Technical Report for Functional Safety

Report No.: SHFS260400028671

May.15, 2026

Client / Applicant:	[redacted] CHINA
Project Title:	ELECTRIC POWER BICYCLE
Module No.:	E-BRO
Tested Standards:	EN ISO 13849-1:2015 + 2023, EN ISO 13849-2:2012
Conclusion	In this report, the safety protection functions (Please refer to the summary of assessment part in the report) of Electrical Control System for EPAC system have been assessed to achieve PL c requirement according to EN ISO 13849-1: 2015 + 2023 & EN 15194:2017+A1:2023.

This evaluation report confirms the achievement of the requirements of functional safety based on the following proofs:
- Proof of systematic safety integrity for defined phases of the life cycle
- Proof of the required safety-related parameters (failure rate, $MTTF_D$, DC, CCF, PFH)
- Proof of the techniques and measures according to EN ISO 13849-1: 2015 + 2023, EN ISO 13849-2:2012

Proofs that processes and methods are established at the manufacturer guaranteeing that unexceptionable processes in terms of risk analysis, design, production, validation, change management and quality management comply with the safety-related standard.

Independent organization for functional safety assessment	Assessor	Approver
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd.	Ken Li	Riven Zhang

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1. Summary

This technical report summarizes the safety performance evaluation results towards the safety related [redacted]

No deviations were found during assessment according to EN ISO 13849-1 [R1] in terms of systematic and probabilistic safety integrity.

The proof of functional safety is based on:

- a basic test for quality management and management of functional safety as part of the examination of the systematic safety integrity, and
- software demands according to EN ISO 13849-1 [R1], Chapter 7 and Annex N
- a determination of the safety-related characteristic values ($MTTF_D$, PFH, Category, DC, CCF) for the quantitative determination of the hardware safety integrity for electronic components
- a supplementary examination of the systematic safety integrity of corresponding sections of the safety life cycle and
- determination of Performance Level (PL) based on the results of the safety-related characteristic values and taking into account the qualitative requirements achievement.

The assessment result for Safety Functions is given in the following table.

SF	SF Function	PL Achieved	Response Time	$MTTF_D$ (years)	PFH	CCF	Safe State
SF1	Prevention of an unintentional self-start of the EPAC	PL c with Cat. 2 DC ≥ 60%	150ms	1352.3	1.02×10^{-6}	75	De-energise the motor
SF2	Prevention of electric motor assistance functions without pedalling, and without activation of the start-up assistance mode	PL c with Cat. 2 DC ≥ 60%	150ms	76	1.02×10^{-6}	80	De-energise the motor
SF3	Prevention of risk of fire in case of management system failure for batteries with capacity above 100 Wh	PL c with Cat. 2 DC ≥ 60%	/	/	/	/	De-energise the motor

Table 1: Safety Function

Above safety functions are implemented with **category 2** architecture according to EN ISO 13849-1 [R1] Category definitions.

2. Definition of Project

Client instructed SGS-CSTC, Competence Functional Safety to conduct the assessment of Functional Safety referring to EN ISO 13849-1 [R1] for Electrical Control System for EPAC**.**

The assessment has to be performed according to the required Performance Level:

PLr = PL c with Category 2.

3. Assessment Period

Beginning of project:	2026-03-05
End of project:	2026-04-28

3.1 Former Assessments

Based on SHFS250700040371.

3.2 Means of Evaluation

The Electrical Control System for EPAC is evaluated through reviewing the documents [D1] to [D5] during the evaluation process, experts from Client are also interviewed.

3.3 Model differences description

Model No.: E-BRO.
Motor Controller for EPAC. The motor controller system mainly consists of motor control circuit and assistant signal detect circuit, system will prevention of electric motor assistance functions without activation of the start-up assistance mode.

4. Description of Subject under Assessment

This Electrical Control System for EPAC detect the assistant input and control the power of motor.

Safety function of Electrical Bike comply with PL c with Category 2 according to EN ISO 13849-1 [R1].

All safety relevant hardware and software versions are listed in Table 2: Module Version.

Product Description	Model	Hardware & Software	Version
ELECTRIC POWER BICYCLE	E-BRO	Hardware	Refer to [D1] to [D5]
		Software	Refer to [D1] to [D5]

Table 2: Module Version

Definition	Ratings
Voltage Supply (DC)	36V
Power	250W
Switch off the power of motor	Within 150ms

