed capacity is settled in respect to the minimum voltage to operate the system and to protect the battery from damage.

Depending on battery type and technology, the difference between designed and rated capacity will be different. A ballpark indication of the ratio between designed and rated capacity is:

Lead acid batteries: designed capacity is 30% of the rated capacity

Lithium batteries: designed capacity is 80% of the rated capacity.

Multiple batteries in a system

Some lithium batteries support multiple batteries in the same system. This will increase the total battery capacity. The feature is called 'stacking'. Please see the combination overview in the Power Communication Port chapter.

When stacking batteries in a system, the following rules apply:

2 batteries

These batteries can be connected without a PJB4 in the system. Always mount the batteries as central as possible in the PCP network to ensure an equal current draw and minimise voltage drop.

3 batteries

Connect the batteries to PJB4 with equal cable length. Use the shortest possible cables, both when connecting batteries and when connecting other PCP devices.

When multiple batteries are used in the system, it automatically assigns an ID to the battery, and the battery capacity read out of the control box will show the toatal capacity of all batteries in the system.

Software

General

Analogue systems do not contain software and can therefore not be changed in functionality.

Each control box software is designed to accomodate the functionality requested by the OEM. The OEM is responsible for verifying that the developed software meets the requested functionality.

LINAK is verifying that the software works according to LINAK specification. LINAK cannot verify that the specification is actually optimal and correct for the respective application.

The OEM is responsible for verifying the software.

Maintenance

LINAK constantly improves and expands the embedded software that is used in LINAK control boxes, controls, batteries, accessories etc.

LINAK provides software and framework updates when it is considered to be of importance for the products. By default, products in field are never updated.

Actuator setup

Each software is developed to work with the chosen/specified actuators/columns. Therefore, systems cannot be built with other parts/products than specified and intended for operation.

The software is built to work with the selected end stop principles, feedback, feedback resolution and current cut-off – therefore unexpected behaviour and potential malfunction can occur if other actuators/columns are connected to the specified channel.

Current cut-off

When selecting a certain actuator or column, a current cut-off is implemented in the software. The current cut-off is not an overload protection and application safety cannot rely on this.

Current cut-off protects the electronics and secures that the actuator can start movement.

Manual mode

Is often a helpfull feature that allows production and service professionals to operate applications beyond the normal allowed movement patterns that can usually be restricted to parallel movement or limited by limit lines.

The manual mode is usually entered by a specified action of the OEM or by using a designated service control (that operates with different commands as opposed to the normal OpenBus™ or Bluetooth® control).

This ensures that a system can be initialised in case of errors or actuator replacement.

Continual activation

Using impulse-drive functionality in a LINAK system supports that movements can be started by a keypress and move without active keypress to a certain position or for a specified amount of time. The use of the impulse-drive functionality requires that the application manufacturer considers risks related to continuously activation according to IEC60601-1. Also, specific requirements in particular standards need to be evaluated before the function is used.

Movements and functions

Movements are handled by different functions in the control box software and can, either alone or combined, move the application according to the OEM request.

Soft start/stop

- Soft start and soft stop ramps up/down the speed to make a smoother operation.
- At normal operation and memory operation: soft start and no soft stop.
- If stop at end stop switch: no soft stop.
- LIFT™ has soft stop as option.

Initialisation

Systems with relative feedback need to be initialised after the system has been assembled, reprogrammed or a part has been changed in the system.

The initialisation direction is specified in the software and can either be when the actuator is in outermost or in innermost position.

Considerations are to be made when deciding on how and when the initialisation shall happen:

- Initialisation is always recommended when the actuator is fully retracted.
- It may be necessary to initialise in the extracted position, if the application or mechanical limitations in the application are restricting or in case that damage may happen if initialising with an inwards moving actuator.
- When operating actuators or columns in parallel, it is extremely important to consider error scenarios for initialisation and feedback system. See semi-parallel and 'stiff application' movement description.
- Only initialise parallel and stiff application movements when both are at end stop.

Software disclaimer

The general LINAK MEDLINE & CARELINE software disclaimer must be accepted prior to software release. The disclaimer states the liability and responsibility for software that LINAK has developed for an OEM.

