

# DEVELOPMENT OF STANDARDS FOR DATA EXCHANGE IN SLEEP MEDICINE

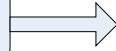
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# Need for polysomnography file exchange file (FEF)

Sleep lab archival of polysomnography recordings



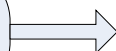
Second opinion, quality control



Multicenter polysomnography study



Pharmacological safety studies



## File exchange format with :

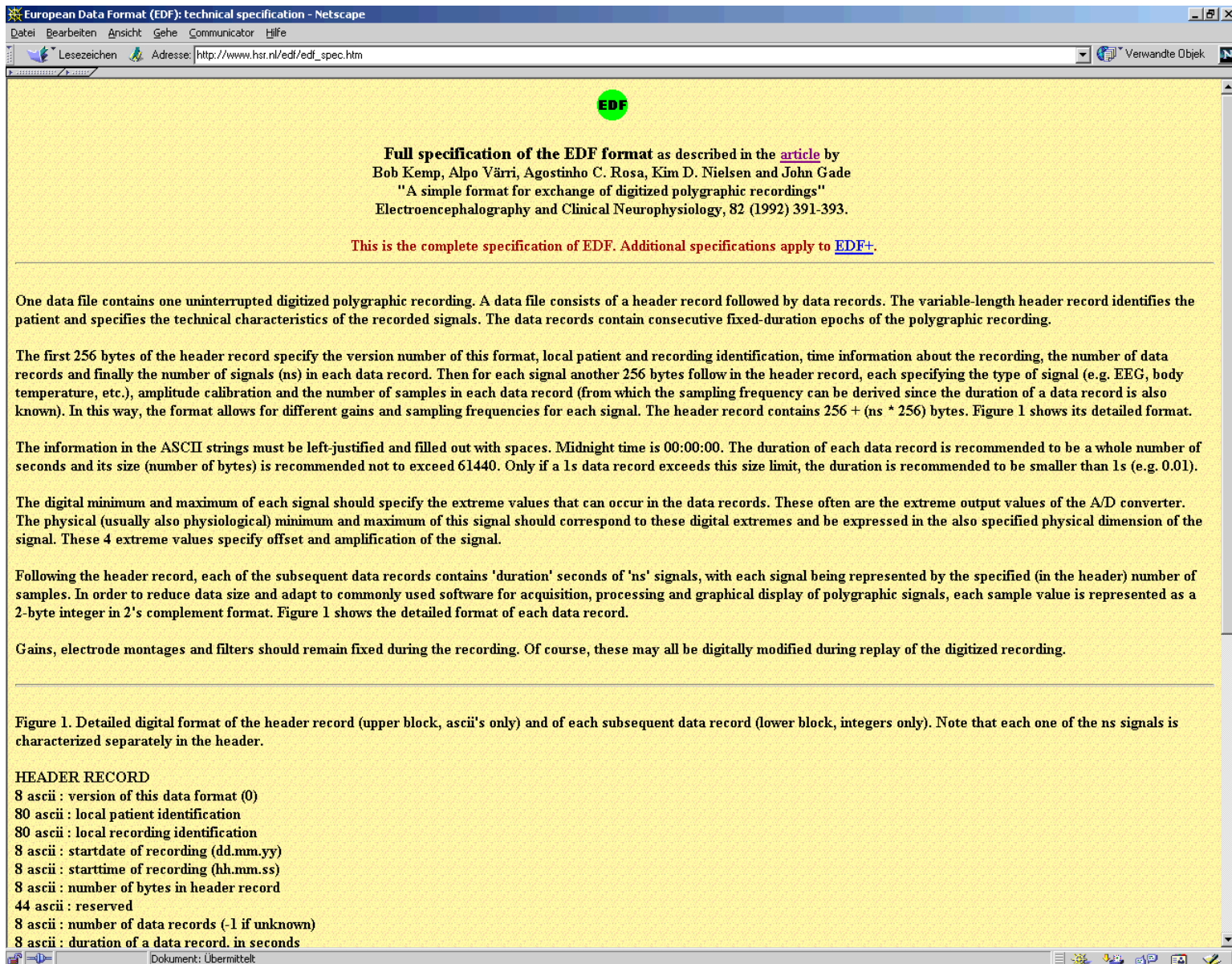
- Site identification + physician
- Subject identification
- Day and time stamp
- Recorded signals
- Recording settings
- Remarks / annotations / comments