Table 3: Ratings Definition

Electric components list：					
No.	Description	Qty.	Model	Manufacture	Technical data
1.	Motor	1	M132	[redacted] TECHNIQUES (SHANGHAI) CO.,LTD.	36V DC, 250W
2.	Controller	1	MC5-E0	[redacted] TECHNIQUES (JIANGSU) CO.,LTD.	36V DC, 250W
3.	Display	1	KD1286	[redacted] Co., Ltd.	36V DC
4.	Sensor	1	KD/PS	[redacted] Co., Ltd.	36V DC
5.	Battery	1	LN-KT-D05	[redacted] Co.,Ltd	36VDC, 10.4Ah, 374.4Wh
6.	Brakes	2	LL-E405DG	LOGAN BICYCLE PARTS [redacted]	--
7.	Front lighting	1	QD-576	JIANDE WUXING BICYCLE CO.LTD	12Vdc
8.	Rear lighting	1	WD558	JIANDE WUXING BICYCLE CO.LTD	12Vdc
9.	Battery charger	1	GPLC084V42Y	[redacted] Ltd.	Input: 110-240V~, 47-63Hz, 1.8A, Output: 42VDC, 2.0A

Table 4: Electric components list

E-bike:

Display:

Motor:

Battery:

Controller：

ESA:

Sensor:

Figure 1: The Photos of Product

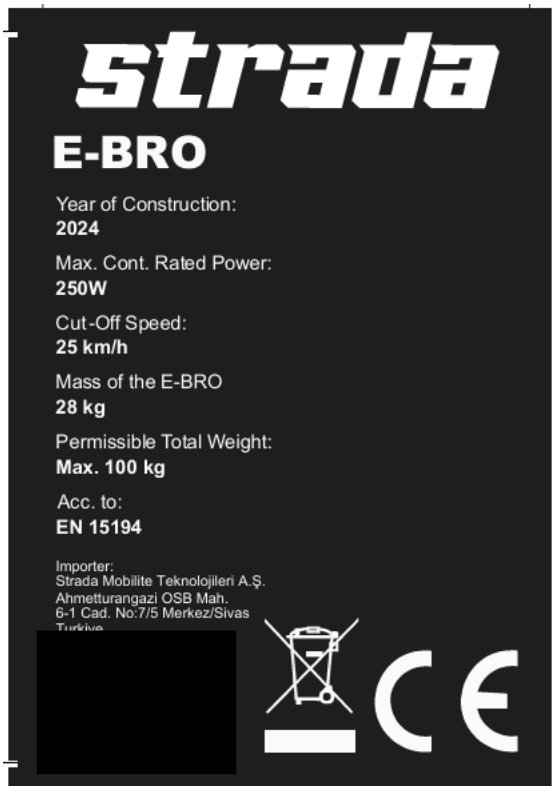

Figure 2 The Photo of nameplate

4.1. Safety function of SF1: Prevention of an unintentional self-start

4.1.1. Safety Function Definition

Normal power start function was defined as, under the power off status, keep pressing on the button of power-up within defined period to switch on the power, other situation to switch on power was considered as an unintentional self-start.

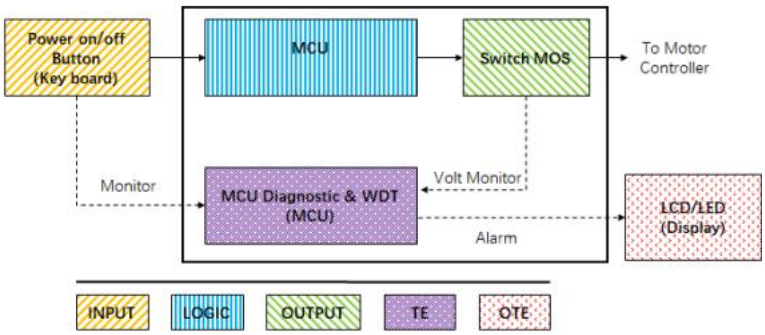

Figure 3: Safety Structure of SF1

4.1.2. Category

According to **Figure** , SF1 function have fulfilled the following ISO 13849-1 [R1] requirements based on the provided Category 2.

4.1.3. Safe State

In case of a failure(s) detected, the motor controller shall switch off the power output and send the alarm information to display, and the system will go into safe state.

4.1.4. Safety Response Time

Safety response time refer to the technical report “SHFS250400017271”.

4.1.5. Structure Analysis

Category and circuit modules description as below table:

Category Modules	Circuit modules description
Input	The power on/off button and power button related circuit on display
Logic	Composed of the circuit of power self-locking and MCU
Output	Power output circuit and DC converter circuits
Test Equipment (TE)	Monitoring circuits for the status of button and working voltage, MCU diagnostic functions.
Output Test Equipment (OTE)	In case of a failure(s) detected, the display shall send the alarm information to LCD and then switch off the power output, the system will go into safe state.

Table 5: Structure Analysis of SF1

Result:

According to above analysis and safety structure diagram, the safety function circuit has been designed with category 2.

4.1.6. Estimate the diagnostic coverage (DC)

Annex E of ISO 13849-1 is used as the guideline to estimate the diagnostic coverage (DC) of the system, which in fact is noted as average DC (DCavg). First diagnostic coverage of circuits used in the system is determined.

