Preface

Only through the dedicated work of the members of the QMS has the available GDT-Data record become possible. Everyone who wants to profit from the results is the called upon to contribute and also take part in the consensus work.

Unfortunately, in the past defective and uncertified versions of GDT interfaces appeared under the disguise of "GDT-Interface", which threaten the objective of standardized data transfers between systems and ultimately undermine the efforts of the QMS for quality standards.

Therefore, we have decided first of all to list the defective implementations and their publishers on the black board for members and thus out them for starters within the QMS. This action is accompanied by a letter of the QMS board of directors to the responsible firma, to subject standard and adapt the software. Otherwise these are requested not to use the name "GDT-Interface" anymore.

Hence: Become a member, contribute and get certified!!

QMS   Qualitätsring Medizinische Software

(= Quality Associocation for Medical Software)

Connecting Medical Measuring Instruments

(GDT - Gerätedaten-Träger (= Device Data Carrier))

Interface Description for

system-independent Data Transfer

between

electronic Data Processing Systems in Surgeries

and Measuring Instruments

Version 2.1   (5/2001)

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1. Introduction

1.1 General Information

The available Interface Description has been compiled by QMS (Qualitätsring Medizinische Software) to define a standardized interface between electronic Data Processing Systems in Surgeries and medical measuring instruments.

The interface (**G**eräte-**D**aten-**T**räger – GDT = Device Data Carrier) is therefore designed to be device-manufacturer- and section neutral. It can be used by standalone devices as well as PC supported measuring devices. If direct communication, as discussed in this document, is technically impossible (for example with older standalone devices using a manufacturer-specific interface), a suitable GDT-driver program should be provided by the manufacturer.

The new version should evolve into a voluntary standard for Data Processing Systems in Surgeries and device manufacturer. The certification takes place through the QMS-working committee GDT. (The interface description is taken over through the central institute as addition to the BDT set description)

Further development of this interface will aim at the implementation of ”PLUG and PLAY” solutions for linking medical devices with electronic data processing systems used in surgeries in order to keep installation efforts to a minimum.

1.2 Glossary of terms

Throughout this interface description, the following terms are used:

GDT	=	**G**eräte-**D**aten-**T**räger (= Device Data Carrier, interface name compliant with BDT, LDT, ADT)
DEVICE	=	medical device (or associated driver program), standalone unit oder PC based measuring instrument
EDP SYSTEM	=	electronic data processing systems used in surgeries
COMPONENT	=	each party to data transfer, EDP or DEVICE
SERVER	=	COMPONENT that waits for external queries and commands and that is capable of processing them (a PC network “Server” answers workstation queries only)
CLIENT	=	a COMPONENT that issues queries and commands

The terms CLIENT / SERVER are used only to describe the send / receive relationship and are not synonym with EDP system and DEVICE.

During installation it has to be decided which component should serve as SERVER and which as CLIENT to avoid conflicts. As the actual purpose of linking devices is the transfer of test data, at least one EDP should work as SERVER (processing of test data) and one DEVICE should at least act as CLIENT (sending of test data) (see 1.4).

1.3 Communication

Generally, there are three different mechanisms for data communication:

- **File Interface**
  DEVICE and EDP system communicate via files that are created with a certain file name and in a certain directory, see below.
- **Serial Interface**
  The attached DEVICE (or driver) communicates with the EDP system via a serail interface.
- **Program-to-Program Interface**
  DEVICE and EDP system support program-to-program interfaces (for example Clipboard, DDE, OLE, UNIX-Pipes, etc.)

This version of the interface description is limited to communication via serial oder file interfaces as of yet. An extension to include program-to-program interfaces is planned. As all data is transferred as BDT data sets, the appropriate data format depends on the method of communication used. (BDT = Büro- und Datentechnik = Office and Data technology)

1.4 Labelling of Interface Properties

1.4.1 General Information

In order to uniquely define the technical description of the interfacing capability for the different COMPONENTS, a special label is used which is defined differently for EDP systems and DEVICES.

In order to determine wether an EDP system can communicate with a DEVICE, you only need to check their interface labels. Communication is possible if at least one transfer method (serial or file) and at least one SERVER-/CLIENT information matches:

The technical documentation of a GDT-capable DEVICE or EDP system must therefore include the relevant information of the type of GDT used.

1.4.2 Minimum Requirements for an EDP system and a DEVICE

The EDP system should at least be able to act as SERVER, i.e. it must be capable of replying to set type 6300 with set type 6301 and of processing set type 6310.

The DEVICE must at least be able to act as CLIENT, i.e. it must be capable of sending set type 6310.

1.4.3 Kennzeichnung für EDV

GDT-<xx>-<nn>	<xx>	=	S	serial data transfer in accordance with GDT is supported
		=	D	data transfer via files in accordance with GDT is supported
		=	SD	both methods are supported
	<nn>	=	10	EDP can act as SERVER
		=	01	EDP can act as CLIENT
		=	11	EDP can act as both, SERVER or CLIENT

Example: GDT-S-10 / GDT-D-11 (EDP system can act serially only as SERVER,
however via file it can be both, SERVER and CLIENT)

1.4.4 DEVICE Labels

GDT-<xx>-<nn>	<xx>	=	S	serial data transfer in accordance with GDT is supported
		=	D	data transfer via files in accordance with GDT is supported
		=	SD	both methods are supported
	<nn>	=	01	DEVICE can act as SERVER
		=	10	DEVICE can act as CLIENT
		=	11	DEVICE can act as both, SERVER or CLIENT

Examplel: GDT-D-10 (DEVICE can act as CLIENT via file only)

1.4.5 EDP system/ DEVICE Sample Combinations

The following are examples of components that can communicate with each other:

EDP	**DEVICE**
GDT-S-11	GDT-SD-01
GDT-D-10	GDT-D-11
GDT-SD-01	GDT-S-01

The following are examples of components that **can not** communicate with each other:

EDP	**DEVICE**
GDT-S-11	GDT-D-11
GDT-SD-10	GDT-S-01

2. Interface Description

2.1 Component Identification (GDT-ID)

The GDT-ID serves as clear indentification of the components that are part of the communication and is defined during installation.
The ID made up of a total of 8 characters which are assigned in a manufacturer and device specific way. As all information is assigned using these IDs, it is essential that all IDs are unique, especially in the case of mulitple DEVICES (for example 2 ECG plotters form the same manufacturer).

2.2 Character Set

The character set allowed within BDT fields is the IBM 8 bit character set (Codepage 437) with characters ≧ 20hex (32 dez.).
More character sets may be supported in addition. The topically used character set is defined in field label 9206.

2.3 Communication via File

2.3.1 File Names

Data are transferred via a BDT- compliant file, the name of which must be defined uniquely during installation. The file name syntax is defined as follows:

<receiver-short name><sender-short name > . <incremental number>
(for example EDV2GER.005)

or

<receiver-short name><sender-short name > . GDT
(for example EDV2GER.GDT)

The file name consists of a maximum of 4 Characters as short name to indicate the receiver and a maximum of 4 characters for the sender of the file (see above).

The file name extension is a three-digit, incrementally increasing number that is continuously assigned to certain file names. The file count starts with consecutive extensions with .001 (leading zeros). This ensures that you can send multiple files, for example from a DEVICE to an EDP system.

If a system supports one fixed file name only, the extension for this file must be **.** GDT (for example EDV1EKG1**.**GDT).

During installation, you choose a device-specific setting for the file type (fixed or progressive) you want to use.

Files are generated by the sender with the extensions increasing incrementally.
If a file with the extension .GDT still exists (i.e. its receiver has not read it yet), the sender should not overwrite it (loss of data).

