

2004 User Group Conference Innovation Realized



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Implementing Testing with DOORS at Dräger Medical

The presentation gives an overview of the new DOORS based testing approach at Dräger Medical (starting from the general concept and the desired traceability, via template descriptions, up to a set of comprehensive DXL tools).

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Dräger medical Overview

A Dräger and Siemens Company

- (65% Dräger and 35% Siemens)
- 5700 employees
- Represented in more than 190 countries
- 100+ years experience in setting technology standards for the acute point of care
- The mission is to provide innovative products, services and integrated solutions that support clinical processes and enable effective and cost-efficient patient care in all CareAreasTM: from Emergency Care, the Operating Room and Anesthesia on to Critical Care, Perinatal Care and Home Care.
- Such as: Ventilation, Monitoring, Anesthesia, IT-Systems, Incubators and Oxygen/Sleep Therapy.





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Zeus Overview (Anesthesia Workplace System)



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- First networked Anesthesia Expert System
- Incorporates Patient Monitoring, full ventilator control and anesthetic drug delivery with "AutoPilot" functions
- First touch screen controlled Anesthesia System
- First complete PC controlled system (6 different processor systems)
- 5 years of development time
- Up to 50 engineers working on the project.
- Several new patents were written



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Dr. Bernd GRAHLMANN Overview

- Requirements Management and DOORS consultant / trainer:
 - among others ~1 year for Dräger Medical
- 3 years Global Manager for first DOORS then all of Requirements Management for General Electric Medical Systems:



- Responsible for all aspects of requirements management: processes and guidelines for req. mgt., validation, verification, DOORS; req. mgt and DOORS trainings (material, organization and conducting); server and client installations / upgrades, maintenance / trouble shooting; helpdesk; evangelist; internal audits; web site development; ... Worldwide and cross-modalities (~2000 engineers).
- 6 years Project Manager / Director:
 - Responsible for the <u>PEP</u> project: Software tool for modeling, simulation and verification of parallel systems; 500,000 lines of code, 30 developers.

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- As a manufacturer of medical devices for anesthesia and intensive care Dräger Medical is highly regulated w.r.t testing (among others by the FDA – the American Food and Drug Administration).
- Validation and verification is a major part of the development (just the Zeus V&V team consists of approximately 10 persons).
- Dräger Medical (anesthesia as well as intensive care department) was looking for an overall solution for validation as well as verification which:
 - satisfies regulations of all kind;
 - ensures proper validation and verification; and
 - is time and cost efficient.

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Requirements for a 'Testing Solution' (#1)



We started by gathering the (user) requirements on such a 'Testing Solution' in a DOORS module (of course ;-).

This DOORS module contained sections on:

- the hierarchy of test specifications / runs (in particular, the division into test cases and further down into test steps;
- information which shall be:
 - global for the test specification / run (such as: test equipment, test duration, overall test result, list of anomalies, etc.)
 - associated with test cases
 - from the test specification point of view (such as: test goal, quality status, auxiliary test equipment, expected run time, test preparation steps, test steps, etc.)
 - from the test run point of view (such as: overall status of test case run, anomalies, product, tester, date, etc.)

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Requirements for a 'Testing Solution' (#2)



- associated with test steps
 - from the test specification point of view (such as: expected result, actual result dummy, etc.)
 - from the test run point of view (such as: actual result, status, anomalies, comments, etc.)
- Developing tests (such as: derive necessary tests from requirement; organize and reference tests; specification of test method; etc.)
- Running tests (such as: time planning; determine test equipment; determine version to be tested; determine set-up; document actual result, status, anomalies, tested configuration; etc.)
- Traceability for tests (such as: determine tests to be (re-)done for requirement; determine test status for requirement; determine test runs on specific configurations; review of test results; etc.)

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Requirements for a 'Testing Solution' (#3)



- Printing / report generation
- Optimization and Re-use (such as: minimize number of tests to be run; minimize testing time; minimize number of tests run on wrong versions, etc.; minimize not relevant test results; compliance with standards and guidelines; re-use in modularity/platform/increment context; etc.)
- Then, we reviewed, clarified and prioritized the requirements and goals.