<table>
<tr><th>Circuits/ Components</th><th>DC</th><th>Diagnosis Methods Description</th></tr>
<tr><td>Input (Power on/off button)</td><td>60%</td><td>The failure mode for power on/off button has been analysed, according to the analysis report, more than 60% dangerous failures could be detected, so the DC for power on/off key could be claimed with 60%.</td></tr>
<tr><td>Logic (MCU)</td><td>60%</td><td>When the product working under normal operating condition, below MCU self-diagnosis has been designed:
<table>
<tr><th>No.</th><th>Items</th><th>Diagnostic Description</th><th>DC Claimed</th></tr>
<tr><td>1</td><td>ROM</td><td>Signature of a single word, CRC32.</td><td>99%</td></tr>
<tr><td>2</td><td>RAM</td><td>Hard errors of RAM were diagnosed with march C.</td><td>90%</td></tr>
<tr><td>3</td><td>Registers</td><td>General registers Inspected by written & read checking
stack pointer, application program status reg. fault mask, primask etc. Inspected by walking bit;</td><td>90%</td></tr>
<tr><td>4</td><td>ADC</td><td>The accuracy of ADC was diagnosed by periodically checking the specified reference voltage.</td><td>90%</td></tr>
<tr><td>5</td><td>Interrupts</td><td>The failure mode for safety-related interrupts have been analysed, according to the analysis report, more than 90% dangerous failures could be detected, so the DC could be claimed with 90%.</td><td>90%</td></tr>
<tr><td>6</td><td>Clock</td><td>A watch dog with independent clock used for MCU clock diagnostic.</td><td>60%</td></tr>
<tr><td></td><td colspan="2">Minimum DC</td><td>60%</td></tr>
</table></td></tr>
<tr><td>Output (Motor drive related circuits)</td><td>90%</td><td>The working voltage of MCU was monitored, in case of any faults detected, MCU will switch off the motor driving circuits and send the alarm information to display, and the system will go into safe state.</td></tr>
</table>

Table 6: DC Analysis of SF1

Result:

The minimum of DC for this system is 60%. Per clause 4.5.3 and Table 5 of EN ISO 13849-1:2015 + 2023, the diagnostic coverage (DC) level is determined to be **LOW** for this system.

4.1.7. $MTTF_D$ Calculation

The system $MTTF_D$ for SF1 has been calculated based on schematic and BOM, the $MTTF_D$ calculation report has been checked and confirmed, the system $MTTF_D$ is as follow :
$MTTF_{D01}$ of SF1 (Power self startup circuit) Refenrence from Technical Report " SHFS250400017271", The power self startup circuit on diplay :
$MTTF_{D01}$ = 1352.3 years

Result:

Refer to table 4 of EN ISO 13849-1: 2015 + 2023, the calculated value for the system $MTTF_D$ of **1352.3** years (PFH=1.02×10^{-6}) results in a **High** level of reliability.

4.1.8. Estimate Common Cause Failure

Annex F of ISO 13849-1:2023 is used as the guideline to estimate the common cause failure (CCF) of the system. This is based on the requirements set forth in IEC 61508-6.

No	Item and Measures Against CCF	Score for control circuit	Maximum possible score	Evidence
1	**Separation/segregation**			
	Physical separation between signal paths	15	15	The sufficient clearances and creepage distances on printed-circuit boards
2	**Diversity**			
	Different technologies/design or physical principles are used	0	20	N/A
3	**Design/application/experience**			
	Protection against over-voltage, over-pressure, over-current, over-temperature, etc.	15	15	According to the BOM, all main components were de-rating used.
	Components used are well-tried.	0	5	N/A
4	**Assessment/analysis**			
	For each part of safety related parts of control system, a failure mode and effect analysis has been carried out and its results considered to avoid common-cause-failures in the design.	5	5	FMEA analysis methods were applied in this project.
5	**Competence/training**			
	Training of designers to understand the causes and consequences of common cause failures.	5	5	ISO13849 Training was held.
6	**Environmental**			
	The system is designed to meet EMC directive	25	25	The product has been executed EMC testing and EMC testing report is available.
	Other influences: Consideration of the requirements for immunity to all relevant environmental influences such as, temperature, shock, vibration, humidity	10	10	The environment testing report is available.
	TOTAL	75	100	

Table 7: Common Cause Failure of SF1

Result:

The estimated CCF for the function of prevention of an intentional power self-start is 75, which is larger than the minimum requirement of 65, thus the calculated CCF meets the requirements set forth in ISO 13849-1.

4.1.9. Evaluation of Safety Function

Summary of relevant technical safety parameters are listed in the following table:

Technical Safety Parameter	Requirement	Result
Performance Level	PL_r = PL c	PL c fulfilled
Category	2	Category 2 fulfilled
PFH ([R1] Annex K, Table K.1)	$10^{-6} \leq PFH < 3\times10^{-6}$ [1/h]	PFH = 1.02×10^{-6} [1/h]
$MTTF_D$ ([R1] Table 6)	$MTTF_D \geq 30$ [years]	$MTTF_D$ = 1352.3 [years]
DC ([R1] Table 7)	DC ≥ 60%	DC = 60%
CCF ([R1] Annex F, Table F.1)	CCF ≥ 65	CCF = 75

Table 8: Technical Safety Parameter of SF1

4.2. Safety function of SF2: Prevention of electric motor assistance functions without activation of the start-up assistance mode

4.2.1. Safety Function Definition

The assistance mode only be activated by below methods:

- Normally pedal under cycling

Other situation was considered as unintentional start-up assistance mode.

