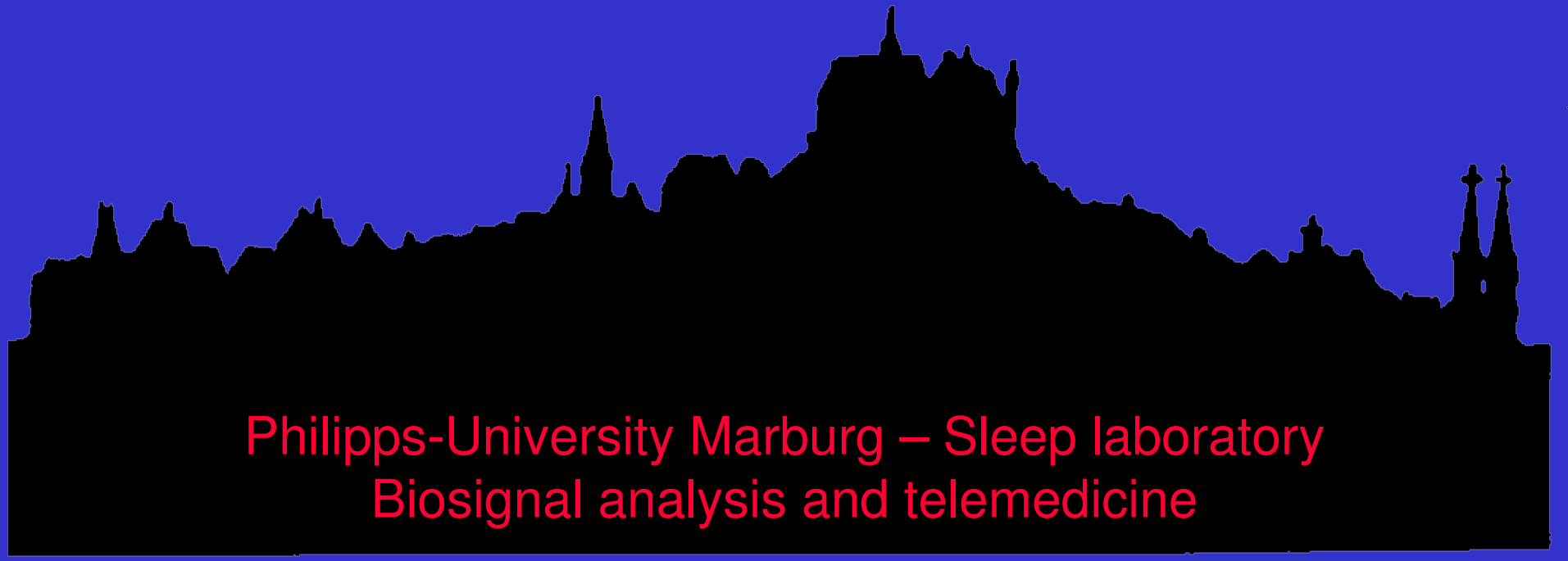
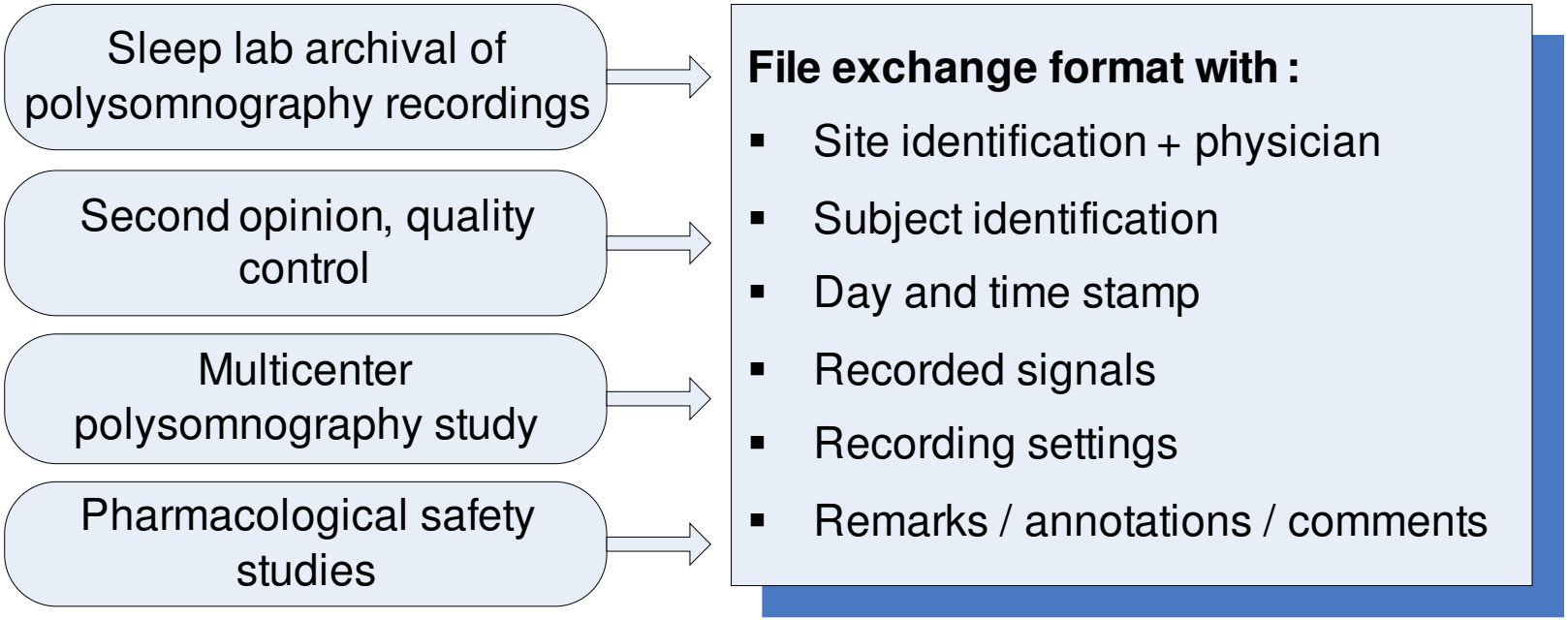
DEVELOPMENT OF STANDARDS FOR DATA EXCHANGE IN SLEEP MEDICINE