The handling through the receiver durch den Empfänger has to be carried out sorted by date/time (FIFO). After reading, the files have to be deleted by the reciever.
To avoid communication problems, the sender should write the communication data without a break. Is a delay necessary, a new file has to be generated for muß eine neue Datei with consecutive extension.

Also, there can be several successive GDT-sets within a file. In one file, several different types of sets can be used by different patients.

2.3.2 Directory

During installation, you choose the drive and the directory used to store the GDT communication files. This information is also needed during device-/EDP configuration.

2.4 Communication via serial Interface

2.4.1 Hardware

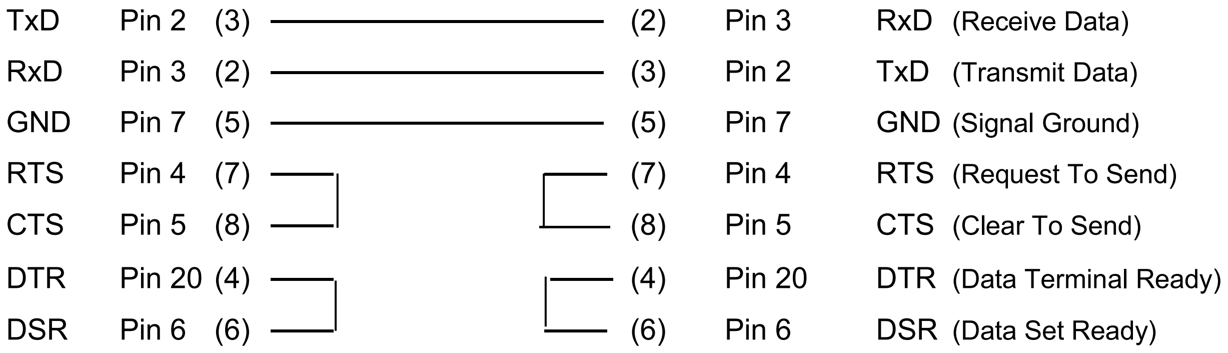
The minimum requirement for communication is a three-phase serial cable (RxD, TxD, GND) without hardware-handshake.
Optionally, other interface signals (RTS, CTS, DTR etc.) may be supported.

Interface parameters (minimum requirement)

Baud Rate	=	2400 Baud	(different values optional)
Data Bits	=	8	
Parity	=	none	
Start Bits	=	1	
Stop Bits	=	1	

Connection cable (minimum requirement)

(Pin assignment for 25-pin ports/values for 9-pin ports provided in brackets)



TxD	Pin 2	(3)	(2)	Pin 3	RxD	(Receive Data)
RxD	Pin 3	(2)	(3)	Pin 2	TxD	(Transmit Data)
GND	Pin 7	(5)	(5)	Pin 7	GND	(Signal Ground)
RTS	Pin 4	(7)	(7)	Pin 4	RTS	(Request To Send)
CTS	Pin 5	(8)	(8)	Pin 5	CTS	(Clear To Send)
DTR	Pin 20	(4)	(4)	Pin 20	DTR	(Data Terminal Ready)
DSR	Pin 6	(6)	(6)	Pin 6	DSR	(Data Set Ready)

2.4.2 Communication Process

Defined labels for BDT data sets and fields (with special labels) are used as data fields. All BDT data are transmitted in a fixed block format (see APPENDIX A). The protocol contains the definition of a software handshake so that an additional, external handshake prodecure (XON-XOFF) is not necessary.

In order to maintain compatibility, sentence and line lenghts for the transmitted BDT files are calculated as CR/LF (as defined in BDT); however, instead of these two characters, only **one** field separator (1CH) is sent because CR is defined as a separator for serial transfer (see example in APPENDIX A).

2.5 Sample Procedures

The examples are based on the following surgery scenario with the components listed.

The surgery works with the software "PRAX_EDV" (GDT-SD-11). Three DEVICES are connected to this program:

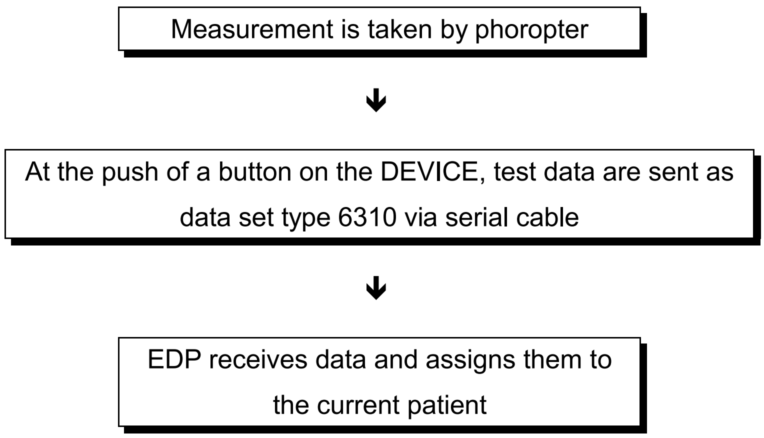
(1) A phoropter (opthalmic test device, test glasses with changeabel lenses) (GDT-S-10), connected via serial cable, which requires you to press a button to send test data to EDP (no root data management of its own) (EDP is SERVER / DEVICE is CLIENT).

(2) A PC based ECG plotter (GDT-D-01) that provides ist own root data management. It is called from the index card (EDP is CLIENT / DEVICE is SERVER). A PC based program used to start the ECG named ECG.BAT is stored in C:\REST_ECG.

(3) A spirometer (GDT-D-10) that provides its own root data management. It is controlled by DEVICE and communicates with an EDP system (EDP system is SERVER / DEVICE is CLIENT).
The spirometer program is called D:\LUFU SPIRO.exe.

1. Communicatio between EDP system and phoropter (not root data management)

EDP system = Server DEVICE = Client



Measurement is taken by phoropter

↓

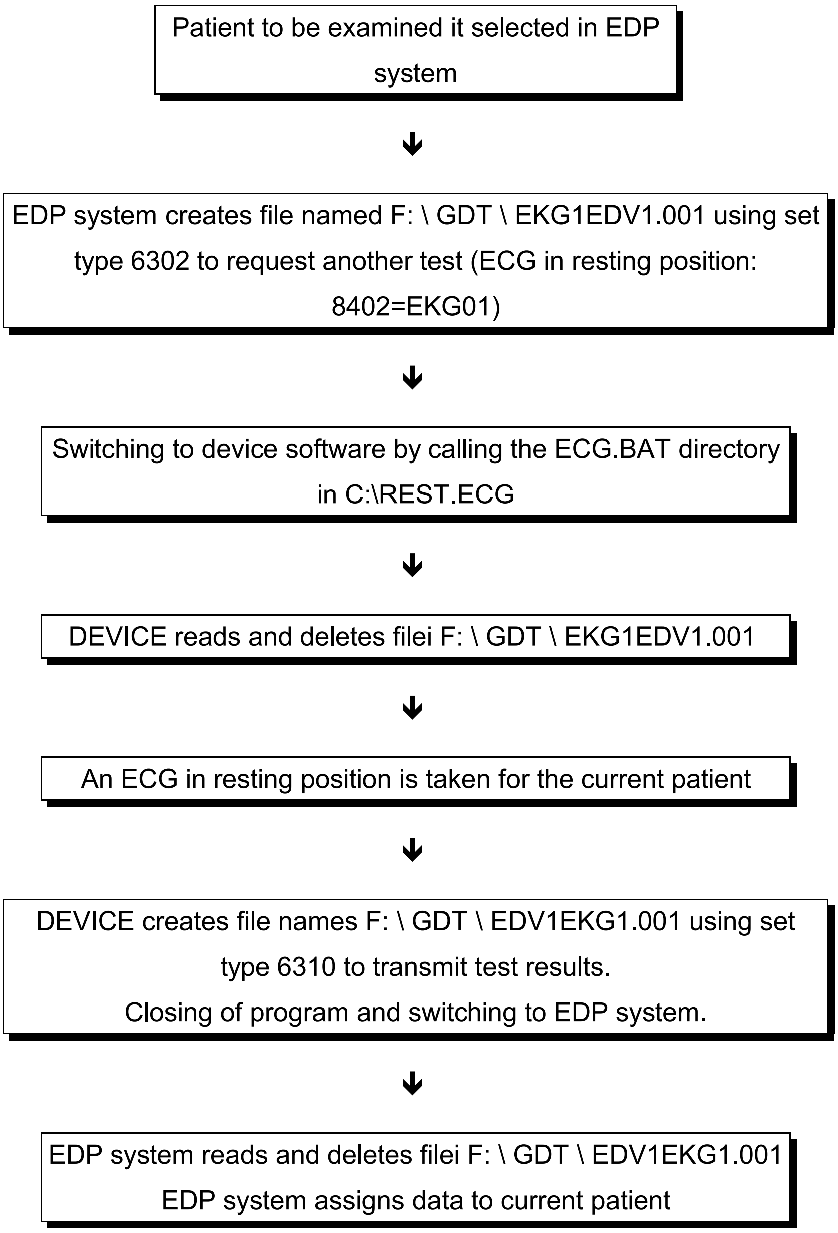
At the push of a button on the DEVICE, test data are sent as data set type 6310 via serial cable