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

## Database of recordings:

- Sleep heart health study
- Phenotyping
- Physionet

# European Data Format (EDF)



The screenshot shows a Netscape browser window with the title "European Data Format (EDF): technical specification - Netscape". The address bar shows "http://www.hsr.nl/edi/edf\_spec.htm". The page content is on a yellow background and features a green "EDF" logo at the top center. The text describes the full specification of the EDF format, citing an article by Bob Kemp, Alpo Värri, Agostinho C. Rosa, Kim D. Nielsen, and John Gade. It details the structure of data files, header records, and data records, including information on sampling frequency, signal types, and header fields. A list of header record fields is provided at the bottom.

**EDF**

**Full specification of the EDF format** as described in the [article](#) by Bob Kemp, Alpo Värri, Agostinho C. Rosa, Kim D. Nielsen and John Gade "A simple format for exchange of digitized polygraphic recordings" *Electroencephalography and Clinical Neurophysiology*, 82 (1992) 391-393.

This is the complete specification of EDF. Additional specifications apply to [EDF+](#).

One data file contains one uninterrupted digitized polygraphic recording. A data file consists of a header record followed by data records. The variable-length header record identifies the patient and specifies the technical characteristics of the recorded signals. The data records contain consecutive fixed-duration epochs of the polygraphic recording.

The first 256 bytes of the header record specify the version number of this format, local patient and recording identification, time information about the recording, the number of data records and finally the number of signals (ns) in each data record. Then for each signal another 256 bytes follow in the header record, each specifying the type of signal (e.g. EEG, body temperature, etc.), amplitude calibration and the number of samples in each data record (from which the sampling frequency can be derived since the duration of a data record is also known). In this way, the format allows for different gains and sampling frequencies for each signal. The header record contains  $256 + (ns * 256)$  bytes. Figure 1 shows its detailed format.

The information in the ASCII strings must be left-justified and filled out with spaces. Midnight time is 00:00:00. The duration of each data record is recommended to be a whole number of seconds and its size (number of bytes) is recommended not to exceed 61440. Only if a 1s data record exceeds this size limit, the duration is recommended to be smaller than 1s (e.g. 0.01).

The digital minimum and maximum of each signal should specify the extreme values that can occur in the data records. These often are the extreme output values of the A/D converter. The physical (usually also physiological) minimum and maximum of this signal should correspond to these digital extremes and be expressed in the also specified physical dimension of the signal. These 4 extreme values specify offset and amplification of the signal.