Thomas Penzel



Philipps-University Marburg – Sleep laboratory
Biosignal analysis and telemedicine

Need for polysomnography file exchange file (FEF)

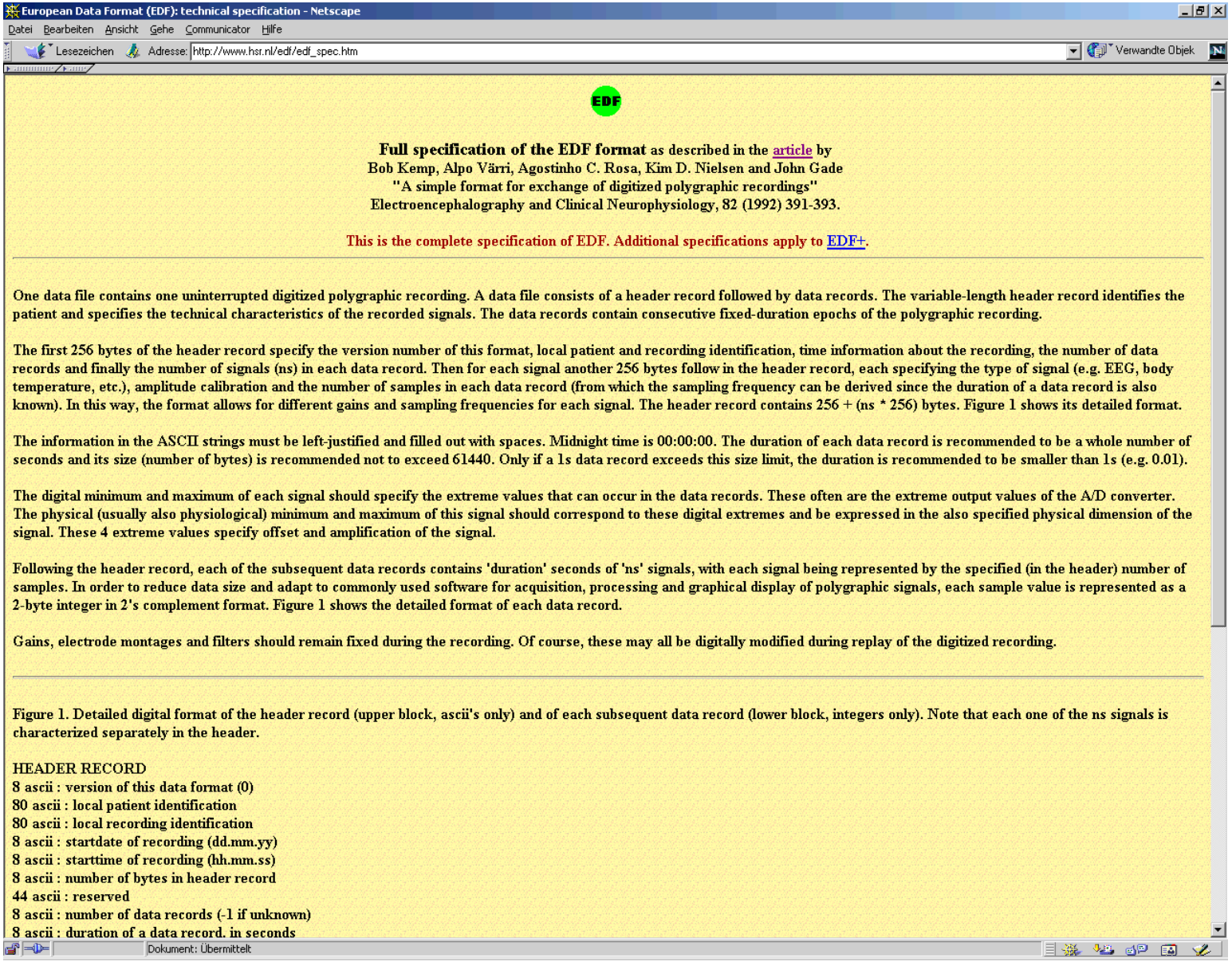


Remark: the PSG report is also needed, but not part of the file .

