



hello, technology

UID

Benutzerfreundlich wachsen

Usability Engineering Prozess für einen Hormon-Injektionspen

Tomas Hansson

14. November 2013



Electronic Registrar (WebDeath), REGISTRAR - CITY OF AUSTIN - ALBERT - [Local Registration]

Functions Registration Edit Reports Queues Window Help

Record Data

General		Decedent	
Date of Death:	01/27/2006	First Name:	
State File Number:		Middle Name:	
SSN:	- -	Last Name:	
EDR Number:		Suffix:	
Medrec:		Date of Birth:	__/__/__
ME Case Number:		Gender:	
		Place of Death:	
		Type of Place of Death:	
		Place of Death:	

Cancel Find Record

Facility: City of Birth:

Street Address: Country:

Father's Name

First Name: Last Name:

Mother's Name Prior to First Marriage

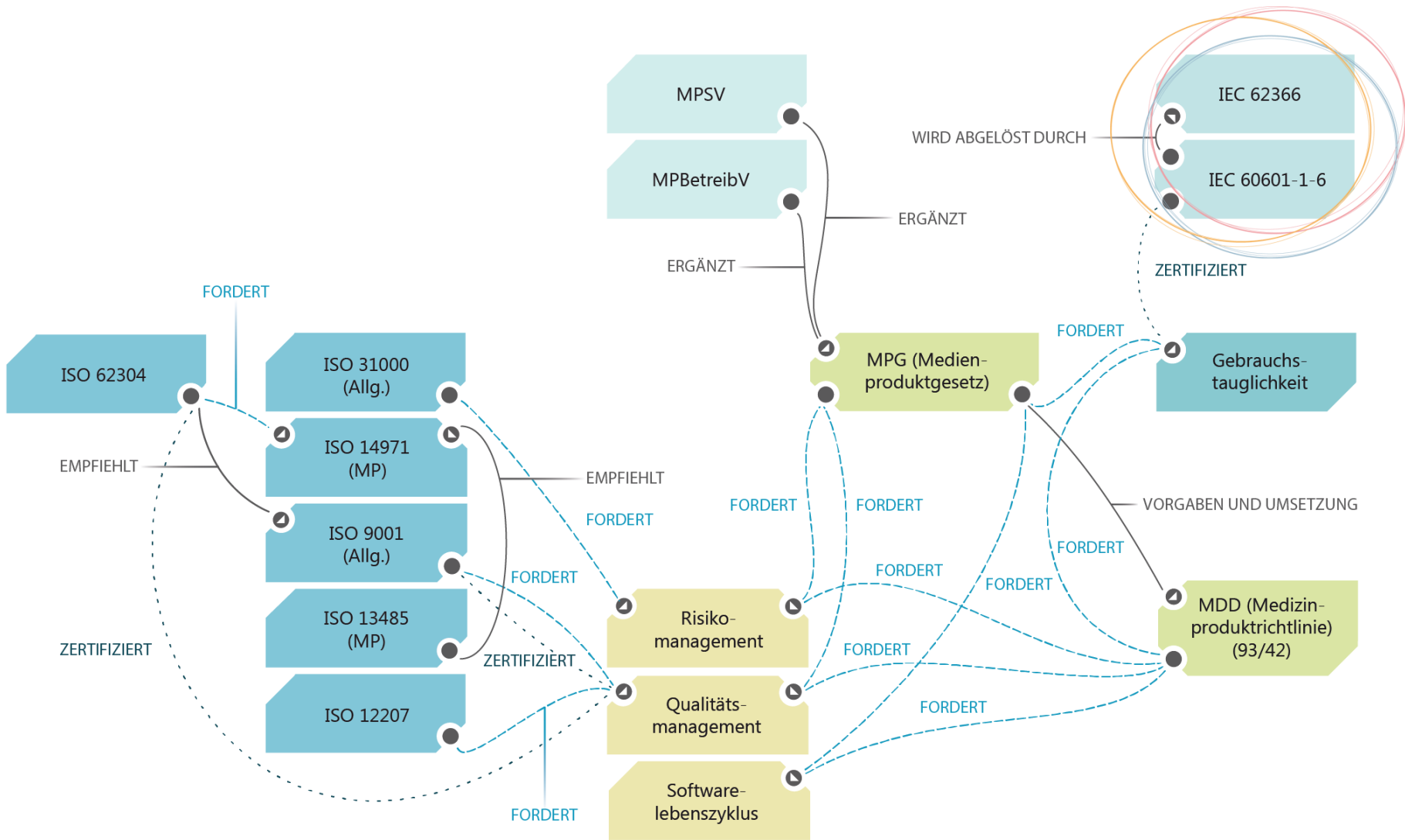
First Name: Last Name:

Records In Queue: 2 Field Name. Field Status. Record Status. CAPS NUM INS 1/27/2006







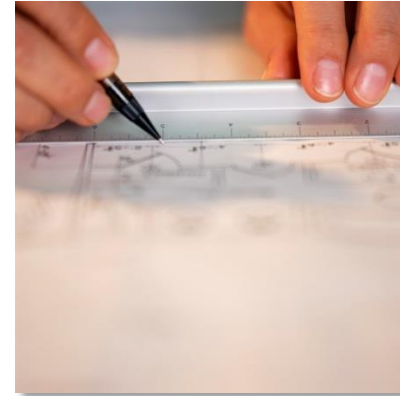


		NORM
		VERORDNUNG
		GESETZ
		ANFORDERUNG
FORDERT		
ZERTIFIZIERT		

USABILITY-AKTE WORUM GEHT ES?



Medizinprodukte-Hersteller ...



...entwickelt Medizinprodukt



...beachtet Normen

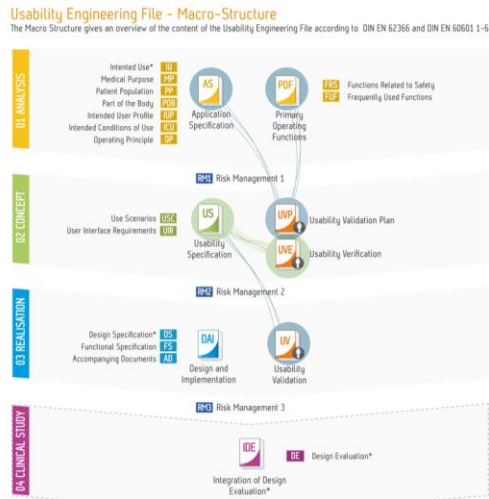


...wendet Methoden zur
Verbesserung der Usability an

USABILITY-AKTE WORUM GEHT ES?



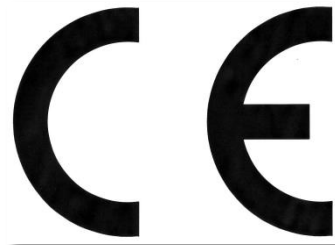
...minimiert Benutzungsfehler -> Risiko



Usability Engineering File



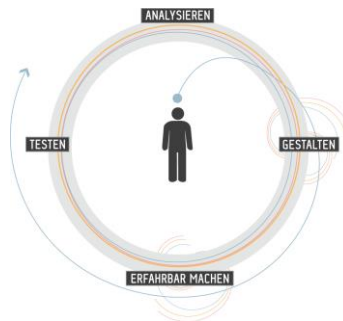
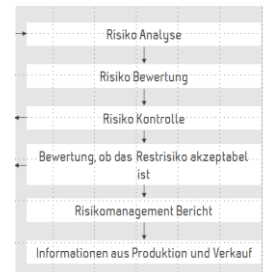
...dokumentiert Prozess