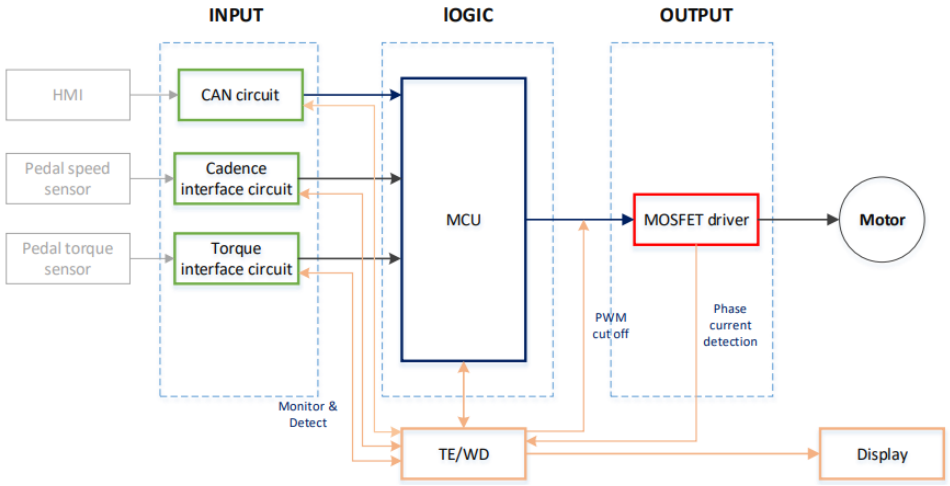

Figure 4: Safety Structure of SF2

4.2.2. Category

According to **Figure** 4, SF2 function have fulfilled the following ISO 13849-1 [R1] requirements based on the provided Category 2.

4.2.3. Safe State

In case of a failure(s) detected, the controller shall stop to output the motor assistant power and send the alarm information to display within defined time, and the system will go into safe state.

4.2.4. Safety Response Time

Safety response time refer to the part of “Rating(s) Definition”.

4.2.5. Structure Analysis

Category and circuit modules description as below table:

Category Modules	Circuit modules description
Input	CAN circuit, Cadence interface circuit, Torque interface circuit
Logic	MCU circuit
Output	MOSFET Drive circuit
Test Equipment (TE)	Watch dog for MCU monitoring; Torque diagnostic circuit; Motor phase current sampling circuit; Diagnostic functions in MCU for random failure control.
Output Test Equipment (OTE)	Sending error alarm message to LCD/LED; Cut off motor power output; System in safe status.

Table 9 Structure Analysis of SF2

Result:

According to above analysis and safety structure diagram, the safety function circuit has been designed with category 2.

4.2.6. Estimate the diagnostic coverage (DC)

Annex E of ISO 13849-1:2023 is used as the guideline to estimate the diagnostic coverage (DC) of the system, which in fact is noted as average DC (DCavg). First diagnostic coverage of circuits used in the system is determined.

Circuits / Components	DC	Diagnosis Methods Description
Input (Pedal sensor)	90%	Below input devices could be matched with this motor controller: Refer to the Report “ CN25A5MI 001”
Logic (MCU)	60%	Please refer to the Report “ CN25A5MI 001”
Output (Motor drive related circuits)	90%	The working voltage of MCU was monitored, in case of any faults detected, MCU will switch off the motor driving circuits and send the alarm information to display, and the system will go into safe state.

Table 10 DC Analysis of SF2

Result:

The minimum of DC for this system is 60%. Per clause 4.5.3 and Table 5 of EN ISO 13849-1:2015 + 2023, the diagnostic coverage (DC) level is determined to be **LOW** for this system.

4.2.7. $MTTF_D$ Calculation

The system $MTTF_D$ for SF2 has been calculated based on schematic and BOM, the $MTTF_D$ calculation report has been checked and confirmed, the system $MTTF_D$ is as follow:

$MTTF_{D01}$ of Display (Start-up Assistance Mode) Refenrence from Technical Report " SHFS250400017271", The Start-up Assistance Mode on diplay :

$MTTF_{D01}$ = 1202.8 years

$MTTF_{D02}$ of Controller (Start-up Assistance Mode)Refenrence from Technical Report " CN25A5MI 001" in this project, Start-up Assistance Mode circuit on controller:
$MTTF_{D02}$ = 439 years.

$MTTF_{D03}$ of Sensor (Start-up Assistance Mode)Refenrence from Technical Report

"MTTFd" the $MTTF_D$ of sensor, The Start-up Assistance Mode circuit on sensor:
$MTTF_{D03}$ = 100 years.