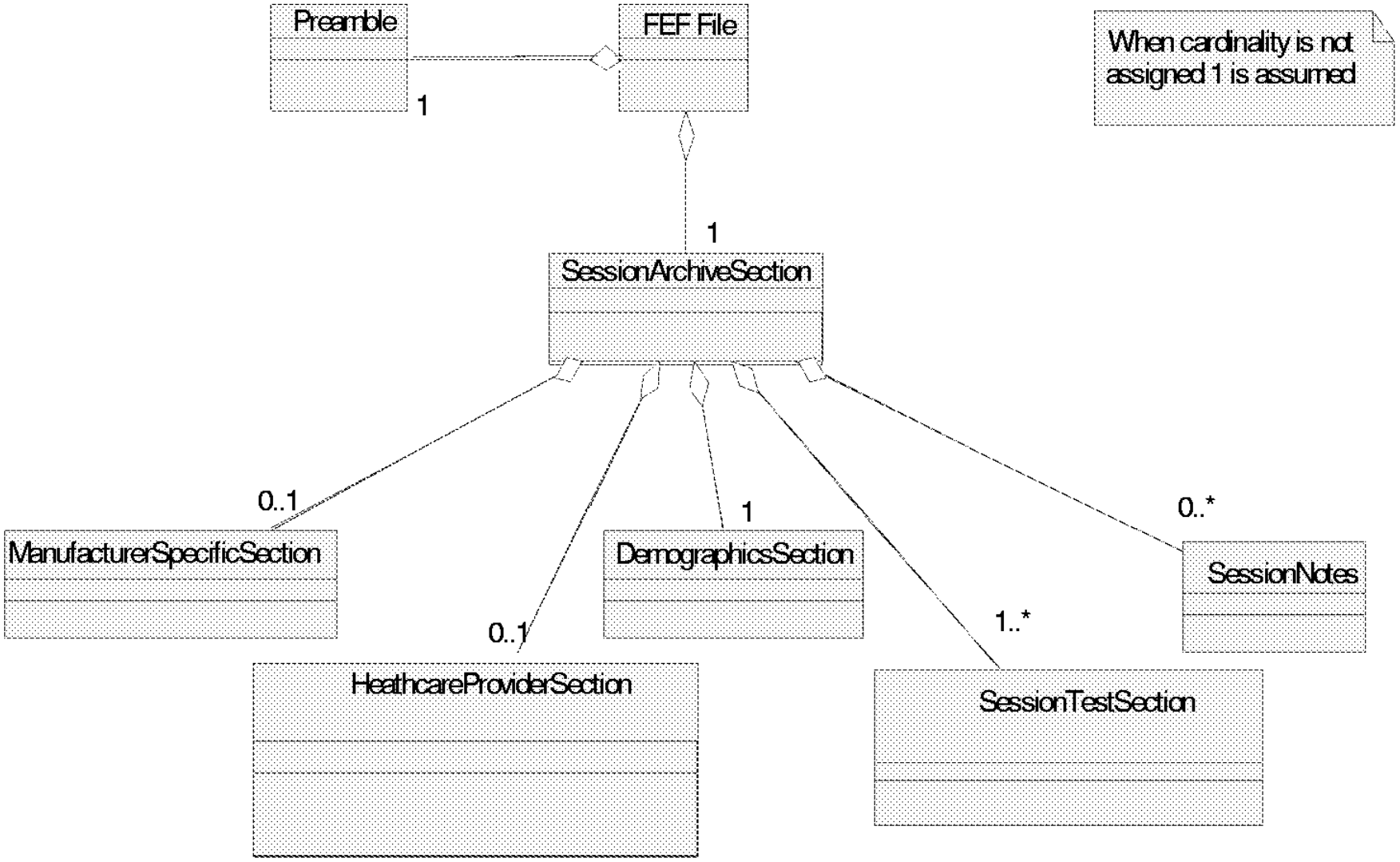
Database of recordings:

- Sleep heart health study
- Phenotypeing
- Physionet

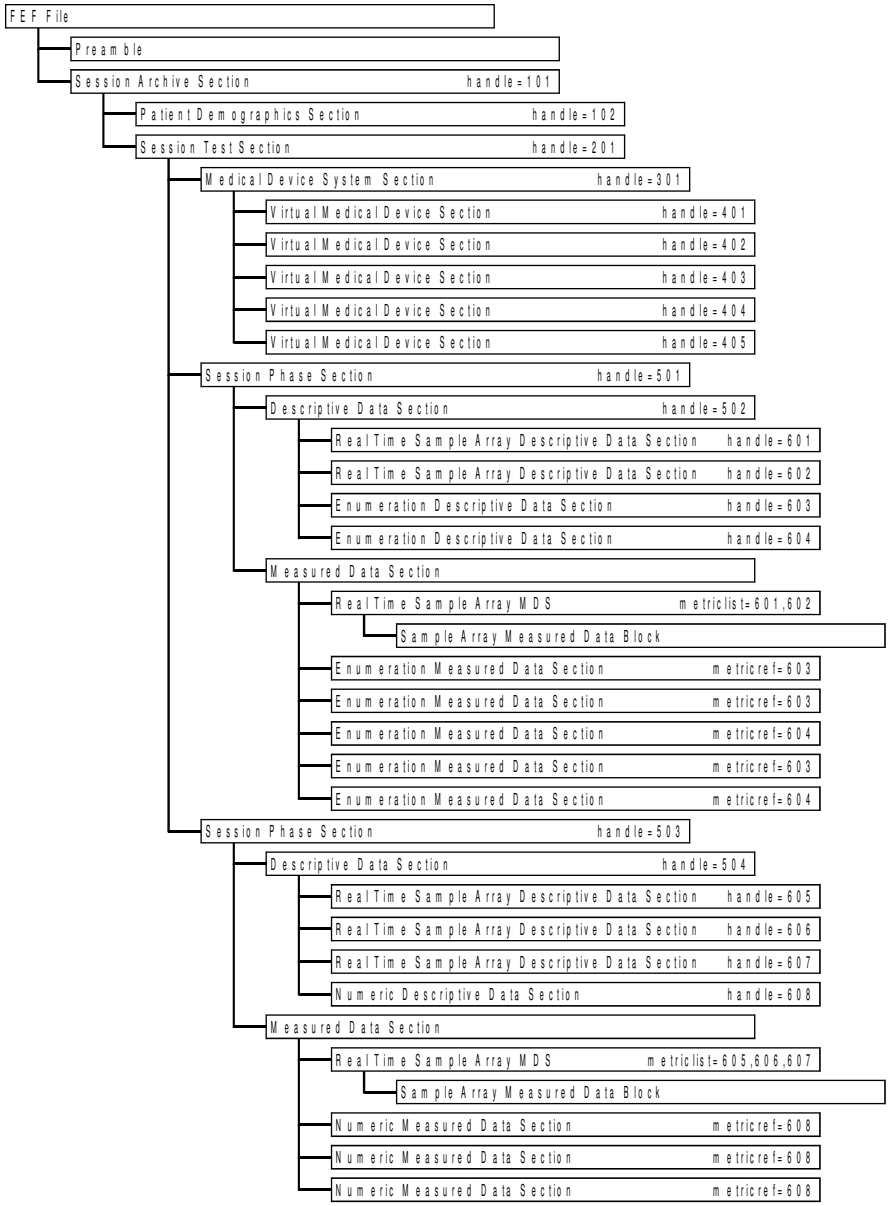
European Data Format (EDF)



Abstract file structure with contents needed



Serialization for a physical file structure



Start of a FEF file – example of an implementation

Preamble

Byte	Depth	Length	Value	
0	0	8	"CEN" CR LF Ctrl-Z EOT 84H	File ID
			0x43454E13101A0484	
8	0	8	1.00	Version
			0x3030303030313030	
16	0	8	1.00 (ASN.1 BER)	Encoding
			0x3030303030313030	
24	0	8	little endian	Endianity
			0x3030303030303030	

SEQUENCE

Triple	Byte	Depth	Tag	Length	Value	Fieldname/Type
1	32	0	A7001+	23442		
			0x7FB659	**0x825B92**		SEQUENCE
2	38	1	A2337	1	101	handle
			0x5F9221	**0x01**	**0x65**	Handle
3	43	1	A2507	4	X045	id
			0x5F934B	**0x04**	**0x58303435**	FEFString
4	51	1	A2513	8	FEF Test	name
			0x5F9351	**0x08**	**0x4645462054657374**	FEFString
5	63	1	A2530	11	Not checked	comments
			0x5F9362	**0x0B**	**0x4E6F7420636865636B6564**	FEFString
6	78	1	A2538	14	2001-02-08T14:30:10,000	starttime
			0x5F936A	**0x0E**	**0x32303031303230383134333033130**	AbsoluteTime
7	96	1	A2539	14	2001-02-08T14:31:20,000	stoptime
			0x5F936B	**0x0E**	**0x32303031303230383134333313230**	AbsoluteTime

FEF file – example continuation

Triple	Byte	Depth	Tag	Length	Value	Fieldname/Type
				SEQUENCE		
8	114	1	A7004+	65		
			0x7FB65C	0x41		SEQUENCE
9	118	2	A2337	1	102	handle
			0x5F9221	0x01	0x66	Handle
10	123	2	A2394	11	abc-123-xyz	patientid
			0x5F925A	0x0B	0x6162632D3132332D78797A	FEFString
11	138	2	A6002+	29		
			0x7FAE72	0x1D		SEQUENCE
12	142	3	C1	10	Mustermann	familyname
			0x81	0x0A	0x4D75737465726D616E6E	FEFString
13	154	3	C2	7	Manfred	givenname
			0x82	0x07	0x4D616E66726564	FEFString
14	163	3	C3	0		middlename
			0x83	0x00		FEFString
15	165	3	C4	0		prefix
			0x84	0x00		FEFString
16	167	3	C5	0		suffix
			0x85	0x00		FEFString
17	169	3	C6	0		degree
			0x86	0x00		FEFString
18	171	2	A2392	8	1960-11-30	dateofbirth
			0x5F9258	0x08	0x3139363031313330	AbsoluteTime
				SEQUENCE OF		
Triple	Byte	Depth	Tag	Length	Value	Fieldname/Type
19	183	1	A7015+	23291		
			0x7FB667	0x825AFB		SEQUENCE OF
				SEQUENCE		
Triple	Byte	Depth	Tag	Length	Value	Fieldname/Type
20	189	2	U16+	23287		[0]
			0x30	0x825AF7		SEQUENCE
21	193	3	A2337	2	201	handle
			0x5F9221	0x02	0x00C9	Handle
22	199	3	A2506	6	X045.1	id
			0x5F934A	0x06	0x583034352E31	FEFString
23	209	3	A2512	9	Session 1	name
			0x5F9350	0x09	0x53657373696F6E2031	FEFString
24	222	3	A2529	9	Test Data	comments
			0x5F9361	0x09	0x546573742044617461	FEFString
25	235	3	A2538	14	2001-02-08T14:30:10,000	starttime
			0x5F936A	0x0E	0x32303031303230383133433303130	AbsoluteTime
26	253	3	A2539	14	2001-02-08T14:31:20,000	stoptime
			0x5F936B	0x0E	0x32303031303230383133433313230	AbsoluteTime