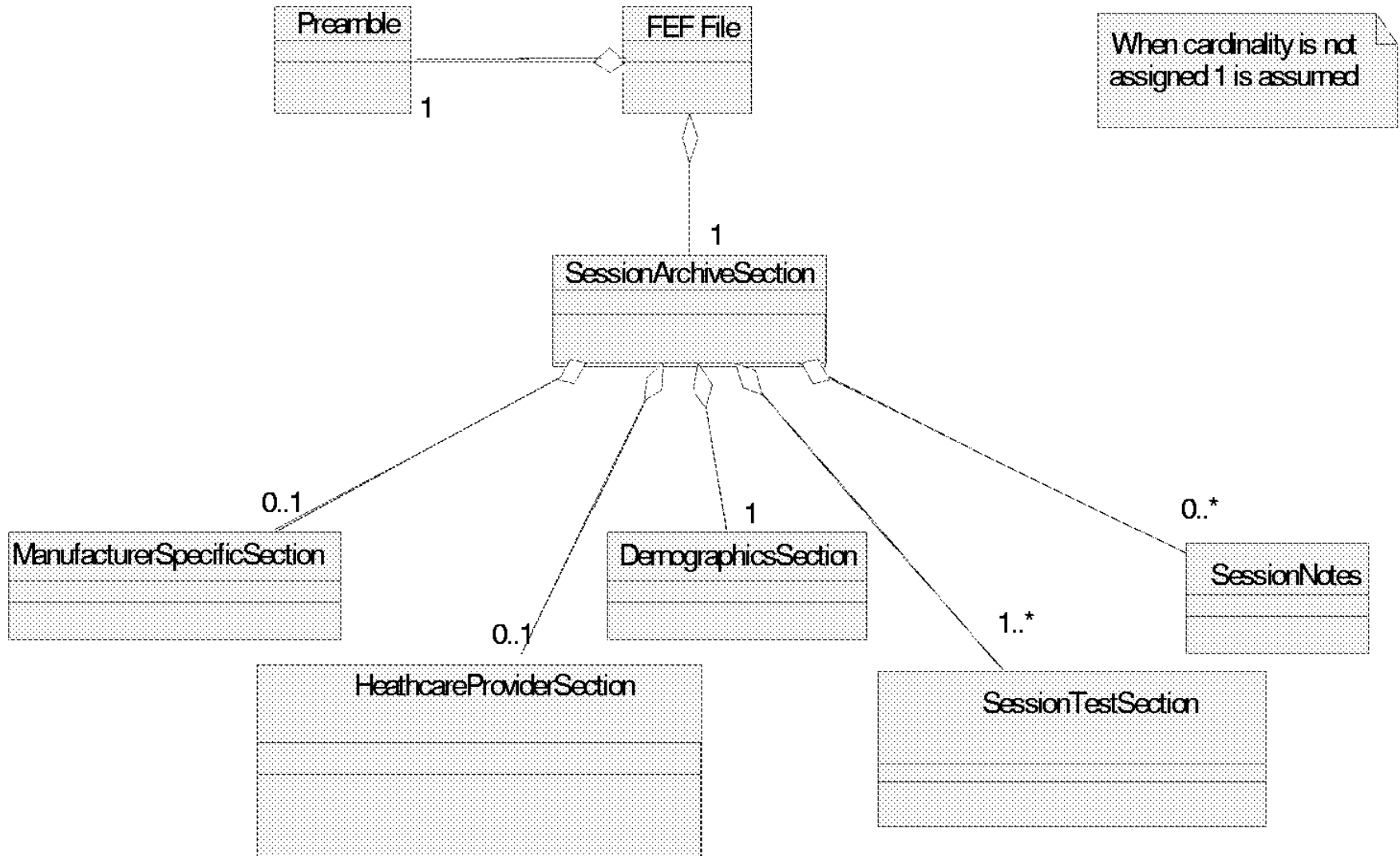
Following the header record, each of the subsequent data records contains 'duration' seconds of 'ns' signals, with each signal being represented by the specified (in the header) number of samples. In order to reduce data size and adapt to commonly used software for acquisition, processing and graphical display of polygraphic signals, each sample value is represented as a 2-byte integer in 2's complement format. Figure 1 shows the detailed format of each data record.

Gains, electrode montages and filters should remain fixed during the recording. Of course, these may all be digitally modified during replay of the digitized recording.

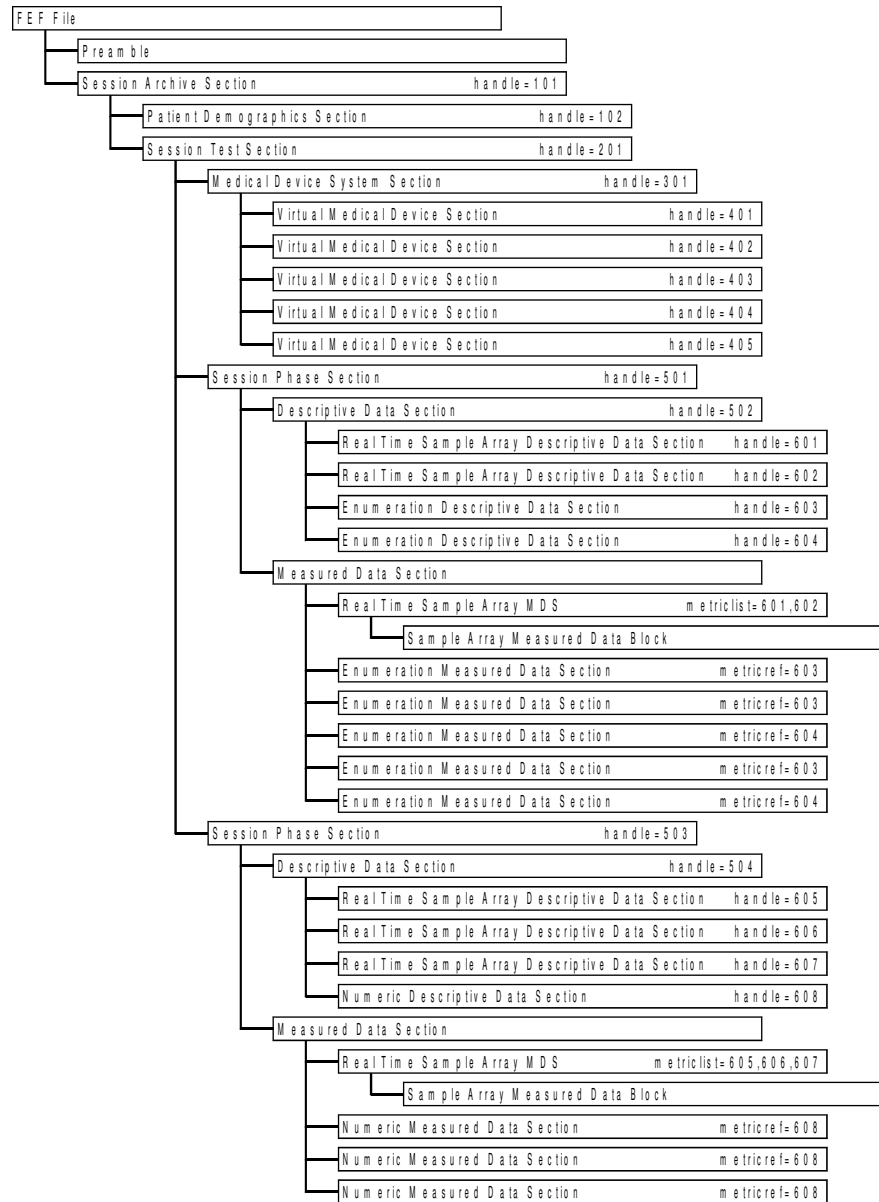
Figure 1. Detailed digital format of the header record (upper block, ascii's only) and of each subsequent data record (lower block, integers only). Note that each one of the ns signals is characterized separately in the header.