Medizinprodukt bekommt CE-Kennzeichnung

USABILITY-AKTE DER WEG ZUM USABILITY ENGINEERING FILE

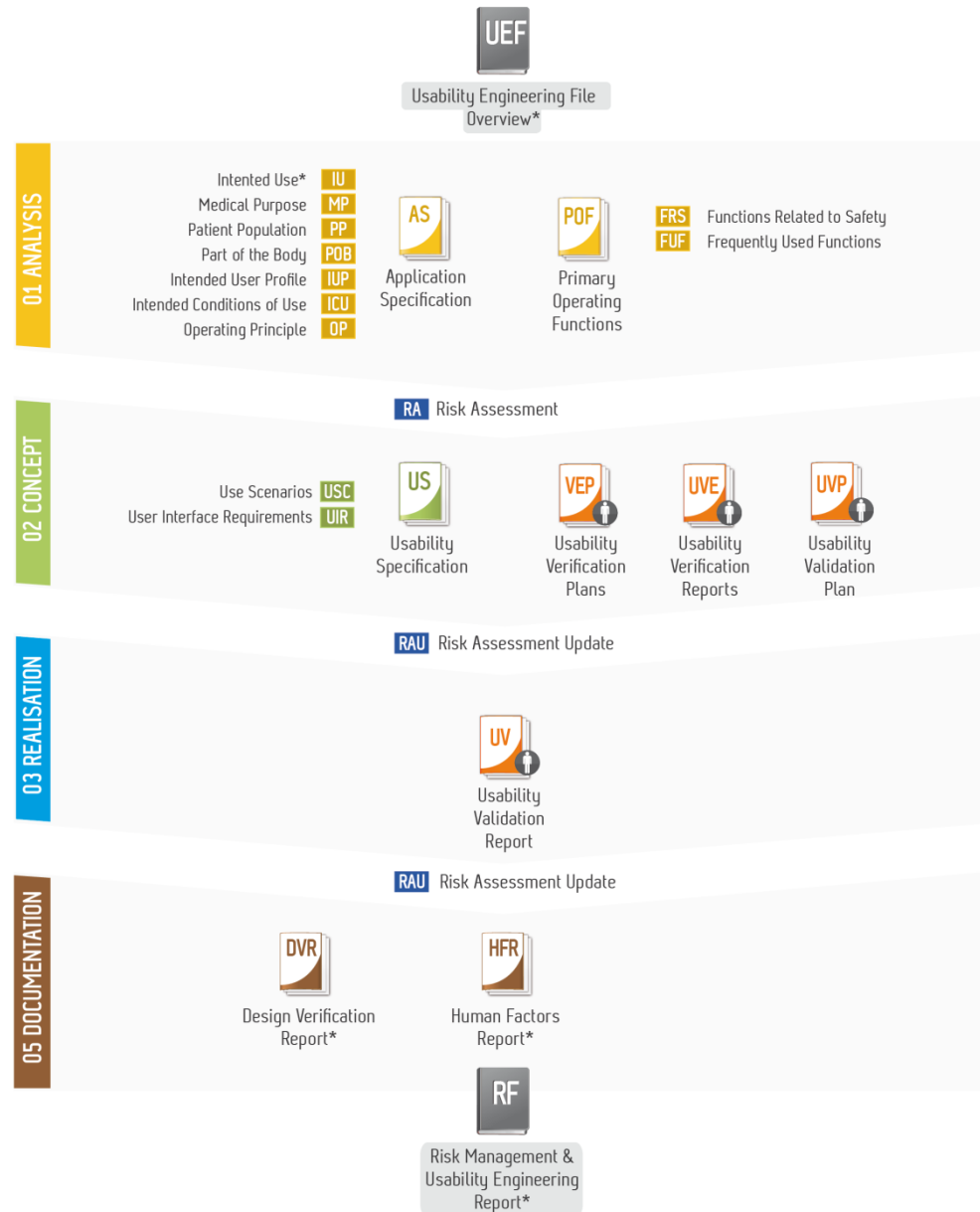
DIN



Usability Engineering File - Macro-Structure

Sandoz SurePal

The Macro Structure gives an overview of the content of the Usability Engineering File according to DIN EN 62366 and DIN EN 60601 1-6.



Usability Engineering File - Macro-Structure

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Usability Engineering File
Overview*

01 ANALYSIS

Intended Use* **IU**
Medical Purpose **MP**
Patient Population **PP**
Part of the Body **POB**
Intended User Profile **IUP**
Intended Conditions of Use **ICU**
Operating Principle **OP**



Application
Specification



Primary
Operating
Functions

FRS
FUF

Functions Related to Safety
Frequently Used Functions

02 CONCEPT

RA Risk Assessment

Use Scenarios **USC**
User Interface Requirements **UIR**



Usability
Specification



Usability
Verification
Plans



Usability
Verification
Reports



Usability
Validation
Plan

JETZT WIRD'S KONKRET!