Calculation the System $MTTF_D$ for Prevention of Start-up Assistance Mode :
The $MTTF_D$= (1/(1/$MTTF_{D01}$ + 1/$MTTF_{D02}$ + 1/$MTTF_{D03}$))=1/(1/1202.8+1/439+1/100)= 76 (years) (PFH=1.02×10^{-6}).

Result:

Refer to table 4 of EN EN ISO 13849-1:2015 + 2023, the calculated value for the system $MTTF_D$ of 76 years (PFH=1.02×10^{-6}) results in a **High** level of reliability.

4.2.8. Estimate Common Cause Failure

Annex F of ISO 13849-1:2023 is used as the guideline to estimate the common cause failure (CCF) of the system. This is based on the requirements set forth in IEC 61508-6.

No	Item and Measures Against CCF	Score for control circuit	Maximum possible score	Evidence
1	**Separation/segregation**			
	Physical separation between signal paths	/	15	The sufficient clearances and creepage distances on printed-circuit boards
2	**Diversity**			
	Different technologies/design or physical principles are used	/	20	N/A
3	**Design/application/experience**			
	Protection against over-voltage, over-pressure, over-current, over-temperature, etc.	/	15	According to the BOM, all main components were de-rating used.
	Components used are well-tried.	/	5	N/A
4	**Assessment/analysis**			
	For each part of safety related parts of	/	5	FMEA analysis

No	Item and Measures Against CCF	Score for control circuit	Maximum possible score	Evidence
	control system, a failure mode and effect analysis has been carried out and its results considered to avoid common-cause-failures in the design.			methods were applied in this project.
5	**Competence/training**			
	Training of designers to understand the causes and consequences of common cause failures.	/	5	ISO13849 Training was held.
6	**Environmental**			
	The system is designed to meet EMC directive	/	25	The product has been executed EMC testing and EMC testing report is available.
	Other influences: Consideration of the requirements for immunity to all relevant environmental influences such as, temperature, shock, vibration, humidity	/	10	The environment testing report is available.
	TOTAL	80	100	Refer to the report: CN25A5MI 001

Table 11 Common Cause Failure of SF2

Result:

The estimated CCF for the function of prevention of an intentional power self-start is 80, which is larger than the minimum requirement of 65, thus the calculated CCF meets the requirements set forth in ISO 13849-1.

4.2.9. Evaluation of Safety Function

Summary of relevant technical safety parameters are listed in the following table:

Technical Safety Parameter	Requirement	Result
Performance Level	PL_r = PL c	PL c fulfilled
Category	2	Category 2 fulfilled
PFH ([R1] Annex K, Table K.1)	$10^{-6} \leq PFH < 3\times10^{-6}$ [1/h]	PFH = 1.02×10^{-6} [1/h]
$MTTF_D$ ([R1] Table 9)	$MTTF_D \geq 30$ [years]	$MTTF_D$ = 76 [years]
DC ([R1] Table 10)	DC ≥ 60%	DC = 88.8%
CCF ([R1] Annex F, Table F.1)	CCF ≥ 65	CCF = 80

Table 12: Technical Safety Parameter of SF2

4.3. Safety function of SF3: Prevention of risk of fire in case of management system failure for batteries with capacity above 100 Wh

4.3.1. Safety Function Definition

Prevention of risk of fire in case of management system failure for batteries, following protection circuits have been defined as safety related function in BMS Part:

- Over voltage protection of charging
- Under voltage protection of discharging
- Deep-Under voltage protection
- Over current protection of charging
- Over current protection of discharging
- High & Low temperature protection of charging
- High & Low temperature protection of discharging.

According to the conclusion in Technical Report No. CN25YQPK 001 Dated 01. 07,2025 Address: 1601-1604, 1801-1804, Tower A Building 2, Shenzhen International Innovation Valley, Dashi 1st Road, Xili Street, Xili Community, Nanshan District, Shenzhen, 518000, it shows that the LN-KT-D05 series battery [redacted] District, Foshan City, 528000 Guangdong, P.R. China) has achieved PL=c acc. to EN ISO 13849-1:2015, EN 15194:2017 clause 4.3.22.