↓

EDP receives data and assigns them to the current patient

2. Communication between EDP system and ECG plotter

EDP system = Client DEVICE = Server



Patient to be examined it selected in EDP system

EDP system creates file named F: \ GDT \ EKG1EDV1.001 using set type 6302 to request another test (ECG in resting position: 8402=EKG01)

Switching to device software by calling the ECG.BAT directory in C:\REST.ECG

DEVICE reads and deletes filei F: \ GDT \ EKG1EDV1.001

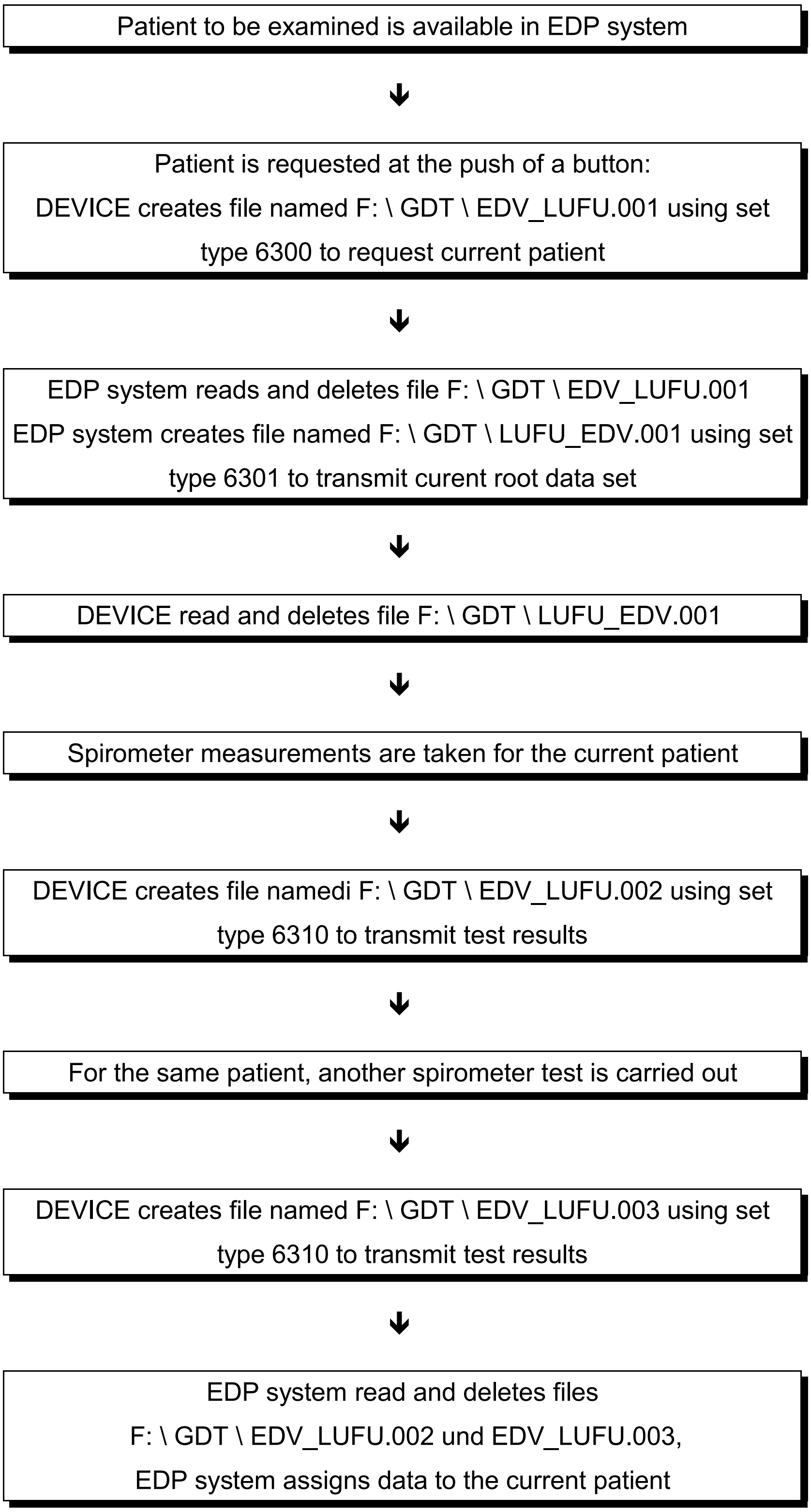
An ECG in resting position is taken for the current patient

DEVICE creates file names F: \ GDT \ EDV1EKG1.001 using set type 6310 to transmit test results.
Closing of program and switching to EDP system.

EDP system reads and deletes filei F: \ GDT \ EDV1EKG1.001
EDP system assigns data to current patient

3. Communication between EDP system and spirometer

EDP = SERVER DEVICE = CLIENT



Patient to be examined is available in EDP system

Patient is requested at the push of a button:
DEVICE creates file named F: \ GDT \ EDV_LUFU.001 using set type 6300 to request current patient

EDP system reads and deletes file F: \ GDT \ EDV_LUFU.001
EDP system creates file named F: \ GDT \ LUFU_EDV.001 using set type 6301 to transmit curent root data set

DEVICE read and deletes file F: \ GDT \ LUFU_EDV.001

Spirometer measurements are taken for the current patient

DEVICE creates file namedi F: \ GDT \ EDV_LUFU.002 using set type 6310 to transmit test results