Specification of FEF

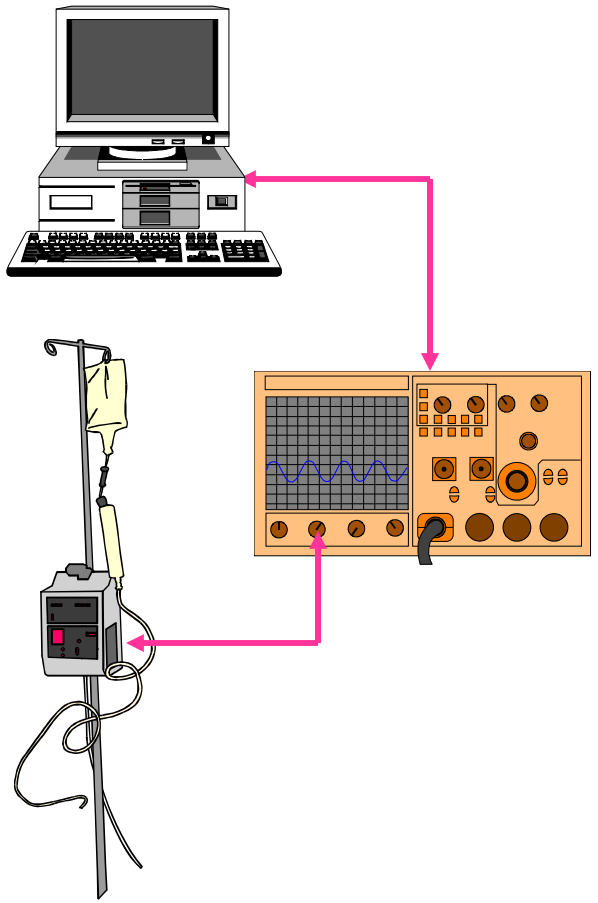
Specification in ASN.1 with Basic Encoding Rules

```
SessionArchiveSection ::= [APPLICATION 7001] SEQUENCE {
    handle                  Handle,
                            -- unique (within a file) handle
    s-archive-id            [APPLICATION 2507] FEFString,
    s-archive-name          [APPLICATION 2513] FEFString,
    s-archive-comments      [APPLICATION 2530] FEFString OPTIONAL,
    starttime               [APPLICATION 2538] AbsoluteTime,
    stoptime                [APPLICATION 2539] AbsoluteTime,
    protection              [APPLICATION 2519] ArchiveProtection OPTIONAL,
    placeholder             Placeholder OPTIONAL,
    manufacturerspecific    [APPLICATION 7002] ManufacturerSpecificSection OPTIONAL,
    healthcareprovider      [APPLICATION 7003] HealthCareProviderSection OPTIONAL,
    demographics            [APPLICATION 7004] PatientDemographicsSection,
    sessions                [APPLICATION 7015] SEQUENCE-OF
                            SessionTestSection SIZE (1..*),

    notes                   [APPLICATION 7016] SEQUENCE-OF
                            SessionNotesSection
                            DEFAULT {},
}
```

Family of Standards for Monitoring

- Facilitate Interoperability of Medical Devices in monitoring (anaesthesia, operating rooms, intensive care, emergency)
  - Enable applications: automatic charting, fluid balancing, etc.
  - Enable vertical integration from device to healthcare record
  - Reduce development cost for custom device drivers
  - Enable Plug&Play device interconnection