Usability Engineering File - Macro-Structure

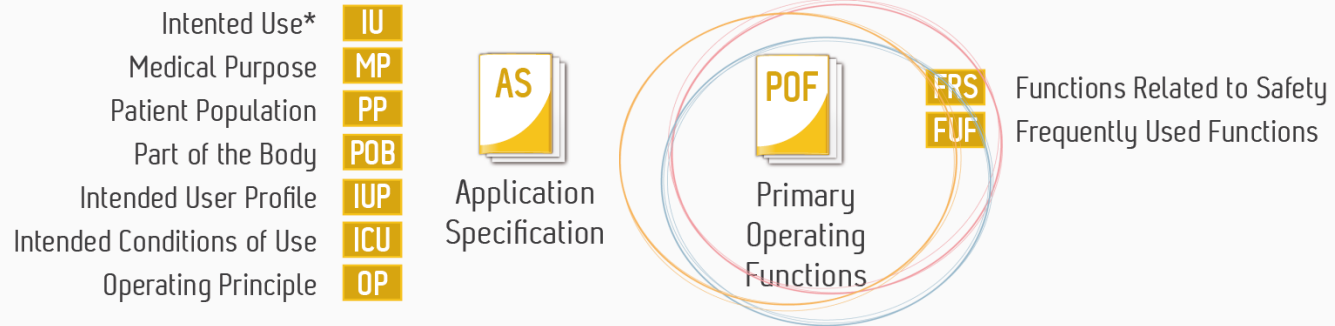
Sandoz SurePal

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Usability Engineering File
Overview*

01 ANALYSIS



02 CONCEPT

RA Risk Assessment



JETZT WIRD'S KONKRET!

POF, FRS UND FUF



FRS Functions Related to Safety
FUF Frequently Used Functions

No.	POFs	Related to Safety	Frequently Used Functions
1	Set dose memory	x	
2	Attach a pre-assembled cartridge		x
3	Exchange pre-assembled cartridge		x
4	Daily injection		x
5	Injection with control		x
6	Disassembly	x	x
7	Low drug waste system		x

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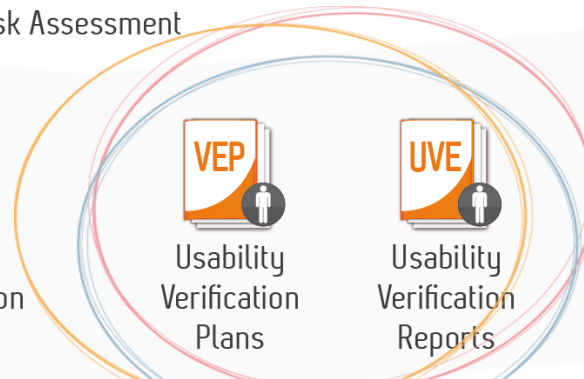


Usability
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Reports



Usability
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RA Risk Assessment





JETZT WIRD'S KONKRET! VERIFIZIERUNG

- Expert Reviews von der Anleitung, Kurzanleitung und Mitbewerber
- Rapid Usability Test mit 10 Teilnehmern in USA

12

MAKING THE INJECTION

13. Insert the pen needle into the skin by your healthcare professional

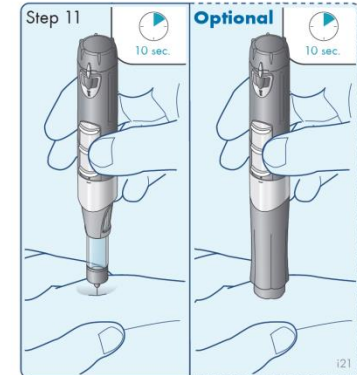


14. After pen needle insertion, press the dose knob in as far as it will go and hold it there. A clicking sound will be heard as the dose is dispensed. Continue to press the dose knob for 5 seconds, before you remove the pen from the skin.

If medication continues to be dispensed after needle insertion, hold the pen against your skin longer the next time you use the pen.