5. References

The assessment in terms of Functional Safety is carried out in accordance with following standards:

Ref. No.	Standard	Title	Date
[R1]	ISO 13849-1	Safety of machinery - Safety-related parts of control systems - Part 1: General principles for design	2023

Table 13: Standards of Functional Safety

The evaluation process also refers to the standard:

Ref. No.	Standard	Title	Date
[R2]	ISO 12100	Safety of machinery – General principles for design – Risk assessment and risk reduction	2010
[R3]	ISO 13849-2	Safety of machinery - Safety-related parts of control systems - Part 2: Validation	2012
[R4]	EN 15194	Cycles - Electrically power assisted cycles - EPAC Bicycles	2017+A1: 2023

Table 14: Standards of Reference

6. Terms and Abbreviation

Terms /Abbreviation	Explanation
EUT	Equipment Under Test
SRP/CS	Safety-Related Part of Control System
PL	Performance Level / Agricultural Performance Level
PFH	Average Probability of a dangerous Failure per Hour
$MTTF_D$	Mean time to dangerous failure
DC_{avg}	Average Diagnostic Coverage
CCF	Common Cause Failure
SF	Safety Function
HW	Hardware
SW	Software

Table 15: Terms and Abbreviation

7. Documentation

Beside the technical report SGS-CSTC has created for the ISO 13849-1 [R1] assessment following documents:

Doc. No.	Document	File Name
[D1]	Qualify Management	Management Book_v1.0
[D2]	Battery Technical Report	TUV Report No．CN25YQPK 001
[D3]	Sensor test report	MTTFd
[D4]	Motor Controller technical Report	CN25A5MI 001
[D5]	The Display Report:	SHFS250400017271

Table 13: References and documents

8. Software safety requirements

Refer to the technical report [D2][D3][D4].

9. Measures to Avoid and Control System Failures

G.1 General

EN ISO 13849-2 [R3] gives a comprehensive list of measures against systematic failure which should be applied, such as basic and well-tried safety principles.

G.2 Measures for The Control of Systematic Failures

Requirement + Inspection	Result – Remark
Use of de-energization	The loss of the electrical supply will achieve a system safe state according to SW Safety Requirement.
Measures for controlling the effects of voltage breakdown, voltage variations, overvoltage, undervoltage	Voltage breakdown, overvoltage, undervoltage will achieve a safe state.
Measures for controlling or avoiding the effects of the physical environment (for example, temperature, humidity, water, vibration, dust, corrosive substances, electromagnetic interference, and its effects)	See the relevant test results.
Program sequence monitoring shall be used with SRP/CS containing software in order detect defective program sequences	Requirements fulfilled. Timing faults, including communication timing and program task timing, are identified and monitored by independent Watchdog.
Measures for controlling the effects of errors and other effects arising from any data communication process (see IEC 61508-2:2010)	Requirements fulfilled. Multiple monitoring measures have been adopted for Master between Slave module communication data, including data rationality check, communication verification, time cycle detection, etc.
In addition, one or more of the following measures should be applied, taking into account the complexity of the SRP/CS and its PL: — failure detection by automatic tests. — tests by redundant hardware. — diverse hardware. — operation in the positive mode. — mechanically linked contacts. — direct opening action.	Requirements fulfilled. The product uses the technology of derating design。

Requirement + Inspection	Result – Remark
— oriented mode of failure. — over-dimensioning by a suitable factor.	

Table17: Measures for The Control of Systematic Failures

G.3 Measures for Avoidance of Systematic Failures

Requirement + Inspection	Result – Remark
Use of suitable materials and adequate manufacturing	Requirements fulfilled. Safety related components information see [D5].
Correct dimensioning and shaping	Requirements fulfilled. Safety related components information see [D5]
Proper selection, combination, arrangements, assembly, and installation of components, including cabling, wiring and any interconnections	Requirements fulfilled. Components are selected and installed properly according to product design specification.
Compatibility	Requirement not applicable No such requirement.
Withstanding specified environmental conditions	Requirements fulfilled. The product has been executed EMC testing according to the requirement, all testing items passed.
Use of components designed to an appropriate standard and having well-defined failure modes	Requirements fulfilled. The components used, especially critical components, have sufficient testing and comply with safe failure modes.
Hardware design review	Requirements fulfilled. The design review during design phase is applied with following the review process.
Computer-aided design tools capable of simulation or analysis	Requirements fulfilled.

Table 18: Measures for Avoidance of Systematic Failures

G.4 Measures for Avoidance of Systematic Failures During SRP/CS Integration

Requirement + Inspection	Result – Remark
Functional testing	Requirements fulfilled. Functional testing had been implemented
Project management	Requirements fulfilled. The project management shall follow, but not limited to below internal process.
Documentation	Requirements fulfilled. The project was development complying with documentation management.

Table 19: Measures for Avoidance of Systematic Failures During SRP/CS Integration

G.5 Management of functional safety

Requirement + Inspection	Result – Remark
Identify the relevant activities in the SRP/CS design process (specification, design, integration, analysis, testing, verification, validation) and details of when they should take place;	Requirements fulfilled. Functional safety management related works products see company quality management.
Identify the roles and resources necessary for carrying out and reviewing each of these activities;	Requirements fulfilled. Functional safety management related works products.
Identify procedures for release, configuration, documentation and modification of hardware and software design;	Requirements fulfilled. Functional safety management related works products.
Establish a validation plan (see 13849-1:2023, 10.1.2);	Requirements fulfilled. Validation plan related works products.
Identify relevant activities before carrying out any modification.	Requirements fulfilled. Functional safety management related works products see company quality management.