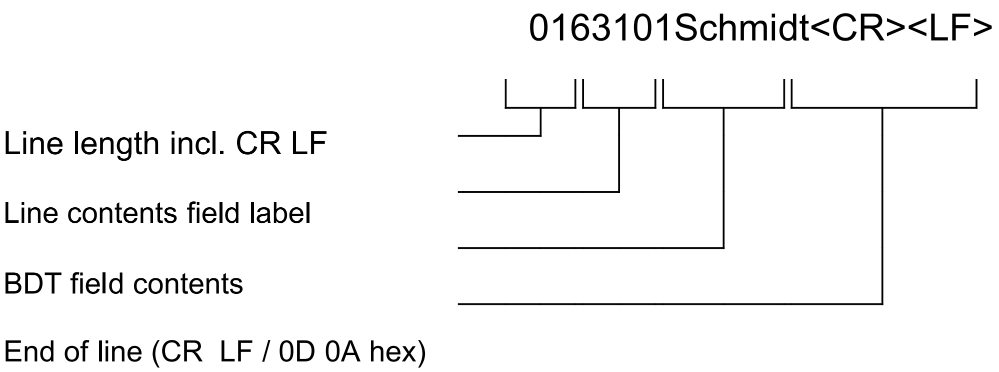
For the same patient, another spirometer test is carried out

DEVICE creates file named F: \ GDT \ EDV_LUFU.003 using set type 6310 to transmit test results

EDP system read and deletes files
F: \ GDT \ EDV_LUFU.002 und EDV_LUFU.003,
EDP system assigns data to the current patient

2.6 Annotated Sample Files

2.6.1 BDT Line Syntax:



0163101Schmidt<CR><LF>

Line length incl. CR LF

Line contents field label

BDT field contents

End of line (CR LF / 0D 0A hex)

2.6.2 Sample File ”Root Data Transfer”

01380006301 ↓ ↵	; Set type ”Root Data Transfer”
014810000173 ↓ ↵	; File Size
0178315EKG_TYP1 ↓ ↵	; Receiver GDT-ID (for example ECP plotter)
0178316PRAX_EDP ↓ ↵	; Sender GDT-ID
014921802.00 ↓ ↵	; Version Number GDT
014300002345 ↓ ↵	; Patient Number
0193101Samplesmith ↓ ↵	; Surname
0143102John ↓ ↵	; First Name
017310301101945 ↓ ↵	; Date of Birth
01031101 ↓ ↵	; Sex (1=male)
0123622178 ↓ ↵	; Height
0123623079 ↓ ↵	; Weight

↓ ↵ = CR und LF (0D 0A hex)

Every syntax line has to be ended with CR and LF (0D 0A hex).

2.6.3 Sample File ”Test Data Transfer”

```
01380006310 ↓ ↲                                                     ; Set Type
014810000962 ↓ ↲                                                    ; File Size
0198315PRAX_EDP ↓ ↲                                                 ; Receiver GDT-ID
0148316LZBD_SYS ↓ ↲                                                 ; Sender GDT-ID
014921802.00 ↓ ↲                                                    ; Version Number GDT
014300002345 ↓ ↲                                                    ; Patient Number
0193101Samplesmith ↓ ↲                                              ; Surname
0143102John ↓ ↲                                                     ; First Name
017310301101945 ↓ ↲                                                 ; Date of Birth
01031101 ↓ ↲                                                        ; Sex (1=male)
0123622178 ↓ ↲                                                      ; Height
0123632079 ↓ ↲                                                      ; Weight
0158402BDM01 ↓ ↲                                                    ; Test: 24h-Blood Pressure
017620023101998 ↓ ↲                                                 ; Test Date
0346220ThisᵥisᵥaᵥTwo-line ↓ ↲                                       ; Result 1. Zeile
0416220resultᵥofᵥ24h-bloodᵥpressureᵥtest ↓ ↲                        ; Result 2. Zeile
0566227Commentsᵥtoᵥaᵥlong-term-bloodᵥ pressureᵥ test ↓ ↲            ; Comment
0506228Summaryᵥ24ᵥhᵥ bloodᵥ pressureᵥ test ↓ ↲                      ; formatted results text
0606228-------------------------------------------------- ↓ ↲
0606228ᵥᵥᵥᵥᵥᵥᵥᵥᵥᵥdayᵥ phaseᵥᵥᵥᵥᵥᵥᵥnightᵥ phase ᵥᵥᵥpercentᵥdecrease ↓ ↲
0596228ᵥᵥᵥᵥᵥᵥᵥᵥ06:00-22:00ᵥᵥᵥᵥ22:00-06:00ᵥᵥᵥᵥday/night ↓ ↲
0606228Ps[mmHg]ᵥᵥᵥᵥᵥ143ᵥᵥᵥᵥᵥᵥᵥᵥᵥᵥᵥᵥᵥᵥ134ᵥᵥᵥᵥᵥᵥᵥᵥᵥᵥᵥᵥᵥ-6ᵥ% ↓ ↲
0606228Pd[mmHg]ᵥᵥᵥᵥᵥᵥ92ᵥᵥᵥᵥᵥᵥᵥᵥᵥᵥᵥᵥᵥᵥᵥ92ᵥᵥᵥᵥᵥᵥᵥᵥᵥᵥᵥᵥᵥᵥ0ᵥ% ↓ ↲
0606228HF[P/min]ᵥᵥᵥᵥᵥᵥ71ᵥᵥᵥᵥᵥᵥᵥᵥᵥᵥᵥᵥᵥᵥᵥ70ᵥᵥᵥᵥᵥᵥᵥᵥᵥᵥᵥᵥᵥ-1ᵥ% ↓ ↲
0178410SYSMXTG ↓ ↲                                                  ; Test-ID (manufacturer-spec.)
0298411Systoleᵥmaxᵥdayᵥphase ↓ ↲                                    ; Testname
0128420142 ↓ ↲                                                      ; Value
0138421mmHg ↓ ↲                                                     ; Unit
017843223101998 ↓ ↲                                                 ; reading date
0158439163400 ↓ ↲                                                   ; reading time
0128462140 ↓ ↲                                                      ; upper threshold
0178410SYSMNTG ↓ ↲                                                  ; next Test-ID
0298411Systoleᵥminᵥdayᵥphase ↓ ↲                                    ; Test name
0128420112 ↓ ↲                                                      ; Value
0138421mmHg ↓ ↲                                                     ; Unit
017843224101998 ↓ ↲                                                 ; reading date
0158439031200 ↓ ↲                                                   ; reading time
```

ᵥ	=	space	(20 hex / 32 dez)
↓ ↲	=	CR and LF	(0D 0A hex)

3. Set Table

Below, you find a decription of sets 6300, 6301, 6302, 6310, and 6311 that have been defined for linking medical devices.

Each set starts with the field "8000" which contains its sentence label.

However, sentence type 6300 „Root Data Request“ requires a sentence type 6301 „Root Data Transfer“ reply.

All remaining sentence types (6301, 6302, 6310, 6311) may be transmitted at any time and do not require a reply.

Generally, the direction of communication is a follows:

6300:	MG	→	PCS
6301:	PCS	→	MG
6302:	PCS	→	MG
6310:	MG	→	PCS
6311:	PCS	→	MG

MG = Medizingerät (medical device)

PCS = Praxiscomputersystem (surgery computer system)

3.1 Set Type Definition: Root Data Request "6300"

SA 6300	Field-	Instance				Description		necessary	Condition
Changes	label	1	2	3	4	Fieldcontents	M/K	Prerequisites	
	8000	1				Sentence ID	M		Root Data Request Set Type
	8100	1				Sentence length	M		Length of this Set
	8315	1				Receiver GDT - ID	K		
	8316	1				Sender GDT - ID	K		
	9206	1				Set Type used	K		1=7Bit, 2=IBM(Standard) CP 437, 3=ISO8859-1(ANSI) CP1252
	9218	1				Version GDT	M		02.10
	3000	1				Patient Number / Patient Label	M		If a DEVICE cannot transmit the patient number, a value of 0 should be sent in order to request patient data of the current patient.