**HEADER RECORD**  
8 ascii : version of this data format (0)  
80 ascii : local patient identification  
80 ascii : local recording identification  
8 ascii : startdate of recording (dd.mm.yy)  
8 ascii : starttime of recording (hh.mm.ss)  
8 ascii : number of bytes in header record  
44 ascii : reserved  
8 ascii : number of data records (-1 if unknown)  
8 ascii : duration of a data record, in seconds

# 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	
			<b>0x43454E13101A0484</b>			
8	0	8	1.00		Version	
			<b>0x3030303030313030</b>			
16	0	8	1.00 (ASN.1 BER)		Encoding	
			<b>0x3030303030313030</b>			
24	0	8	little endian		Endianness	
			<b>0x3030303030303030</b>			
SEQUENCE						
Tripl e	Byte	Depth	Tag	Length	Value	Fieldname/Type
1	32	0	A7001+	23442		
			<b>0x7FB659</b>	<b>0x825B92</b>		SEQUENCE
2	38	1	A2337	1	101	handle
			<b>0x5F9221</b>	<b>0x01</b>	<b>0x65</b>	Handle
3	43	1	A2507	4	X045	id
			<b>0x5F934B</b>	<b>0x04</b>	<b>0x58303435</b>	FEFString
4	51	1	A2513	8	FEF Test	name
			<b>0x5F9351</b>	<b>0x08</b>	<b>0x4645462054657374</b>	FEFString
5	63	1	A2530	11	Not checked	comments
			<b>0x5F9362</b>	<b>0x0B</b>	<b>0x4E6F7420636865636B6564</b>	FEFString
6	78	1	A2538	14	2001-02-08T14:30:10,000	starttime
			<b>0x5F936A</b>	<b>0x0E</b>	<b>0x3230303130323038313433303130</b>	AbsoluteTime
7	96	1	A2539	14	2001-02-08T14:31:20,000	stoptime
			<b>0x5F936B</b>	<b>0x0E</b>	<b>0x3230303130323038313433313230</b>	AbsoluteTime