Developing a 'Testing Solution' (#1)

Based on the requirements / goals we then developed / proposed a 'Testing Solution':

- Using brainstorming and performing working sessions
- Using prototypes / dummies to test alternatives
- Associating solutions to the corresponding requirements (as an attribute in the DOORS module)
- Testing approaches on real test specifications





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DXL Traceability Attributes



We developed a sophisticated DXL traceability attribute:

- analyzing two different attributes:
 - the module type such as *TS* (Test Specification), *TR* (Test Report),
 TSR (Technical System Requirements), *RMHA* (Risk Management Hazard Analysis), etc.
 - the object type such as *Test Case*, *Test Step*, *Anomalies*, etc.
- displaying different information (in addition to the *Module Type*, the *Object Type*, the *ID* and the *Object Heading/Text*) depending on their values, e.g.:
 - Overall Status and Anomalies for a Test Case Object found in a TR (Test Report).

<- TS (Test_Case) Zeus.TS.Demo-180:

- Power-Down from System-Standby
 - <- TR (*Test_Case*) Zeus.TR.Demo-12092004-180:
 - Power-Down from System-Standby |Passed|
 - <- TR (*Test_Case*) Zeus.TR.Demo-11092004-180:

Power-Down from System-Standby |Failed| CQ-ID42

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DXL Traceability Attribute Code Extract



... } else if (omodtype=="TR") {

```
string overallresult = probeRichAttr_(linkedObject,"aPJ Overall Test Run Status", false)
string oresult = probeRichAttr (linkedObject,"aPJ Test Run Status", false)
string oanomalies = probeRichAttr_(linkedObject,"aPJ Anomalies", false)
oanomalies = clean_pard(oanomalies,"")
string oanomaliesclassification = probeRichAttr_(linkedObject,"aPJ Anomalies Classification", false)
string oanomaliesevaluation = probeRichAttr (linkedObject,"aPJ Anomalies Evaluation", false)
if (otype == "Test Case") {
              displayRich sIndent omodtype " ({\\b \\i " otype "}) " //
                            "{\\b " identifier(linkedObject) "}: "
              displayRich s plus Indent "{\\b " oheading "}" "{\\i " otext "}" //
                            "{\\b \\i | ooverallresult "|}" "{\\i oanomalies "}"
} else if (otype == "Test Step") { // if Test Case
              displayRich sIndent omodtype " ({\\b \\i " otype "}) " //
                            "{\\b " identifier(linkedObject) "}: "
              displayRich s_plus_Indent "{\\b |" oanomaliesclassification "| }" //
                             "{\\i " oanomaliesevaluation "}"
```

} else ...

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Advantages of DXL Traceability Attributes



- Main part is in a separate include file which is used by different traceability attributes (impact or trace, each time as 1, 2 or all step)
- Dräger deploys thin clients where the include file is taken from a share. Thus, an update of the include file updates all modules.
- The DXL works for modules of all kind.
- The result is nicely formatted and only contains relevant information.
- DXL attributes are much quicker than layout DXL (only re-calculated upon request – via Tools -> Refresh DXL Attributes).
- DXL attributes do not have scrolling problems + you can grab (copy) the text.
- DXL attributes can easily be backup'ed (via Tools->Functions->Copy Attributes). Thus, all traceability is recorded (and remains in baseline).
- Light-years ahead of traceability visualization in Rational's ReqPro ;-) © Bernd@Grahlmann.net



TS/TR Template (Test Spec Views)

The TS & TR Template has some views showing the Test Specification:

#Test Spec	= ID + main + aPJ Object Type + aPJ Expected Result
#Test Spec with 1 step trace	= ID + main + aPJ Object Type + aPJ Expected Result +
	aPJ DXL 1 trace
#Test Spec wth Actual Result	= ID + main + aPJ Object Type + aPJ Expected Result +
	aPJ Actual Result
#Test Spec with traces&impact	= ID + aPJ DXL all impact + main + aPJ Object Type +
	aPJ Expected Result + aPJ DXL 1 trace
#Test Spec with version	= ID + main + aPJ Object Type + aPJ Expected Result
	aPJ start version + aPJ last version

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Test Specification View

ID	Zeus.TS.Demo	Туре	Expected Result
Zeus.TS. Demo-180	5.1.1.1 Power-Down from System-Standby	Test_ Case	
Zeus.TS. Demo-182	Preconditions Zeus is in System-Standby mode.	Test_ Prep	
Zeus.TS. Demo-183	Press the 'Power Down' button.	Test_ Step	Zeus displays a confirmation box, whether you want to 'Power Down'.