3.2 Set Type Definition: Root Data Transfer "6301"

SA 6301	Field-	Instances				Description	necessary		Condition
Changes	label	1	2	3	4	Field Contents	M/K	Prerequisites	
	8000	1				Sentence ID	M		Root Data Transfer Set Type
	8100	1				Sentence Length	M		Length of this Set
	8315	1				Receiver GDT - ID	K		
	8316	1				Sender GDT - ID	K		
	9206	1				Set Type used	K		1=7Bit, 2=IBM(Standard) CP 437, 3=ISO8859-1(ANSI) CP 1252
	9218	1				Version GDT	M		02.10
	3000	1				Patient Number / Patient Label	M		
	3100	1				Prefix / Additional Name of Patient	K		e.g. Lord
	3101	1				Name of Patient	M		
	3102	1				Patient First Name	M		
	3103	1				Patient Birth Date	M		DDMMYYY
	3104	1				Patient Title	K		
	3105	1				Patient Insurance Number	K		
	3106	1				Patient Residence	K		Zip Code
	3107	1				Patient Street	K		Street and Number
	3108	1				Insurance Status	K		1=Member, 3=Family Member of Insured, 5=Retired
	3110	1				Patient Sex	K		1=Male, 2=female
	3622	1				Patient Height	K		
	3623	1				Patient Weight	K		
	3628	1				First Language of Patient	K		

3.3 Set Type Definition: New Test Request "6302"

SA 6302	Field-	Instances				Description	necessary		Condition
Changes	label	1	2	3	4	Field Contents	M/K	Prerequisites	
	8000	1				Sentence ID	M		New Data Request Set Type
	8100	1				Sentence Length	M		Length of this Sentence
	8315	1				Receiver GDT - ID	K		
	8316	1				Sender GDT - ID	K		
	9206	1				Set Type used	K		1=7Bit, 2=IBM(Standard) CP 437, 3=ISO8859-1(ANSI) CP 1252
	9218	1				Version GDT	M		02.10
	0102	1				The resposible one for the software	K		e.g. firm
	0103	1				Software	K		Name of software
	0132	1				Release state of software	K		Software versionnumber
	3000	1				Patient Number / Patient Label	M		
	3100	1				Prefix / Additional Name of Patient	K		e.g. Lord
	3101	1				Name of Patient	M		
	3102	1				Patient First Name	M		
	3103	1				Patient Birth Date	M		DDMMYYYY
	3104	1				Patient Title	K		
	3105	1				Patient Insurance Number	K		
	3106	1				Patient Residence	K		Zip Code
	3107	1				Patient Street	K		Street and Number
	3108	1				Insurance Status	K		1=Member, 3=Family Member of Insured, 5=Retired
	3110	1				Patient Sex	K		1=Male, 2=female
	3622	1				Patient Height	K		
	3623	1				Patient Weight	K		
	3628	1				First Language of Patient	K		
	8402	1				Device and method specific field	K		Requested Test Type, e.g.. EKG01 (see Appendix B)
	8410	1				Test-ID	K		

3.4 Set Type Definition: Test Data Transfer "6310"

SA 6310	Field-	Instances				Description	necessary		Condition
Changes	label	1	2	3	4	Field Contents	M/K	Prerequisites	
	8000	1				Sentence ID	M		Transfer Data Set Type
	8100	1				Sentence Length	M		Length of this Sentence
	8315	1				Receiver GDT - ID	K		
	8316	1				Sender GDT - ID	K		
	9206	1				Set Type used	K		1=7Bit, 2=IBM(Standard) CP 437, 3=ISO8859-1(ANSI) CP 1252
	9218	1				Version GDT	M		02.10
	0102	1				The responsible one for the software	K		e.g. firm
	0103	1				Software	K		Name of software
	0132	1				Release state of software	K		Software versionnumber
	3000	1				Patient Number / Patient Label	M		If a DEVICE cannot transmit the patient number, a value of 0 should be sent in order to request patient data of the current patient.
	3100	1				Prefix / Additional Name of Patient	K		e.g. Lord
	3101	1				Name of Patient	K		
	3102	1				Patient First Name	K		
	3103	1				Patient Birth Date	K		DDMMYYYY
	3104	1				Patient Title	K		
	3105	1				Patient Insurance Number	K		
	3106	1				Patient Residence	K		PLZ ORT
	3107	1				Patient Street	K		Straße und Hausnummer
	3108	1				Insurance Status	K		
	3110	1				Patient Sex	K		1=Member, 3=Family Member of Insured, 5=Retired
	3622	1				Patient Height	K		1=Male, 2=female
	3623	1				Patient Weight	K		
	3628	1				First Language of Patient	K		
	8402	1				Device and method specific field	M		Requested Test Type, e.g.. EKG01 (see Appendix B)

3.4 Set Type Definition: Test Data Transfer "6310"

SA 6310	Field-	Instances				Description	necessary		Condition
Changes	label	1	2	3	4	Field Contents	M/K	Prerequisites	
	6200	1				Day treatment data were saved	K		DDMMYYYY Test Date
	6201	1				Time treatment data were saved	K		HHMMSS; time (6 digits) of indicated test
	6205	n				Current Diagnosis	K		
	6220	n				Results	K		
	6221	n				Third Party Results	K		for example results that were automatically generated by the device
	6227	n				Comments	K		
	6226	n				Number of following Lines of the Identifier 6228	K		Herewith can the GDT length restriction be bypassed when transferring 6228. If, for example, a value of 2 is transferred, the following two lines 6228 form one complete line which has to be assembled by the receiver.
	6228	n				Result Table Text, formatted	K		any result text formatted by the device
	6302	n				Attribute for (Archive-)file	K		Attribute to classify the Data
	6303		1			File format	m	If field 6302 exists	Description of file format (e.g. PDF)
	6304		1			Information about the Content of file	m	If field 6302 exists	Description of what is located under the following adress(es) (WWW adress or UNC path) e.g. Protocols, Items/values of the Test Date
	6305		1			Reference to the file	m	If field 6302 exists	**U**niform **R**esource **L**ocator (WWW-address or UNC-Path) e.g. \\FS1\TEST\BILD1.PDF
	6330, 6332, 6334, ..., 6398	n				Name of open Category	K	Even and the following uneven identifier build a value pair respectively	
	6331, 6333, 6335,..., 6399		1			Content of open Category	m	in case previous identifier „ Name of open Category“ exists	
	8410		n			Test-ID	m	20 Signs alnum if field(s) > = 8411 < = 8480	Header to transfer single Measurement value groups
	8411			1		Test Name	K		
	8428			1		Test Material ID	K		
	8429			1		Test Material Index	K		
	8430			1		Test Material Label	K		
	8431				n	Test Material Specification	K		
	8437			1		Unit(s) for Data Stream	m	if field(s) 8438 <> (blank)	for example. Hz, dBA
	8438			n		Data Stream	K		for example (50,-30),(100,-20),(150,-22),(200,-17),.....etc
	8418			1		Test Status	K		B = already reported, K = corrected value or missing
	8420			1		Result Value	K		
	8421			1		Unit	m	if field(s) 8420, 8461, 8462 <> (blank)	

8432		1	Reading Date	K	DDMMYYYY ; Single Reading Date
8439		1	Reading Time	K	HHMMSS ; Time (6 digits) of Single Reading
8460		1	Standard Value Text	K	
8461		1	lower Threshold Standard Value	K	Value is transm. in Unit 8421
8462		1	upper Threshold Standard Value	K	Value is transm. in Unit 8421
8470		n	Comments	K	Test Notes
8480		n	Results Text	K	
8990	1		Signature	K	Name/Short Name of Person conducting the Test