# FEF file – example continuation

Tripl e	Byte	Dept h	Tag	Length	SEQUENCE	Value	Fieldname/Type
8	114	1	A7004+	65			
			<b>0x7FB65C</b>	<b>0x41</b>			SEQUENCE
9	118	2	A2337	1	102		handle
			<b>0x5F9221</b>	<b>0x01</b>	<b>0x66</b>		Handle
10	123	2	A2394	11	abc-123-xyz		patientid
			<b>0x5F925A</b>	<b>0x0B</b>	<b>0x6162632D3132332D78797A</b>		FEFString
11	138	2	A6002+	29			
			<b>0x7FAE72</b>	<b>0x1D</b>			SEQUENCE
12	142	3	C1	10	Mustermann		familyname
			<b>0x81</b>	<b>0x0A</b>	<b>0x4D75737465726D616E6E</b>		FEFString
13	154	3	C2	7	Manfred		givenname
			<b>0x82</b>	<b>0x07</b>	<b>0x4D616E66726564</b>		FEFString
14	163	3	C3	0			middlename
			<b>0x83</b>	<b>0x00</b>			FEFString
15	165	3	C4	0			prefix
			<b>0x84</b>	<b>0x00</b>			FEFString
16	167	3	C5	0			suffix
			<b>0x85</b>	<b>0x00</b>			FEFString
17	169	3	C6	0			degree
			<b>0x86</b>	<b>0x00</b>			FEFString
18	171	2	A2392	8	1960-11-30		dateofbirth
			<b>0x5F9258</b>	<b>0x08</b>	<b>0x3139363031313330</b>		AbsoluteTime
							SEQUENCE OF
Tripl e	Byte	Dept h	Tag	Length	SEQUENCE	Value	Fieldname/Type
19	183	1	A7015+	23291			
			<b>0x7FB667</b>	<b>0x825AFB</b>			SEQUENCE OF
							SEQUENCE
Tripl e	Byte	Dept h	Tag	Length	SEQUENCE	Value	Fieldname/Type
20	189	2	U16+	23287			[0]
			<b>0x30</b>	<b>0x825AF7</b>			SEQUENCE
21	193	3	A2337	2	201		handle
			<b>0x5F9221</b>	<b>0x02</b>	<b>0x00C9</b>		Handle
22	199	3	A2506	6	X045.1		id
			<b>0x5F934A</b>	<b>0x06</b>	<b>0x583034352E31</b>		FEFString
23	209	3	A2512	9	Session 1		name
			<b>0x5F9350</b>	<b>0x09</b>	<b>0x53657373696F6E2031</b>		FEFString
24	222	3	A2529	9	Test Data		comments
			<b>0x5F9361</b>	<b>0x09</b>	<b>0x546573742044617461</b>		FEFString
25	235	3	A2538	14	2001-02-08T14:30:10,000		starttime
			<b>0x5F936A</b>	<b>0x0E</b>	<b>0x3230303130323038313433303130</b>		AbsoluteTime
26	253	3	A2539	14	2001-02-08T14:31:20,000		stoptime
			<b>0x5F936B</b>	<b>0x0E</b>	<b>0x3230303130323038313433313230</b>		AbsoluteTime