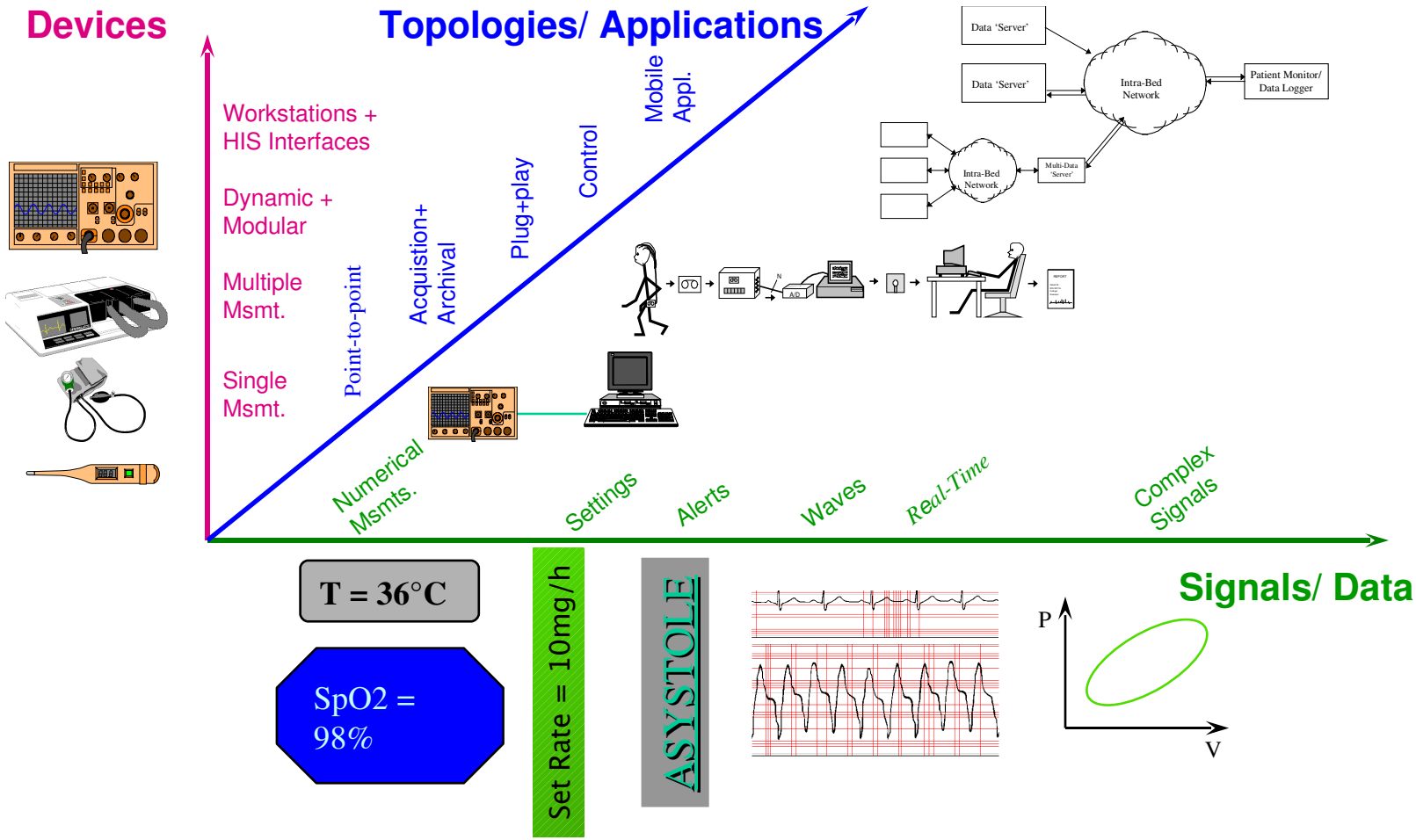


Strategic Requirements

Device communications is an increasingly global business

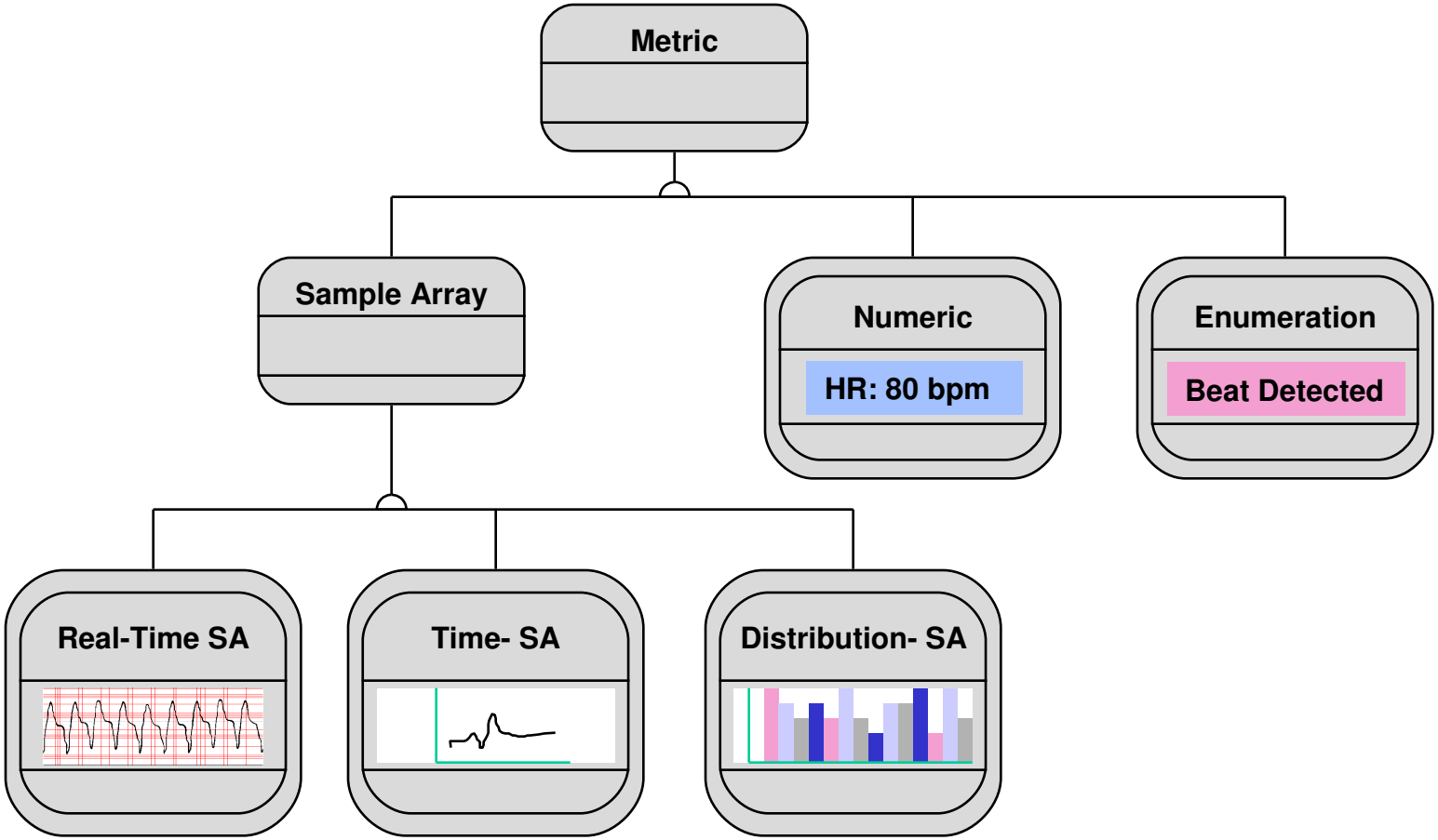
- Standards complement and are not compete
  CEN/TC251/WGIV and IEEE 1073 have complemented each other's work and are now synthesising it all into a harmonised family in ISO – where the numbers will be in a series ISO 11073-xxxx.
- Replace devices only when timely
  The earlier standards will only gradually, i.e. when appropriate, be incorporated into a harmonised family in ISO by development of specific use-case based profiles