3.5 Set Type Definition: Test Data Display "6311"

SA 6311	Field-	Instances				Description	necessary		Condition
Changes	label	1	2	3	4	Field Contents	M/K	Prerequisites	
	8000	1				Sentence ID	M		Test Data Display Set Type
	8100	1				Sentence Length	M		Length of this Sentence
	8315	1				Reciever GDT ID	K		
	8316	1				Sender GDT ID	K		
	9206	1				Set Type used	K		1=7Bit, 2=IBM(Standard) CP 437, 3=ISO8859-1(ANSI) CP 1252
	9218	1				Version GDT	M		02.10
	3000	1				Patient Number/Patient Label	M		If a DEVICE cannot transmit the patient number, a value of 0 should be sent in order to request patient data of the current patient.
	3100	1				Prefix/ Additional Name of Patient	K		e.g. Lord
	3101	1				Patient Name	K		
	3102	1				Patient First Name	K		
	3103	1				Patient Birth Date	K		DDMMYYYY
	3104	1				Patient Title	K		
	6200	1				Day Treatment Data were saved	K		DDMMYYYY Date of Test to be displayed
	6201	1				Time Treatment Data were saved	K		HHMMSS; time (6 digits) of indicated test
	8402	1				Device and Method specific field	K		Type of Test to be displayed for example ERGO00 (see App. B)
	8432	1				Reading Date	K		DDMMYYYY ; Date of Single Reading
	8439	1				Reading Time	K		HHMMSS ; HHMMSS ; Time (6 digits) of Single Reading

4. Field Table

This table shows the field labels used in sets 6300, 6301, 6302, 6310, and 6311.

* Changes to the field table are indicated on the left as follows:

*L	=	change of length
*N	=	new field; in Version 1 this denotes a new field label which in accordance with the central institute (Zentralinstitut) was assigned especially to GDT
*R	=	change of rule; in Version 1 this denotes a rule number for format/content verification not provided by the KBV Verification Module
*Nx.x	=	new field from Version x.x

	FK	*Name*	*Length*	*Type*	*Rule*	*Example*
***N2.1**	*0102*	*The responsible one for the software*	*<=60*	*alnum*		*Firm xxx*
***N2.1**	*0103*	*Software*	*<=60*	*alnum*		*PraxisMed*
***N2.1**	*0132*	*Release state of software*	*<=60*	*alnum*		*Version 4.30b*
	3000	*Patient Number / Patient Label*	*<=10*	*alnum*		*123456*
	3100	*Prefix / Additional Name of Patient*	*<=15*	*alnum*		*Lord*
	3101	*Patient Name*	*<=28*	*alnum*		*Smith*
	3102	*Patient First Name*	*<=28*	*alnum*		*Mary*
	3103	*Patient Date of Birth*	*8*	*datum*	*020/304*	*12041946*
	3104	*Patient Title*	*<=15*	*alnum*		*Dr.*
	3105	*Social Security Number of Patient*	*<=12*	*alnum*		*123456M789*
	3106	*Patient Residence*	*<=30*	*alnum*		*50859 Köln*
	3107	*Patient Street*	*<=28*	*alnum*		*Holzweg 106*
	3108	*Insurance Status MFR*	*1*	*num*	*116*	*3*
	3110	*Patient Sex*	*1*	*num*	*112*	*1*
	3622	*Patient Height in cm*	*var*	*float*		*175.50*
	3623	*Patient Weight in kg*	*var*	*float*		*90.50*
	3628	*First Language of Patient*	*<=60*	*alnum*		*english*
	6200	*Day treatment data were saved*	*8*	*date*	*008*	*12031993*
	6201	*Time treatment data were saved*	*6*	*time*	*090*	*HHMMSS 132201*
	6205	*Current Diagnosis*	*<=60*	*alnum*		*Diabetes*
	6220	*Results*	*<=60*	*alnum*		*high blood pressure*
	6221	*Third Party Results*	*<=60*	*alnum*		*suspected obstruction*

	FK	*Name*	*Length*	*Type*	*Rule*	*Example*
***N2.1**	*6226*	*Number additional Lines*	*<=4*	*num*		*2*
***N**	*6227*	*Comments*	*<=60*	*alnum*		*stress test terminated*
***N**	*6228*	*Result Table Text, formatted*	*<=60*	*alnum*		*see Appdx. for examples*
***N2.1**	*6302*	*Attribute for (Archive-)file*	*<=60*	*alnum*		*000001*
***N2.1**	*6303*	*File format*	*<=60*	*alnum*		*PDF*
***N2.1**	*6304*	*Information about the Content of file*	*<=60*	*alnum*		*Analysis of Data*
***N2.1**	*6305*	*Reference to the file (URL)*	*<=60*	*alnum*		*\\FS1\DATA\00712.PDF*
***N2.1**	*6330-6398*	*Name of open Category*	*<=60*	*alnum*		
***N2.1**	*6331-6399*	*Content of open Category*	*<=60*	*alnum*		
	8000	*Sentence ID*	*4*	*alnum*		*6301*
	8100	*Sentence Length*	*5*	*num*		*00747*
***N**	*8315*	*Receiver GDT - ID*	*8*	*alnum*		*ROP200U1*
***N**	*8316*	*Sender GDT - ID*	*8*	*alnum*		*PRAX_EDV*
***L**	*8402*	*Device and method-specific field*	***<=6***	*alnum*		*EKG01, see Appdx. B*
	8410	*Test ID*	*<=20*	*alnum*		*FEV1*
	8411	*Test Name*	*<=60*	*alnum*		*Obj. refr. cyl. right*
	8418	*Test Status*	*1*	*alnum*		*B*
	8420	*Result Value*	*var*	*float*		*-3.7*
	8421	*Unit*	*<=60*	*alnum*		*dpt*
	8428	*Test material ID*	*<=8*	*alnum*		
	8429	*Test material index*	*2*	*num*		
	8430	*Test material name*	*<=60*	*alnum*		
	8431	*Test material specification*	*<=60*	*alnum*		
	8432	*Reading date*	*8*	*date*	*008*	*31011994*
***N**	*8437*	*Unit(s) for Data float*	*<=60*	*alnum*		*min, mmHg, mmHg*
***N**	*8438*	*Data float*	*<=60*	*alnum*		*5,120,80... or* *(5,120,80),(10,128,92)..* *can contain float values.*
***N *R**	*8439*	*Reading Time*	*6*	*time*	***090***	*HHMMSS 125600*
	8460	*Standard ValueTtext*	*<=60*	*alnum*		
***N**	*8461*	*Standard Value Lower Threshold*	*var*	*float*		*-15*

	FK	*Name*	*Length*	*Type*	*Rule*	*Example*
***N**	*8462*	*Standard Value Upper Threshold*	*var*	*float*		*12*
	8470	*Test Notes*	*<=60*	*alnum*		
	8480	*Results Text*	*<=60*	*alnum*		
	8990	*Signature*	*<=60*	*alnum*		*Dr. Cooper*
***N2.1**	*9206*	*Set Type used*	*1*	*num*		*2*
***N**	*9218*	*Version GDT*	*5*	*alnum*		*01.00 oder 02.00*

datum = date format DDMMYYY

num = numeric, in case of fixed field length, the field nees to be filled with a leading zero

alnum = alphanumeric

float = floating-point number

5. Rules Table

According to their nature, the rules are devided into groups:

000 - 099	Format Verification
100 - 199	Contents Verification
200 - 299	Existence Verification
300 - 399	Context Verification

Rule Number	*Category*	*Verification*	*Description*
008	*Format*	*DDMMYYYY*	*DD=Day;MM=Montht;YYYY=Year*
020	*Format*	*DDMMYYYY*	*Value Range: DD=00-31 MM=00-12 /YYYY=0000-9999)*
<u>090</u>	*Format*	*HHMMSS*	*HH=Hour;MM=Minute;SS=Second* *Value Range: HH=00-24 / MM=00-59 / SS=00-59* *(00 is to be used if there is no other value for seconds)*
112	*Contents allowed*	*1, 2*	
116	*Contents allowed*	*1, 3, 5*	*Insurance Status MFR*
304	*Context*	*Date lesser or greater Device Date*	*Avoiding erroneous entries*

6. Appendixes

6.1 Appendix A Block Format for Serial Data Transfer with Samples

6.1.1 Transfer Protokoll

A BDT file is transmitted in several blocks. Receipt of a block must be confirmed within 10 seconds by sending an ACK (06h) followed by a 1 (31h) if the block is received correctly and completely, or followed by a 0 (30h) if it was transmitted incorrectly.