Table 20: Management of functional safety

10. Assessment Results

10.1 Scope of assessment

The following figures show the general procedure:

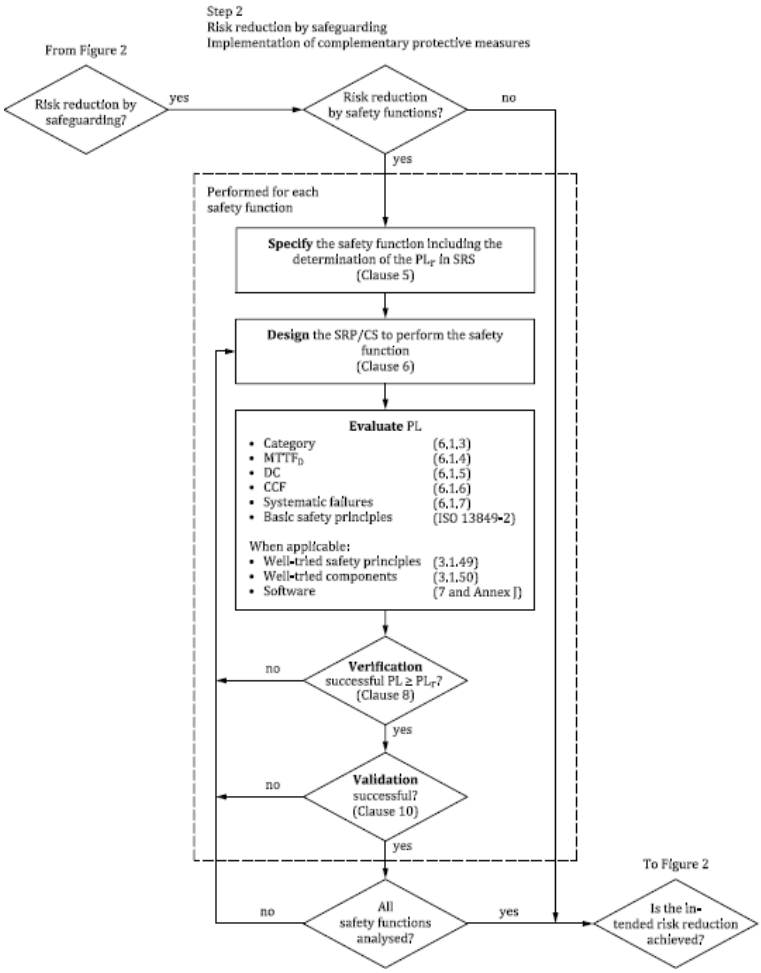

Figure 7: Process of Designing of Safety System

Assessment results:

The assessment includes all relevant activities while safety lifecycle of Functional Safety and norm conformity application of development process of safety lifecycle. The assessment was conducted by submitted customer's documents and acceptance test at the manufacturer.

10.2 Quality Management

Result	
Input information: Quality management.	☒ No deviations found in terms of test regulations. ☐ Deviations detected, result acceptable. ☐ Requirements of test regulations not fulfilled. ☐ Not considered / not applicable.
Requirement: Requirements according to EN ISO 13849-1: 2015 + 2023 [R1] quality management related. **Assessment:** Functional safety management is documented of see chapter 7 and a general quality management procedure was following and the Client quality management. **Limitations:** None.	
Recommendation: None.	

10.3 Tool Qualification

Result	
Input information: N/A.	☐ No deviations found in terms of test regulations. ☐ Deviations detected, result acceptable. ☐ Requirements of test regulations not fulfilled. ☒ Not considered / not applicable.
Requirement: Requirements according to EN ISO 13849-1 [R1]. **Assessment:** Not used in this project. **Limitations:** None.	
Recommendation: None.	

10.4 Risk Assessment

Result	
Input information: None.	☐ No deviations found in terms of test regulations. ☐ Deviations detected, result acceptable. ☐ Requirements of test regulations not fulfilled. ☒ Not considered / not applicable.
Requirement: Requirements according to EN ISO 13849-1: 2015 + 2023 [R1]. **Assessment:** Not applicant in this project. **Limitations:** None.	
Recommendation: None.	

10.5 Electromagnetic interference (EMI) immunity

Result	
Input information: EMC Testing Report.	☒ No deviations found in terms of test regulations. ☐ Deviations detected, result acceptable. ☐ Requirements of test regulations not fulfilled. ☐ Not considered / not applicable.
Requirement: Requirements according to EN ISO 13849-1 [R1], Annex L. **Assessment:** This product has been selected Route D which follow generic EMI standards for functional safety. **Limitations:** None.	
Recommendation: None.	