Different degrees of complexity

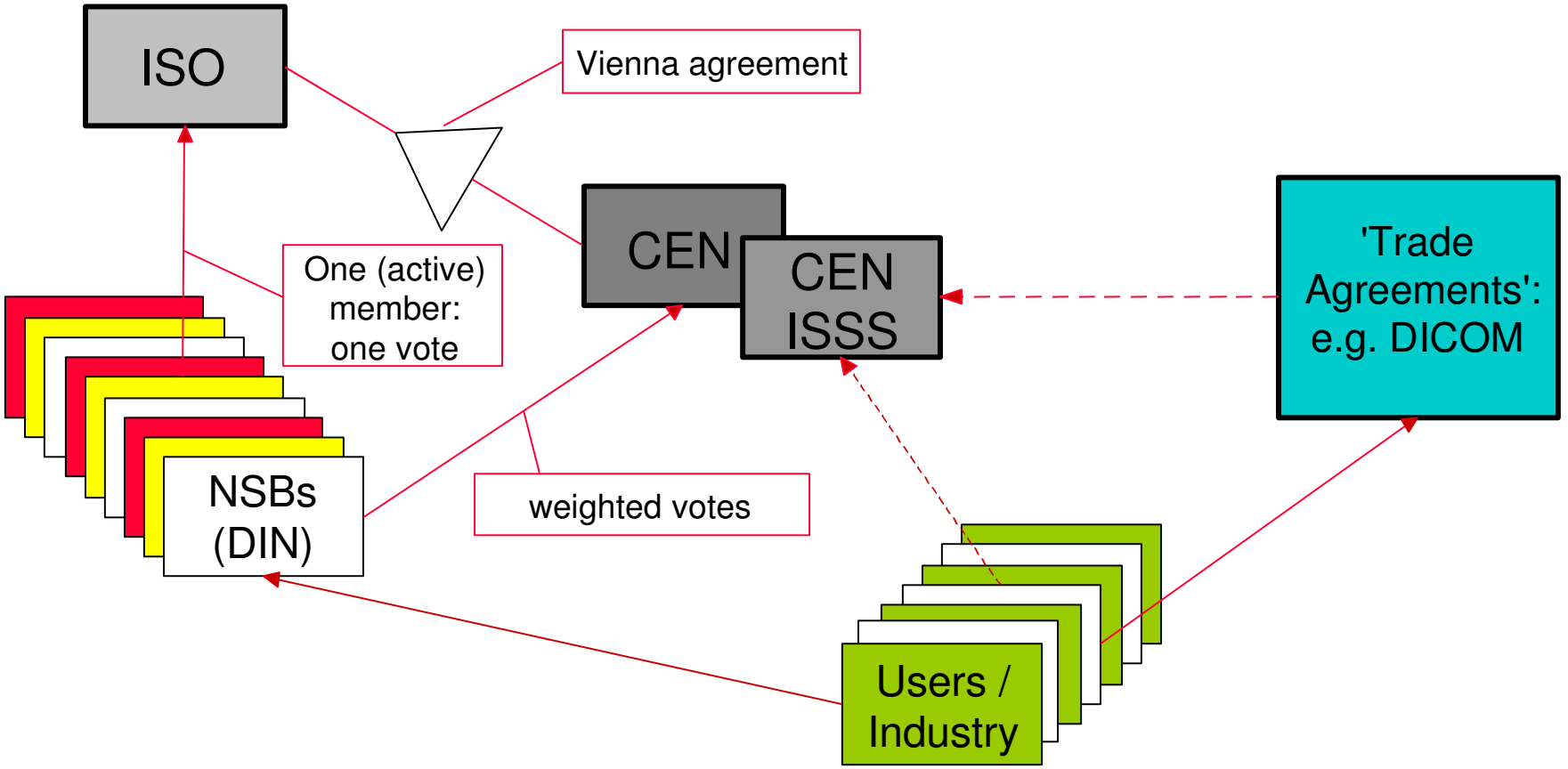


Point of care medical device communication and data storage

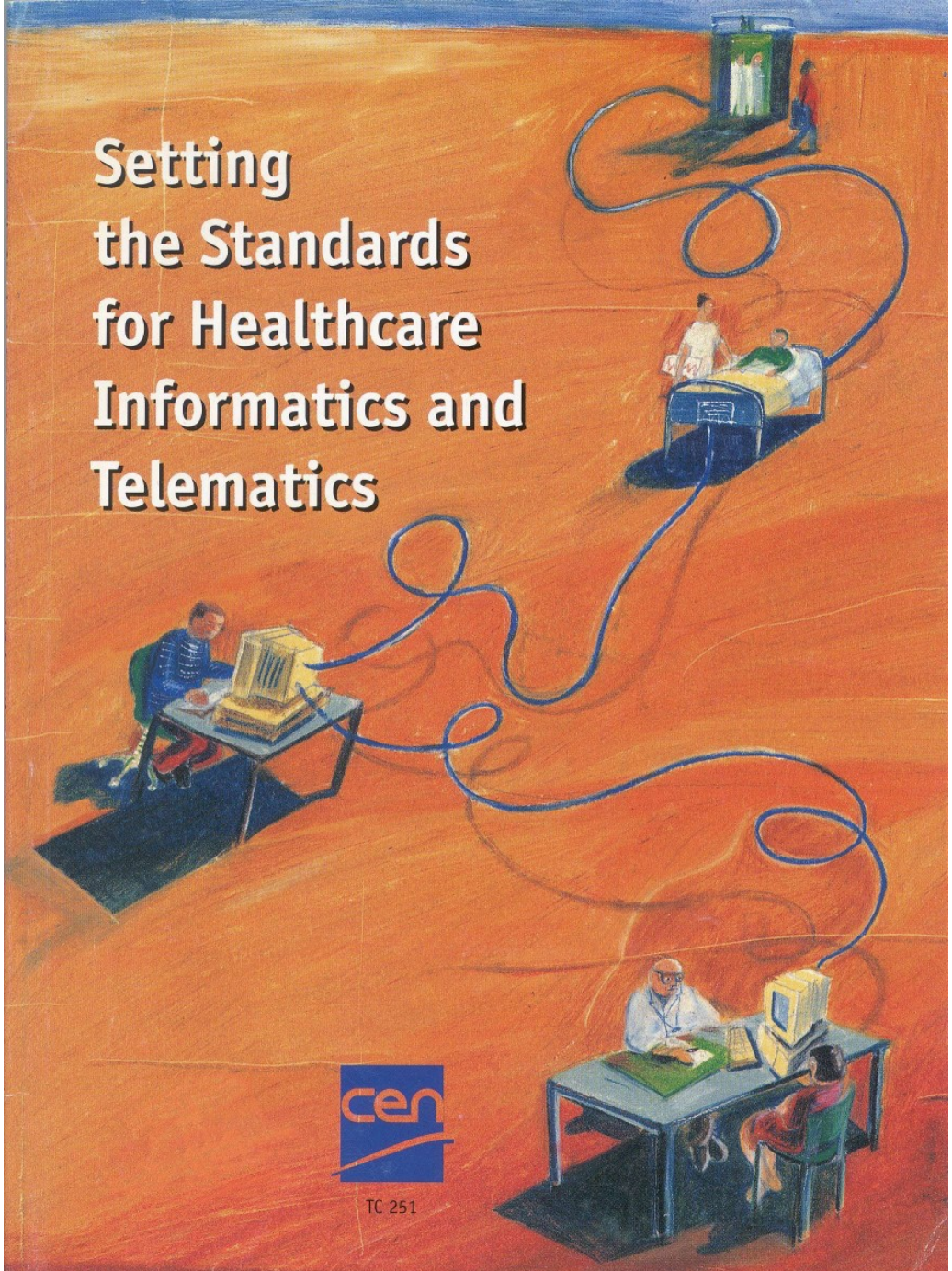
„Metric“-Spezialisierungen (Vererbung)



International Standardization bodies



Setting the Standards for Healthcare Informatics and Telematics



CEN

TC 251