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TS/TR Template (Test Run Views)

The TS & TR Template has some views showing the Test Run/Report:

#Test Run all with impac	t = ID + main + aPJ Object Type + aPJ Expected Result +
	aPJ Actual Result + aPJ Test Run Status +
	aPJ Anomalies + aPJ Anomalies Details +
	aPJ DXL all impact + aPJ Anomalies Class +
	aPJ Anomalies Evaluation + aPJ Overall Test Run Status
#Test Run for Tester	= ID + main + aPJ Object Type + aPJ Expected Result +
	aPJ Actual Result + aPJ Test Run Status + aPJ Anomalies +
	aPJ Anomalies Details
#Test Run with Date&IDs	= ID + main + aPJ Object Type + aPJ Expected Result +
	aPJ Actual Result + aPJ Anomalies + aPJ Test Run Status +
	aPJ Overall Test Run Status + aPJ Product Version ID +
	aPJ Tester + aPJ Test Date
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Test Run for Tester View

ID	Zeus.TR.Demo-11092004	Туре	Expected Result	Actual Res.	TR Status	Anomalies	A-Details
Zeus.TR. Demo- 11092004- 185	5.1.1 Power-Down	Headi ng					
Zeus.TR. Demo- 11092004- 180	5.1.1.1 Power-Down from System- Standby	Test_ Case				CQ- ID42	
Zeus.TR. Demo- 11092004- 182	Preconditions Zeus is in System- Standby mode.	Test_ Prep					
Zeus TR. Demo- 11092004- 183	Press the 'Power Down' button.	Test_ Step	Zeus displays a confirmation box, whether you want to 'Power Down'.	Powers down without confirma tion box.	Not OK	CQ- ID42	No confir mation box

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Test Report all with Impact View



ID	Zeus.TR.Demo-11092004	Туре	Expected Result	Actual Res.	TR Status	Anomalies	A-Details	DXL all impact (use 'Refresh DXL Attributes')	A-Class	A-Evaluation	Overall TR Status
Zeus.TR.Demo- 11092004-180	5.1.1.1 Power- Down from System- Standby	Test_ Case				CQ-ID42		 <- TS (Test_Case) Zeus.TS.Demo-180: Power-Down from System-Standby <- GRS (Req) Zeus.GRS.Demo-51: The power shall be turned off automatically once the operating system finished the 'Suspend to disc'. <- GRS (Req) Zeus.GRS.Demo-52: The turn off shall be controlled via a confirmation dialog. <- GRS (Req) Zeus.GRS.Demo-37: It shall be possible to turn off Zeus completely being in mode 'System- Standby' using the 'Power Down' key. 			Failed
Zeus.TR.Demo- 11092004-182	Preconditions Zeus is in System-Standby mode.	Test_ Prep									
Zeus. TR.Demo- 11092004-183	Press the 'Power Down' button.	Test_ Step	Zeus displays a confirmation box, whether you want to 'Power Down'.	Powers down without confirm ation box	Not OK	CQ-ID42	No confir mation box	<- TR (Anomalies) Zeus.TR.Demo-11092004- 35: #Anomalies# see linked objects	С	Confirm ation box must appear!	

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TS/TR Template (Filter Views)

The TS & TR Template has some views with special filter:

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TS/TR Template (Help Views)

The TS & TR Template has some views offering help:

#hlp Edit View (Help) = ID + main + aPJ Object Type + aPJ TPLHelp

#hlp all attributes = ID + main + aPJ Object Type + all attributes

#hlp-Edit View (Help) = ID + main + aPJ Object Type + aPJ TPLHelp * explicitly clears filter

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All Traces View Seen from Requirements Specification (#1)

- The DXL traceability attributes offer full traceability from requirements all the way to the test results.
- At your wishing the most important attributes are shown.

ID	Zeus.GRS.Demo	о Туре	All traces (use 'Refresh DXL Attributes')
Zeus.GRS. Demo-52	The turn off shall be controlled via a	🚽 Req	<- TS (Test_Case) Zeus.TS.Demo-187:
	confirmation dialog.		Cancel Power-Down from System-Standby <- TR (<i>Test_Case</i>) Zeus.TR.Demo-12092004-187: Cancel Power-Down from System-Standby <i>Passed</i>
			<- TR (Test_Case) Zeus.TR.Demo-11092004-187: Cancel Power-Down from System-Standby Not tested <- TS (Test_Case) Zeus.TS.Demo-180:
			Power-Down from System-Standby <- TR (<i>Test_Case</i>) Zeus.TR.Demo-12092004-180: Power-Down from System-Standby <i>Passed</i>
			<- TR (<i>Test_Case</i>) Zeus.TR.Demo-11092004-180: Power-Down from System-Standby <i>Failed</i> CQ-ID42