The software disclaimer will be approved through the OneConnect portal.

Software approvals

The LINAK software development process is certified according to IEC62304, Class A.

If an OEM requests IEC 62304 compliance, contact your LINAK sales support to handle the procedure and determine how to obtain traceability as to risks and requirements.

IEC62304 compliance must be requested before project start.

System considerations

Quick release

If the OEM identifies critical movements or positions, these must be handled by the application risk management. If the actuator is to be moved despite a malfunction, this may be done by the use of quick release which allows the actuator to move without power.

If quick release is used on actuators with relative feedback, the control box can lose control of the actuator position and it will be necessary to initialise the system again.

Manual Lowering

For patient lift systems manual lowering can be chosen when ordering the actuator. This allows the user to lower the patient in case of loss of power.

Note that if manual lowering is used in combination with actuators with relative positioning (i.e. dual Hall), then the system needs to be initialised after use of the manual lowering.

LINAK Communcation Interface

General

LINAK Communication Interface (LCi™) is used by both LINAK digital services (like OneConnect™) or by third party products or systems.

LCi access is protected by an asymmetric key system that allows the OEM to control who can access their application.

The LCi terms and conditions apply for the use of LCi.

Specification

The LCi specification describes how the interface is used both as cabled (UART) and Bluetooth®.

The OEM is responsible for following the specification of LCi to ensure no malfunctioning of the system.

The specification needs to be combined with a secure key for the specific software and potentially also a set of metadata files.

Metadata

Metadata files are available for a range of selected LINAK products. The metadata files describe which data can be accessed and where to read them.

System control

System control allows the OEM to control the LINAK system through LCi.

Parallel to the LCi communication, the power request hardware signal must be activated. If the power request is not active, the system will not move.

The OEM is responsible for evaluating the risk for their own control, controlling the system.

LCi timing

When using LCi, it is important to consider the speed and timing of the interface when creating functionality in an OEM or third party LCi Client.

LCi client development

LCi requires significant programming expertise and a strong understanding of UART or Bluetooth communication.

LINAK can assist with basic LCi system design and can help plan how an LCi client will interact with a LINAK system but is unable to support, troubleshoot, or debug the UART or Bluetooth development itself.

Approvals and certifications

General

If LINAK must update a product approval, the customers often face renewal of their corresponding application approval.

LINAK constantly maintains and develops the product portfolio to stay in front as market leader, to stay competitive and to be able to secure the supply chain by using alternative components.

LINAK offers a wide range of products in the MEDLINE & CARELINE product portfolio. Most of these products are approved in accordance with 60601-1 and other relevant healthcare standards.

LINAK is delivering components for medical device manufacturers. The application manufacturer is always responsible for obtaining the needed approval of the application, where LINAK supports the manufacturer.

UL marking

If special articles are created with an X in the type code, the UL marking is usually not on the label. If needed, contact LINAK sales support, of the UL mark can be added.

Be non-specific

Before applying for a new approval, the customer should not be too specific in their documentation when specifying a LINAK item.

Since LINAK cares about customer satisfaction, the 'non-specific' terminology is introduced to support customers when applying for approvals.

LINAK items consist of an item number and an item name (the ‘ordering example’ in the sales backup and data sheet). These are both belonging to a certain product type.

Product types are for instance CO61, LA40, HB80, HB400 and more.

In many projects, the item number is special, thus the item name might also become special - to some degree.

The best advice is to apply for a product type, to cover all items as widely as possible within all items in that product group.

If this is not possible, the item name should be used instead.

In case this is not accepted by the test authority, then use the item number, having in mind that now the application approval and test report will only be valid for that specific item number.

This means that the reference should be as non-specific as possible.

Description of 'non-specific' product approval identification

When applying for approvals or renewing approvals in the future, LINAK will introduce what is called 'non-specific'.

'Non-specific' are options or features represented by letters or digits in the item name, but which are not related to safety of the product.

Safety-related topics are of course focus areas when updating approvals.

