

Projekt: xxxxxx

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1 Document history

Distribution List

Name	Version of Document

Revision History

Details of what has been changed in each revision of the document.

Version	Date	Author	New	Modified	Invalidated
1.0		ST/SJ			

Approvers / Reviewers

Name	Function	Date of Approval	Signature

2 Introduction

Sources

Description of the xxxxxxxx and the xxxxxxxx process

Definitions

Term	Definition
Axxxxxxxxx	The axxxxxx is an instrument for xxxxxxxxxxx xxxxxxxxxxx. To perform a test the axxxxxxxxx is mounted with a xxxxxx. The axxxxx controls all processes in the xxxxxxx.
xxxxxxxxxx	The xxxxxxxxxxx is a disposable xxx unit for performing one xxxxx test. The xxxxxxx is mounted with storage chambers which contain all fluids necessary for the xxxxxxxxxxx test. Further the xxxxxxxxxxx contains xxx, one waste and one xxxxxxxxxxx chip.
Storage chamber	The storage chambers are tubes filled xxxxxxxxxxx. One end of the tube is sealed with a fluid in the other opening a xxxxxxxxxxx is inserted. The storage chambers are used for storing liquids, for moving liquids and as xxxxxxxxxxx chambers.
xxxxx	xxxxx
xxxxx	xxxxx
xxxxx	xxxxx

Acronyms and Abbreviations

Term	Definition
CE	Cxxx Exxxx
DPV	xxxxxxxxxxxxxxxx
EDD	Electrochemical Detection Device
HDD	Hard disk drive
LSB	xxxxxxxxxxxxxxxx
RE	Reference xxxxxxx
SG	
SNR	Signal to noise ratio
UI	User Interface
WE	Working xxxxxxx

3 Referenced Documents

No.	Title	Rev
1	XXXXXXXXXXXXX	
2	XXXXXXXXXXXXX	
3	XXXXXXXXXXXXX	
4	XXXXXXXXXXXXX	
5	XXXXXXXXXXXXXXXXX	
6		
7		
8		
9		
10		

4 Reasons for the new development

We develop innovative products and solutions for xxxxxxxx analysis. Our focus lies on the development of the xxxxxxxx– the first system worldwide which enables you to perform fully automated xxxxxxxx xxxxxxxxxx on the spot. Forxxxxxxx offer customer-specific solutions such as development, validation, small-series production of kits and xxxxxx-solutions.

5 Intended Use

The intended use of the device is to analyse the xxxxxxxx ... in cobination with a xxxxxxx specifically developed for this purpose and using xxxxxxxxxxas sample. In principle, the device can be used for a variety of tests, each requiring a specific xxxxxxx and analysing process. The device shall only be used with the peripheral devices listed in the manual.

6 Commercial aspects

Cost for Manufacturing	
Quantities	

7 Product classification and life cycle

The product will be classified as a class ___ product, whereas the product life cycle is defined to be 5-7 years including permanent product improvements.

8 Requirement Specification

Priority (1: high, 2: medium, 3: low)

high: "must be realized" for serial production and prototype

medium: "should be realized" (strong recommendation)

low: "can be realized"

priority 2 and 3 are not a must be for prototype release!

Mark Validation / Verification with "cross" when appropriate and possible

Nr.	Requirements of Customers	Pri	VD	VF
1	Market demands			
General requirements				
1-10	Space-saving design of the analyzer.	1		
1-20	The analyzer is a table top unit.			
1-30	Simple and ergonomic operation.	1		
1-40	Identification of xxxxxxxx, xxxxxxxx, user and xxxxxxxx.	1		
1-50	Integrated visualisation, operator guidance, documentation and communication.	1		
1-60	Use of standard interfaces.	1		
1-70	Flexibility and scalability, e.g. by network organization of several analyzers.	3		
1-80	Connection to external laboratory information and xxxxx data management systems and databases.	2		
1-90	Modular design of the xxxxxxxx.	1		
1-100	Use of UL listed components.	1		
1-110	The xxxxxxxx has to be installed with standard tools.	1		
1-120	Easy cleanability and xxxxxxxx are to be considered.	1		
Device Costs				
Detailed Demands as derived from market demands				
2	Device Characteristics (Hardware and Construction)			
Analyzer system components				
2-10	One xxxxxxx system consists of the xxxxxxx (EDD) itself and an xxxxxxx workstation The EDD is the actual xxxxxxx instrument. <ul style="list-style-type: none"> The xxxxxxx can control all xxxxx functions by a remote control system. The xxxxxxx contains all software packages which are necessary for an xxxxxxx development. 	1	x	x
Overview EDD Components				
2-30	Connection to a Test xxxxxxxxxx For purpose of self testing all important functions by means of a test xxxxxxx that is to be designed an electric connection possibility or space for it has to be provided. For test xxxxxxx see 8-180		x	x
xxxxxx Retainer				

Requirement Specifications (Lastenheft)



Nr.	Requirements of Customers	Pri	VD	VF
2-60		1	x	x
2-70	xxxxxxxx	2	x	x
2-80	xxxxxxxxxxx	1	x	x
2-90	xxxxxxxxxxxxx	1	x	x
Moving Unit A:				
2-100	<ul style="list-style-type: none"> xxxxxxxxxxxxxxxxx 	1	x	x
Contact Array				
2-110	Centring the xxxxxxxxxxx: The contact array must be designed to provide the function of centring the xxxxxxx by two locating pins that are part of the cartridge and positioned near the detection chamber	1	x	x
2-120	Pressing on the Chip: The contact array must be designed to provide the function of pushing down the detection chip to ensure the tightness of the system detection –chamber / detection-chip on the one hand and otherwise to set a defined height of the detection-chamber. For this purpose the detection-chip must be pushed down as far as it will go. The force for this purpose is 100 to 120N at most.	1	x	xx
2-130	Electrical Contact: The contact array must provide the function of electrical contacting the electrodes of the detection chip. For details see electrochemical detection unit.	1	x	x
2-140	Lancing of Storage Chambers: The storage chambers of the xxxxx must be pushed against the bottom of the xxxxx (base plate) to lance the storage chambers (activation of the storage chambers). Activation of the storage chambers happens nearly simultaneously (because of tolerances of the storage chambers and the lancing system). The storage chambers must be pushed down during the whole operating process to avoid any leakage of liquid. There must be the possibility to close selected valves before and during the activation process. Forces for lancing storage chambers: Table 2	1	x	x
Mechanic xxxxxx Control Elements				
2-150	Overview: The mechanical cartridge control is performed by <ul style="list-style-type: none"> 13 pumping pistons, one for the xxxxx, one for the xxx chamber 4 for large storage chambers and 6 for small storage chambers, 7 switching units for the valves 1 moving unit for the magnet. 	1		
13 Pumping Units				
	<ul style="list-style-type: none"> 			

Requirement Specifications (Lastenheft)



Nr.	Requirements of Customers	Pri	VD	VF