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All Traces View Seen from Requirements Specification (#2)

The DXL Attribute column allows for standard DOORS filtering on column contents ⁽²⁾

Column	Type		objects.	192
ID Zeus.GRS.Demo Type All traces (use 'Refresh DXL Attributes')	Attribute Main Attribute DXL Attribute	— А F	ccepted: Rejected:	3 (5.76%) 49 (94.23%)
ontains: [Failed]	à	•		
Match Case	🦵 Regular Expressio	n		
Match Case Refresh Simple Add	F Regular Expression	m		
✓ Match Case Refresh Simple Add dvanced Options Rules	F Regular Expression	n		Description
✓ Match Case Refresh Simple Add dvanced Options Rules Column 'All traces (use 'Refresh DXL Att	T Regular Expression	n "[Failed]" (c	ase sen.	Description

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DXL to Apply Template

We developed DXL to apply those TS/TR templates to existing or newly created modules:

- adding outline (asks if not empty)
- adding *attributes* and *attribute types* (without overwriting existing)
- adding views (overwriting existing)
- updating *front-matter*

=> You update the template and you can 'easily' populate this update to all existing DOORS module ☺

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Special Case 'Alarms'

For the anesthesia product Zeus there is the special case of alarms:

- Zeus has important requirements on alarms (having to be raised in case of problems):
 - class of alarm, suspend properties, volume properties, silencing properties, impact on lights and various displays, activation properties, etc.
- Most of those properties / requirements were in a huge Excel file, others in different Word files with requirements specifications.
- Test specifications to test those properties / requirements were written by manually looking up the values in Excel and Word and translating them (using a common schema) into a test step with an expected result.

=> Very time consuming, error prone and difficult to maintain up-to-date 혽

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New Alarm Tests Approach

DXL Attribute in Test

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Alarmlist M	Iodule	ID	Zeus.TS.Alarms-Diva	Туре	Alarmtesttypes	Alarmtestspec
		Zeus.TS.A-Diva_70	FUN_LEVEL_LOW	Test_ Step	All	Alarmdialoge: A) Im Alarminfo werden alle aktuell anstehenden Alarme gelistet. Zeit, Priorität, Alarm, Grenzen. Erklärung und Hilfetext werden in der Liste aufgeführt.
ID	Zeus:AL:Alarmlist	🚦 Туре	Susp.Group	Clas	\$ ⁻	B) Im Alarmlog werden alle Alarme, die seit dem Start des Cases aufgetreten sind, angezeigt.Unterscheidung Patienten- bzw. technischer Alarm.
Zeus.AL _526	FUN_LEVEL_LO	W Alarm	Apnoe HLM	Ala	urm	C) Dieser Alarm gehört zur Alarm Klasse, er beendet die (einfache) Stummschaltung sofort. Alarm-Zeitverhalten: 1. Alarm-Iasse: Alarm, Caution oder Advisory Class: Alarm 2. Alarm w. Schutch eine Vorauswahl unterdrückt
All 'stan migrate	dard' alarm prope d into one DOOR	erties have l S Alarmlist	been Module.			Suspend Group: Apnoe HLM 3. Mind. Lautstärke des Alarmtons minimum Volume: — 4. Alarm bricht All Silence nach definierter Zeit ab limit silence to: — 5. Bei Alarmierung blinkt der Messwert im Value Tool
Test Sp	ecification module	es:				flashing parameter: none 6. Tech. Hinweise werden als Kopfzeile im Value Tool dargestellt
– con Alaı	tain Test_Step ob rm objects from th	ojects which e Alarmlist	n are linked Module	l to	the	 value tool display: [CO2[O2[S1] 7. Tech. Alarm wird auf Hinweisniveau runtergestuft degradable: 8. Alarm ist in General Standby aktiviert standby visible: —
– an a are	attribute <i>Alarmtes</i> to be done (typica	ally = All)	hoose whic	ch te	ests	 9. Alarmquittierung durch die Silence Taste Silence deactivated: X 10. Alarm erscheint mit zusatz. Alarminfo-Dialog Open Alarminfo Dialog: X
– a Dž attri	XL attribute Alarn ibute values and g	ntestspec I enerating t	ooking up t he test spe	the cific	cation.	Alarm aktiv in Mode: i) Alarm ist in Aktuator Standby (A.S.) aktiv? active in A.S.: — ii) Alarm ist in Therapy Off (T.O.) aktiv? active in T.O.: —
	=> quick	, fully autor	matic, no e	rror	S,	MEDIBUS:
ernd@Grahlmann.n	et	easy up	date 🙂			b) MEDIBUS codepage: 2 c) MEDIBUS prio: 2