When applying for future approvals, LINAK will state as many 'non-specific' letters/digits as possible in our approval documentation. The intention is to reduce the number of updates required for our customers.

Critical component

A critical component is wording used at test houses for describing and identifying components that cannot be changed without reapproval.

Example

Below is an item example before and after introduction of 'non-specific', indicated by an asterisk, ' * '. The remaining characters are either safety-critical or related to the item name and can therefore NOT be left out when applying for an approval.

	Example
Combi code	HB2005V3410000 5B00362120N00000
'Non-specific'	HB200*****SSSS*****S******SSSS
Combi code for customer approval documentation	HB200*****0000*****6******0000

* is 'non-specific'

S is related to a listed critical component in the product, and cannot be left out.

Combination code overview can be found in Appendix 1.

Recommendations

LINAK recommends customers to be less specific when applying for their application approval and to apply for appliction approvals using the 'non-specific' terminology.

It could potentially keep after sales approval maintenance cost as low as possible.

The current LINAK test house, Underwriters Laboratories, has pre-acknowledged the use of 'non-specific' in general. However, the terminology will of course be evaluated case by case.

APPENDIX 1

Actuators

LA20
LA20******SS***S*S****S*S*S***
LA23
LA23*****S**SS
LA24
LA24**********SS**********S**SSS
LA27
LA27****SS****SS*
LA27******S**SS****S*****S***SS
LA28
LA28*****S****SS*
LA31
LA31***S*S**SS*
LA31**S***SS****S**S***SS
LA32
LA32*****S****SS*
LA34
LA34*****S****SS*
LA40
LA40******SS***S*S*********SS*S*
LA42
42******SS***S*S**********S****

LA44
LA44******S****SS*
LA44******S***SS***S****S***SS
KA30
KA30******SS***S*S**********S**
KA19
KA19******SS***S*S**********S**

Lifting columns

BL1
BL1*S**SS******
LC1
LC1******SSS********S*S**SSSS
LC2
LC2****S*******
LC3
LC3******SSSS*******S*SS*SSS

LIFT

COL50
COL50*S*SSSS******S
BAL50
BAL50*SS**S****
CHL50
CHL50*SSSSS**SSS

Control Boxes (CO41, CO53, CO61, CO65, CO71, CA63 etc.)

COS**S*SS**SS*S

Accessories

PJ2
PJ2**S*SS**SSSS
PJB4
PJB4*SSSSSSSSS
OPS
OPS**S*SS**S*SS
SLS
SLSS**********
MJB
MJBSSS****S**S*
UBL2
UBL2S**S***S***SSSSSSS
UBL3
UBL3S******S****SSSSSSS
UBL4 Motion
UBL4MS********S****SSS
USB-A
USBAS*SS**
QLCI2
QLCIS**SS*SS

Batteries

BA16
BA16*S***SSS
BA18
BA18*SS*S*SS
BA19
BA19*S****SS
BA21
BA21*S******
BA22
BA22*S***S**

Controls

HB20
HB2**********
HB70
HB7*S*****S****
HB7********SSS-**SSSSSS**S*SSS
HL70
HL7*S*****S****
HL7********SSS-**SSSSSS**S*SSS
HB80
HB8*S*********
HB8********SSS- **SSSSSS**S*SSS
HL80
HL8*S*********

HL8********SSS-**SSSSSS**S*SSS
HD80
HD8*S*********
HD8*******SSSS- **********S*SSS
ACC
ACC********SSS-*SSSSSSS**S*SSS
ACO
ACOS*****+**S**
ACO*******SSSS-**SSSSSS****SSS
ACK
ACK**********
ACT
ACTSSSS*+***** FS********
FSE
FSE*****S* IROS**SS****
DPH
DPH Series
DP
DP1*********
HB30
HB3********S-*****S*SSS
FS3
FS3****S*SSSSS-***SSS*S**S*SSS
HB100, HB190
HB1********SSS*****S******SSSS
HB200

HB200*****SSSS*****S******SSSS
ABL
ABL***SSSSSSSSS
HB400
HB400**********S-**SSSSSS**S*S
SCO
SC01********

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