# Specification of FEF

## Specification in ASN.1 with Basic Encoding Rules

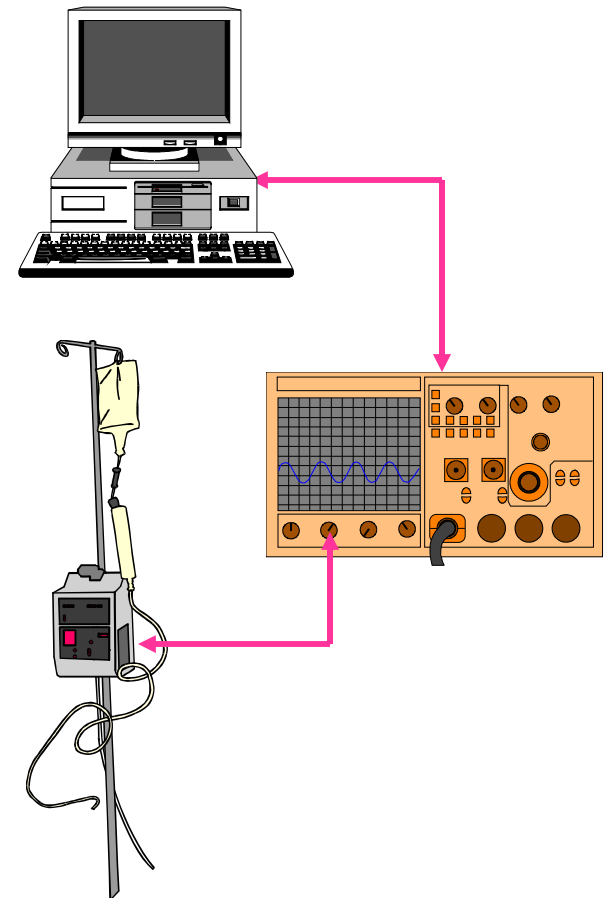
```
SessionArchiveSection ::= [APPLICATION 7001] SEQUENCE {
  handle                Handle,
                        -- unique (within a file) handle
  s-archive-id         [APPLICATION 2507] FEFString,
  s-archive-name       [APPLICATION 2513] FEFString,
  s-archive-comments   [APPLICATION 2530] FEFString 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



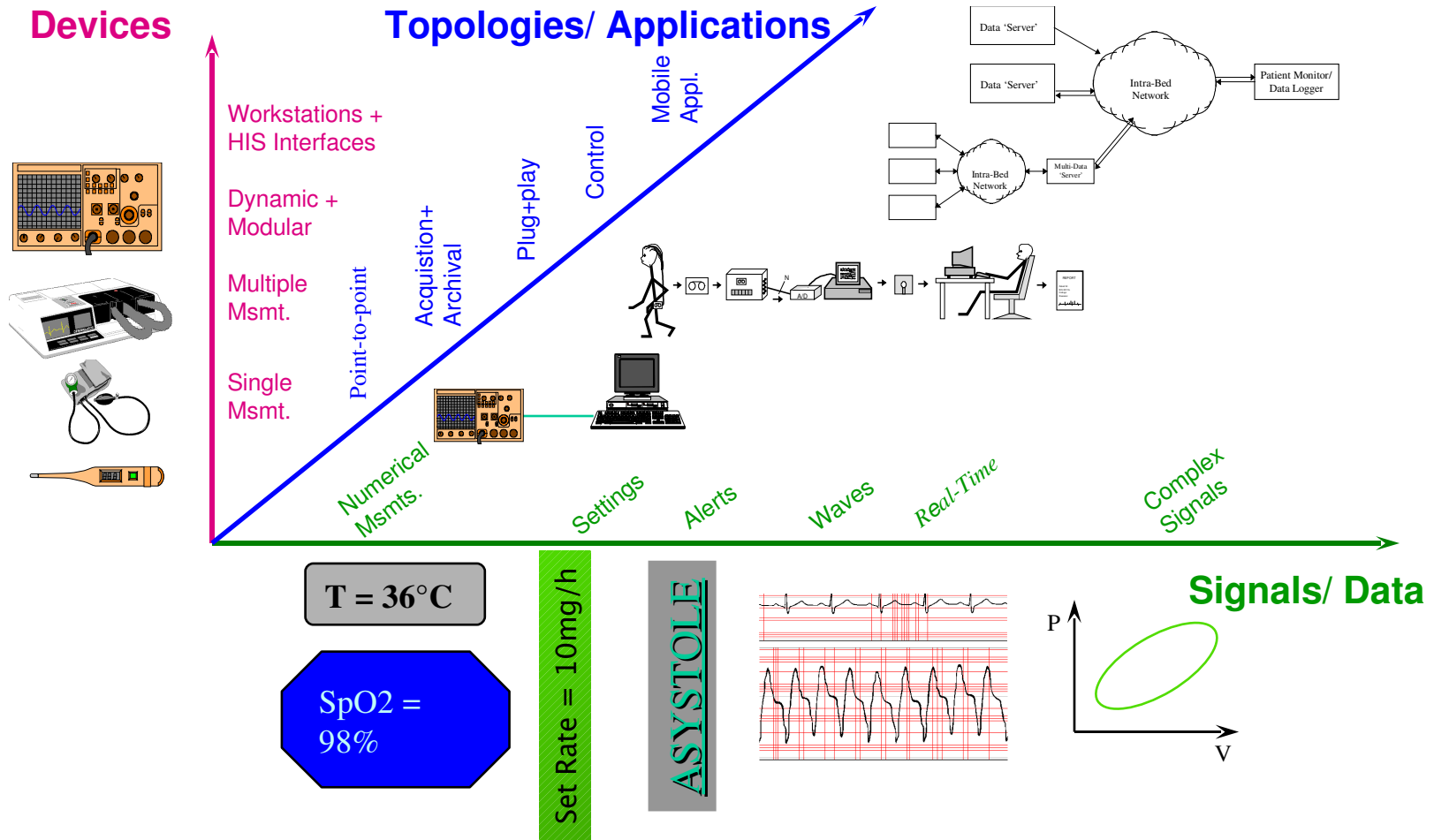