6.1.2 Transmission Block

A transmission block has the following structure:

<Sending Sequence Count> <Label> [<Data Field>] <CRC-16> <CR>

6.1.3 Field Description

Sending Sequence Count

Length: 1 Byte.

The sending sequence count counts periodically from 1 (31h) to 9 (39h). If a transmission block has to be re-sent due to incorrect transmission, the sending sequence count remains the same. A value of 0 (30h) is used for synchronization. This value is applied during the first transmission just after starting and when a transmission error occurs.

Label

Length: 3 Bytes

The following labels are defined:

B00	Start of a BDT data transfer/first BDT data block
B01	BDT data block
B02	End of a BDT data transfer / last BDT data block

Data Field

Length: max. 128 Bytes

The actual BDT data are contained in the data field. Multiple BDT lines may be combined into a single data field, or a single BDT line may be spread over multiple data fields. The character 1 Ch (Field Separator FS) is used to separate two adjoining BDT lines. BDT sentence and line lengths are calculated inclusive of CR/LF.

Apart from the field separator, no other ASCII character used in a data field may be less than 20h.

CRC-16

Length: 4 Bytes

16 Bit CRC via sending sequence count, label and data field. This is sent as ASCII Hex, for example 2A9Eh is sent as 32h 41h 39h 45h.

(See Appendix C for information on generating check sums.)

CR

Length: 1 Byte

Carriage Return (0Dh) concludes the transmission block.

6.1.4 Examples

Note: The character '|' stands for the field separator (1Ch).

To illustrate this point, the data field length has been limited to 32 characters.

6.1.5 Root Data Requirements

The client sends:

C: 1B00 013 8000 6300|014 8100 00075| 017 8315 QMS-STAR|017 <CRC> <CR>

S: <ACK> 1

C: 2B02 8316 ROP200U1|014 9218 01.00<CRC> <CR>

S: <ACK> 1

The server replies:

S: 7B00 013 8000 6301|014 8100 00142|<CRC> <CR>

C: <ACK> 1

S: 8B01 017 8315 ROP200U1|017 8316 QMS-STAR|014 9218 0<CRC> <CR>

C: <ACK> 1

S: 9B01 1.00| 014 3000 10027|012 3101 Axt|014 3102Berta <CRC> <CR>

C: <ACK> 1

S: 1B02|017 3103 31121937|010 31102 <CRC> <CR>

C: <ACK> 1

6.1.6 Behavior in case of Transmission Errors

If <ACK> 0 is received or if a timeout occurs, the last transmission block will be re-sent. If the same error occurs twice in succession, the sending sequence count will be set to 0 and transmssion will be repeated starting with the first BDT data block. Transmission will be terminated by the sender if the second attempt at transmitting a BDT file fails. High level error handling is used.

6.1.7 Sample Transfers containing Transmission Errors

Transmission Block Repeat

```
C: 1B00 013 8000 6300|014 8100 00075|017 8315 QMS-STAR|017 <CRC> <CR>
S: <ACK> 1
C: 2B02 8316 ROP200U1|014 9218 01.00<CRC> <CR>
S: <ACK> 0                                       ; error occurred
C: 2B02 8316 ROP200U1|014 9218 01.00<CRC> <CR>   ; re-sending block with sending sequence
                                                 count remaining the same (this example 2)
S: <ACK> 1                                       ; block is received correctly
```

Synchronisation upon Transmission Error

```
C: 1B00 013 8000 6300|014 8100 00075|017 8315 QMS-STAR|017 <CRC> <CR>
S: <ACK> 1
C: 2B02 8316 ROP200U1|014 9218 01.00<CRC> <CR>
S: <ACK> 0                                       ; error occurred
C: 2B02 8316 ROP200U1|014 9218 01.00<CRC> <CR>
S: <ACK> 0                                       ; error re-occurred
C: 0B00 013 8000 6300|014 8100 00075|017 8315QMS-STAR|017 <CRC> <CR>
                                                 ; re-synchronization
                                                 ; sequence count 0
S: <ACK> 1
C: 1B02 8316 ROP200U1|014 9218 01.00<CRC> <CR>
S: <ACK> 1
```

Transmission terminated upon Transmission Error

C: 1B00 013 8000 6300|014 8100 00075|017 8315 MEDISTAR|017 <CRC> <CR>

S: <ACK> 1

C: 2B02 8316 ROP200U1|014 9218 01.00<CRC> <CR>

S: <ACK> 0 ; error occurred

C: 2B02 8316 ROP200U1|014 9218 01.00<CRC> <CR>

S: <ACK> 0 ; error occurred

C: 0B00 013 8000 6300|014 8100 00075|017 8315 QMS-STAR|017 <CRC> <CR>

S: <ACK> 1

C: 2B02 8316 ROP200U1|014 9218 01.00<CRC> <CR>

S: <ACK> 0 ; error occurred

C: 2B02 8316 ROP200U1|014 9218 01.00<CRC> <CR>

S: <ACK> 0

Transmission terminated by sender. Receiver remains ready to receive.

Root Data Request Transmission Error

The following situation may cause both the client and the server to attempt to send a BDT file:

C: 1B00 013 8000 6300|014 8100 00075|017 8315 QMS-STAR|017 <CRC> <CR>

S: <ACK> 1

C: 2B02 8316 ROP200U1|014 9218 01.00<CRC> <CR>

S: [<ACK> 1] ; the server sends confirmation of file receipt, which is not received by the client

C: 2B02 8316 ROP200U1|014 9218 01.00<CRC> <CR> ; re-sending the same block

S: 7B00 013 8000 6301|014 8100 00142|<CRC> <CR> ; the server is already ending the first block of the requested root data

C: **0**B00 013 8000 6300|014 8100 00075|017 8315 QMS-STAR|017 <CRC> <CR> ; the client re-sends data using re-synchronization

S: 7B00 013 8000 6301|013 8100 0141|<CRC> <CR> ; the server repeats the first block of root data (ACK 1 from the client is missing)

C: **0**B00 013 8000 6300|014 8100 00075|017 8315 QMS-STAR|017 <CRC> <CR> ; the client re-attempts synchronization

S: **0**B00 013 8000 6301|014 8100 00141|<CRC> <CR> ; the server re-sends data using re-synchronization

S: 0B00 013 8000 6301|014 8100 00141|<CRC> <CR> ; the server re-attempts synchronization

This transmission is terminated by both the server and the client upon timeout („wait for ACK“) (vgl. 6.1.6).

6.2 Appendix B The device and method-specific field "8402"

Field 8402 has been re-defined as follows as part of a BDT review (medical devices connection and data transfer):

Field Label: 8402

Name: device and method-specific field

Function: This field is used to group the data to be transmitted.