10.6 Safety requirements specification

Result	
Input information: Safety requirement specification	☒ No deviations found in terms of test regulations. ☐ Deviations detected, result acceptable. ☐ Requirements of test regulations not fulfilled. ☐ Not considered / not applicable.
Requirement: Requirements according to EN ISO 13849-1 [R1] clause 5.2 **Assessment:** The required information of functional requirements specification and safety Integrity requirements specification had been defined in requirements specification, specify requirements regarding the functional safety of the system and its elements during production, operation, service and decommissioning, see safety requirement specification. **Limitations:** None.	
Recommendation: None.	

10.7 Decomposition of SRP/CS into subsystems

Result	
Input information: N/A	☐ No deviations found in terms of test regulations. ☐ Deviations detected, result acceptable. ☐ Requirements of test regulations not fulfilled. ☒ Not considered / not applicable.
Requirement: Requirements according to EN ISO 13849-1[R1]. **Assessment:** Not applicable in this project. **Limitations:** None.	
Recommendation: None.	

10.8 Module Analysis

Result	
Input information: Specification	☒ No deviations found in terms of test regulations. ☐ Deviations detected, result acceptable. ☐ Requirements of test regulations not fulfilled. ☐ Not considered / not applicable.
Requirement: Requirements according to EN ISO 13849-1 [R1] clause 6.1.10 Fault consideration. **Assessment:** During project development lifecycle, important faults and failures are under consideration. Software specification of this system had been carried out to establish the faults. **Limitations:** None.	
Recommendation: None.	

10.9 Well-tried component

Result	
Input information: None.	☐ No deviations found in terms of test regulations. ☐ Deviations detected, result acceptable. ☐ Requirements of test regulations not fulfilled. ☒ Not considered / not applicable.
Requirement: Requirements according to EN ISO 13849-1 [R1]. **Assessment:** Some components like Fuse are well-tried, some components like MCU and ASIC are not well-tried. In general, not all used. **Limitations:** None.	
Recommendation: None.	

10.10 Verification of the achieved performance level

Result	
Input information:	☒ No deviations found in terms of test regulations. ☐ Deviations detected, result acceptable. ☐ Requirements of test regulations not fulfilled. ☐ Not considered / not applicable.
Requirement: Requirements according to EN ISO 13849-1 [R1], clause 8. **Assessment:** Achieved performance level had been verified in Validation test report For each individual safety function, the PL of the related safety function fulfilled the required performance level (PLr) determined. **Limitations:** None.	
Recommendation: None.	

10.11 Ergonomic aspects of design

Result	
Input information: None.	☐ No deviations found in terms of test regulations. ☐ Deviations detected, result acceptable. ☐ Requirements of test regulations not fulfilled. ☒ Not considered / not applicable
Requirement: Requirements according to EN ISO 13849-1 [R1], clause 9. **Assessment:** Not applicable in this project. **Limitations:** Not applicable.	
Recommendation: Not applicable.	

10.12 Validation

Result	
Input information: Safety reqiurement specification	☒ No deviations found in terms of test regulations. ☐ Deviations detected, result acceptable. ☐ Requirements of test regulations not fulfilled. ☐ Not considered / not applicable.
Requirement: Requirements according to EN ISO 13849-1 [R1], clause 10. **Assessment:** The specified safety function, the category achieved, the performance level achieved had been validated by analysis and testing. Characteristics and the required performance level of safety function, DC_{avg}, system structure, $MTTF_D$ and CCF had been analysed. Functional validation is applied in Test Report. EMC tests and Environmental tests for this SRP/CS were performed, the EMC & Environmental report is available, EMC Test Report. **Limitations:** None.	
Recommendation: None.	

10.13 Maintainability of SRP/CS

Result	
Input information: Product specification	☒ No deviations found in terms of test regulations. ☐ Deviations detected, result acceptable. ☐ Requirements of test regulations not fulfilled. ☐ Not considered / not applicable.
Requirement: Requirements according to EN ISO 13849-1 [R1], clause 11. **Assessment:** Preventive or corrective maintenance had been defined in to maintain the specified performance of the SRP/CS. **Limitations:** None.	
Recommendation: None.	

10.14 Technical documentation

Result	
Input information: Product specification	☒ No deviations found in terms of test regulations. ☐ Deviations detected, result acceptable. ☐ Requirements of test regulations not fulfilled. ☐ Not considered / not applicable.
Requirement: Requirements according to EN ISO 13849-1 [R1], clause 12. **Assessment:** The designing documents relevant to the safety-related part shall be documented for internal purposes in product specification. The documents have a unique document number and templates for document creation are used. **Limitations:** None.	
Recommendation: None.	

10.15 Information for use

Result	
Input information: Product specification	☒ No deviations found in terms of test regulations. ☐ Deviations detected, result acceptable. ☐ Requirements of test regulations not fulfilled. ☐ Not considered / not applicable.
Requirement: Requirements according to EN ISO 13849-1 [R1], clause 13. **Assessment:** Product specification contains the information about safety function provided by the SRP/CS, the designer of the SRP/CS provide information for use that describes the necessary maintenance tasks for the SRP/CS. **Limitations:** None.	
Recommendation: None.	

----------End of the report----------