If the injection button stops before the dose is dispensed: If the injection button stops before the dose is dispensed, the dose window will show the amount of medication dispensed. Remove the pen needle from the pen. Remove the pen needle from the pen as described in step 15. Press the dose knob to "0" by holding the pen against the skin as illustrated in illustration 12a. The dose knob will now be fully pressed to "0".

Give the injection



11 **Hold the needle in for 10 seconds after the dose knob stops turning.** The drug is injected when "0" appears in the dose display window.

12 Remove the pen needle from the fold of skin. You may observe some dripping from the pen needle. This is normal.

Note: If the dose display window does not show "0" the pre-assembled cartridge held less than the complete dose. You will have to give two injections to get the complete prescribed dose.

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Usability Engineering File - Macro-Structure

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- FRS** Functions Related to Safety
- FUF** Frequently Used Functions

RA Risk Assessment

02 CONCEPT

- Use Scenarios **USC**
- User Interface Requirements **UIR**



Usability
Specification



Usability
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Usability
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Usability
Validation
Plan



ID	Objective
PO1	<p>Measure the number of subjects that successfully perform the injection procedure into the injection pad.</p> <p>Acceptance Criteria: 85% of all subjects have to fulfill this objective (pass).</p>
PO2	<p>Measure the number of subjects that safely perform the disassembly: A subject has to succeed in performing the disassembly of the Pen without getting punctured.</p> <p>Acceptance Criteria: 85% of all subjects have to fulfill this objective (pass).</p>

JETZT WIRD'S KONKRET! VALIDIERUNGSSTUDIEN

- Validierungsstudie **in Deutschland**
 - 60 Testpersonen insgesamt (30 Kinder, 30 Erwachsene, 50% Laien, 50% mit Pen-Erfahrung)

- Validierungsstudie **in USA** (gefordert von der FDA)
 - 45 Testpersonen insgesamt (Kinder, Caregivers, erwachsene Patienten)



01

Intended User Profile
Intended Conditions of Use
Operating Principle

IUP
ICU
OP

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Use Scenarios
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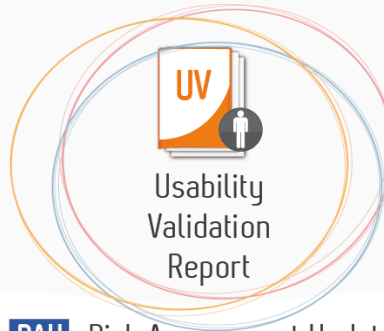
Usability
Verification
Reports



Usability
Validation
Plan

03 REALISATION

RAU Risk Assessment Update



RAU Risk Assessment Update

05 DOCUMENTATION



Design Verification
Report*



Human Factors
Report*

RE

01 ANALYSIS

Intended User Profile
Intended Conditions of Use
Operating Principle

IUP
ICU
OP

Application Specification

Primary Operating Functions

02 CONCEPT

RA Risk Assessment

Use Scenarios
User Interface Requirements

USC
UIR

US
Usability Specification

VEP
Usability Verification Plans

UVE
Usability Verification Reports

UVP
Usability Validation Plan

03 REALISATION

RAU Risk Assessment Update

UV
Usability Validation Report

05 DOCUMENTATION

RAU Risk Assessment Update

DVR
Design Verification Report*



HFR
Human Factors Report*

RE

JETZT WIRD'S KONKRET! FAZIT

- All activities helped to continuously **optimize the usability** of SurePal and its IFU.
- The Usability Validation was successful, **all acceptance criteria were met**.
- Both children and adults are able to use the pen **safely and effectively**.
- SurePal and its IFU are able to **fulfill their intended use**.





VIELEN DANK FÜR IHRE
AUFMERKSAMKEIT!



hello, technology



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BILDQUELLEN

Folie 2: http://www.mh-hannover.de/auf_intensivstation.html?&L=1

Folie 3: <http://www.dshs.state.tx.us/vs/ebirth/>

Folie 4: <http://www.yankodesign.com/2010/10/20/push-pull-tug-of-war-is-over/>

Folie 5: http://blockcolour.co.uk/?attachment_id=132

Folie 25: http://static.asif.im/wp-content/uploads/fatal_error.jpg