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Alarm Test DXL Extract

```
if ((All == true) || (Std == true) || (SuspGroup == true)) {
     string oalarm_SuspGroup = probeRichAttr_(linkedObject,"aPJ Suspend Group", false)
     displayRich "2. Alarm wird durch eine Vorauswahl unterdrückt"
     aux = ""
     while (!null oalarm_SuspGroup && line oalarm_SuspGroup) {
          aux = aux oalarm_SuspGroup[match 0] "|"
          oalarm_SuspGroup = oalarm_SuspGroup[end 0 + 2:] // move past newline
     if (aux != "") aux = "|" aux
     else aux = Show EMPTY
     displayRich " " "{\\b \\i Suspend Group: }" "{\\b " aux "}"
```

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TS/TR Template (Special Alarms Views)



The TS & TR Template has some views showing the Alarmtests (the main ones are):

#Test Alarms =

ID + main + aPJ Object Type + aPJ Alarmtesttypes + aPJ Alarmtestspec

#Test Alarms Run for Tester =

ID + main + aPJ Object Type + aPJ Alarmtesttypes + aPJ Actual Result +

aPJ Test Run Status + aPJ Anomalies + aPJ Anomalies Details

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Special Case: Tests with Calculations of Results



 For some tests we replaced slow and error prone manual calculations by quick, safe, automatic DXL calculations (using attribute values of the *Test Step* object or linked objects), such as:

// DXL attribute for L-Flow

/* ------ Bernd@Grahlmann.net 11/05/2004------This function sets the attribute it is driving. aPJ Calc L-Flow = VA * Delta_P / P0 / t */

real VA= obj."aPJ Mess VA"real Delta_P= obj."aPJ Mess Delta P"real P0= obj."aPJ Mess P0"int t= obj."aPJ Mess t"

// Only if there are measured values
if ((VA != 0.0) && (Delta_P != 0.0) && (P0 != 0.0) && (t != 0)) {
 // Check that there is no division by zero is already checked above
 obj.attrDXLName = ((VA * Delta_P) / P0) / realOf(t)
}

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Project Overview DXL Toolset



- We developed an additional DXL *Project Overview* Toolset to:
 - have a **Design History File Index** like module listing all project documents;
 - managing document locations, reference tags, versions, status, responsibles, etc.
 - allow for comfortable, centralized *printing* of pre-prepared DOORS reports (combining a view with a page setup)

Zeus:Project_Overview.Diemo	State 🚦	Version	Report	Report Description
2.3.2.1 TS - Systemtest Specifications (for GRS)				
/Telelogic-UGC 2004/Zeus.TS.Demo		current	Zeus.TS.De mo-TR-A3ls	Zeus.TS.Demo: • View: #Test Run for Tester • Page Setup: aPJ std_a3_landscape_full
© Dr. Bernd GRAHLMANN <u>Bernd@Grahlmann.net</u> <u>www.grahlmann.net</u> +33 6 82 86 68 03	RELE ASED	1.0 (Telelogic UGC 2004)	Zeus.TS.De mo-TR-A3ls	Zeus.TS.Demo: • View: #Test Run for Tester • Page Setup: aPJ std_a3_landscape_full
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Conclusions



Based on DOORS 7 and DXL we have implemented a powerful 'Testing Solution' at Dräger Medical:

- Satisfying the requirements of Dräger Medical, in particular:
 - traceability from requirements to test results
 - time and cost efficient
 - satisfying regulatory 'constraints'
- Migrating all system level requirements and test specifications of the 300+ men year Zeus project to DOORS (including restructuring, etc.)
- Re-building the Testing of alarm properties such that it has become automatic, quick and error-safe ⁽²⁾
- Embedding it into an overall Dräger Medical DOORS environment (providing specialized template application, printing, etc.)

=> Full success thanks to a rigorous project and the unique power of DOORS 7 & DXL 💓

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 Special Thanks to the Engineering + V&V Teams at Dräger Medical !!!

• Discussion is open for questions / comments / etc.

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Contact Information



- Feel free to contact me after the conference if you:
 - Have questions / comments / etc. with respect to the presentation, the project, etc.
 - Want to implement this or a similar solution in your company
 - Are interested in *Requirements Management* and (in particular)
 DOORS related *Consultancy* or *Training*.

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