Type: The previous type, **2 (alnum)** has been expanded to **1 - 6 (alnum)**..

Rule: The field contents are made up of text containing up to 4 characters to acts as a group label followed by two-digit numbering from 00 through 99 (for example LUFU09), where 00 is always reserved for use as a field for a non-specified test within that group. The group label ALLG (often ALLG00) is used for tests that cannot be classified more precisely.

The field contents list is dynamic and is managed **centrally by the ZI.**
The groups and field contents listed below therefore represent a provisional list that may be expanded as needed.

Unlike label 8402, test IDs (lable 8410) may be assigned in a manufacturer-specific way (see Appendix B of BDT 2/94).

ALLE_ _ Allergology

ALLE01	Anamnesis recordation allergologic
ALLE02	Result recordation allergologologic
ALLE03	Diagnosis recordation allergologologic
ALLE04	Prick test
ALLE05	Intracutan test
ALLE06	Provocations test
ALLE07	Invitro test
ALLE08	Insect poison
ALLE09	Epicutan test
ALLE10	daily hypo-sensitive treatment

ALLG_ _ General Tests

ALLG00	non-specified tests

APNO_ _ Apnoe during sleep

APNO00	Transient cessation of respiration, general
APNO01	Long Term screening of transient nocturnal cessation of respiration
APNO02	Polysomnography

AUDI_ _ Audiometric Tests

AUDI00	Audiometry, general
AUDI01	Pure sound threshold audiogramm
AUDI02	EEG audiometry

BDM_ _ Blood pressure tests

BDM00	Blood pressure, general
BDM01	long term blood pressure

EKG_ _ Electorcardiography

EKG00	ECG, general
EKG01	ECG in resting position
EKG02	Arrhythmic ECG
EKG03	Late potential ECG
EKG04	Long term ECG

ERGO_ _ Stress Tests

ERGO00	Stress test, general
ERGO01	Stress ECG
ERGO02	Flow Volume under stress
ERGO03	Analysis of blood gases
ERGO04	Blood gases under stress
ERGO05	Spiroergometry
ERGO06	Analysis of gases in breath
ERGO07	Pulsoximetry
ERGO08	Indirect calorimetry
ERGO09	Indirect calorimetry with cover
ERGO10	HZV measurement via CO2-reinhalation
ERGO11	breath impulse measurement via CO2-reinhalation

HÄMA_ _ Haemograms

HÄMA01	small haemogram
HÄMA02	large haemogram
HÄMA03	manuelles Differentialblutbild
HÄMA04	Retikulozyten
HÄMA05	CD4/CD8

LUFU_ _ Lung function Tests

LUFU00	Lung function, general
LUFU01	Slow Spirometry
LUFU02	Forced Spirometry (Flow-Volume)
LUFU03	MVV (Maximal Voluntary Ventilation)

LUFU04	Bodyplethysmography
LUFU05	FRC pl (Lung volume - Bodyplethysmography)
LUFU06	FRC He (Lung volume - Helium back inhalation)
LUFU07	Resistance using cover pressure methods
LUFU08	Resistance using impulse oscillation methods
LUFU09	Resistance using oszilloresistometric methods
LUFU10	Compliance
LUFU11	Breathing muscle strength measurement
LUFU12	Breathing impulse measurement
LUFU13	Diffusion Single-Breath
LUFU14	Diffusion Steady-State
LUFU15	Diffusion Rebreathing
LUFU16	Diffusion membrane factor
LUFU17	Capnography
LUFU18	Rhinomanometry
LUFU19	Analysis of breath in resting position

NEUR_ _ Neurological Tests

NEUR00	Neurology, general
NEUR01	Long term EEG
NEUR02	EEG with simultaneous ECG
NEUR03	Motor NLG
NEUR04	Sensor NLG
NEUR05	Evoked potentials
NEUR06	Rotation test
NEUR07	Nystagmus analysis
NEUR08	Intermittened test
NEUR09	Posture
NEUR10	Biofeedback
NEUR11	ERG/EOG
NEUR12	EMG of eye muscles

OPTO_ _ Ophthalmology

OPTO00	Ophthalmology, general
OPTO01	Calculation of refraction index, objectiv

OPTO02	Calculation of refraction index, subjectiv
OPTO03	Refraction values glasses/contact lense
OPTO04	Measurement of sensitivity to light (Visus)
OPTO05	Visual field measurement
OPTO06	Eye ball pressure measurement
OPTO07	Cornea measurement (curvature radius/position of axes)
OPTO08	Cornea measurement (3D geometrical data)
OPTO09	Fundus images
OPTO10	Angiographic images
OPTO11	Aperture lamp images
OPTO12	Topographic images
OPTO13	Layered images
OPTO14	generic images

PROV_ _ Provokation Tests

PROV00	Provocation, general
PROV01	Specific aerosol provocation
PROV02	Non-specific aerosol provokation
PROV03	Cold air provocation
PROV04	Bronchodilatation

SONO_ _ Sonographical Tests

SONO00	Sonography, general
SONO01	Ultrasound doppler

URO_ _ Urology

URO00	Urology, general
URO01	Uroflowmetry

6.3 Appendix C   C-Program for Calculating CRC-16

```
short crc16(char *s, short len)
{
        short bte, crc, i;

        crc = 0;
        while (len > 0) {
            len = len - 1;
            bte = *s;
            s = s + 1;
            i = 8;
            while (i > 0) {
              i = i - 1;
              if (bte & 0x0080) {
                crc = crc ^ 0x8000;
              }
              if (crc & 0x8000) {
                crc = crc << 1;
                    crc = crc ^ 0x8005;
              } else {
                crc = crc << 1;
              }
              bte = bte << 1;
            }
        }
        return crc;
}
```

6.4 Appendix D: Borland Pascal 7. 0 Program for Calculating CRC-16

```
program Crc16Dem; { CRC16-Demo for Borland Pascal 7.0 }

{$B-,I+,P+,T-,X+}

function UpdateCrc16 (InitCrc: Word; var Data; Len: Word): Word;
        { CRC-16-Weiterberechnung, InitCrc sollte beim 1. Block 0 sein }
type CrcByteArray = array[1..65535] of Byte;
var Crc, I, J: Word;
    B       : Byte;
begin
  Crc := InitCrc;
  for I := 1 to Len do begin
    B := CrcByteArray(Data)[I];
    for J := 1 to 8 do begin
      if (B and $80) <> 0 then Crc := Crc xor $8000;
      if (Crc and $8000) <> 0 then begin
        Crc := Crc shl 1;
        Crc := Crc xor $8005;
      end
      else Crc := Crc shl 1;
      B := B shl 1;
    end;
  end;
  UpdateCrc16 := Crc;
end;

function Crc16 (var Data; Len: Word): Word;
        { CRC-16-Berechnung, InitCrc := 0 }
begin
  Crc16 := UpdateCrc16(0, Data, Len);
end;

function Crc16Str (const St: String): Word;
        { CRC-16-Berechnung fﾁr Strings unter Nichtberﾁcksichtigung
```

```
           des L”ngenbytes }
type TDataStr = record
       Len: Byte;
       Data: array[1..255] of Char;
     end;
var DataStr: ^TDataStr;
begin
  DataStr := @St;
  Crc16Str := Crc16(DataStr^.Data, DataStr^.Len);
end;

begin { Crc16Dem }
  if ParamCount = 0 then WriteLn('Aufruf:  crcdemo  Demostring')
  else begin
    Write(ParamStr(1) + ': ');
    WriteLn(Crc16Str(ParamStr(1)));
  end;
end.
```