# Strategic Requirements

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Device communications is an increasingly global business

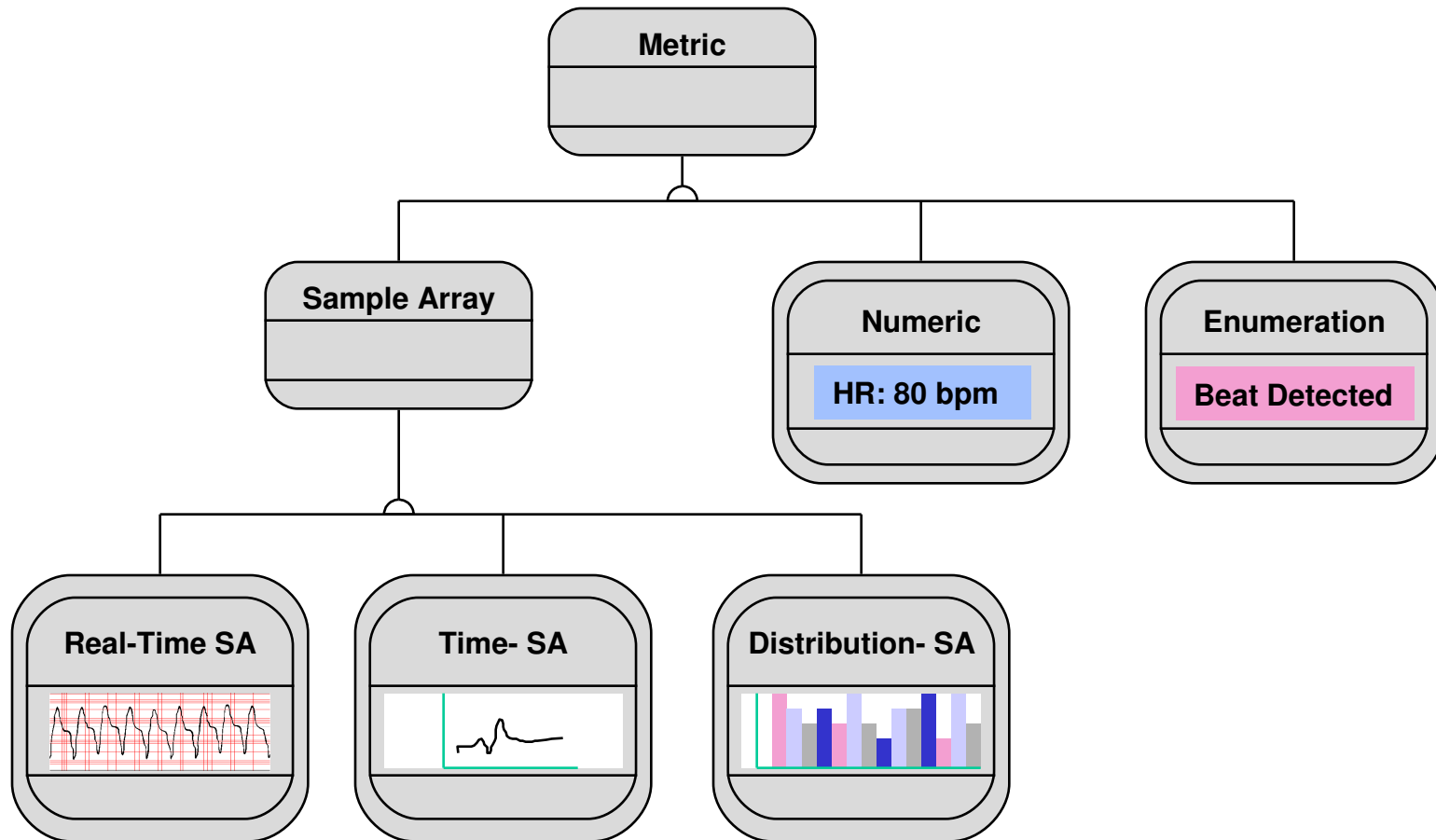
- Standards complement and are not compete  
CEN/TC251/WGIV and IEEE 1073 have complemented each other's work and are now synthesising it all into a harmonised family in ISO – where the numbers will be in a series ISO 11073-xxxx.
- Replace devices only when timely  
The earlier standards will only gradually,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

# Different degrees of complexity

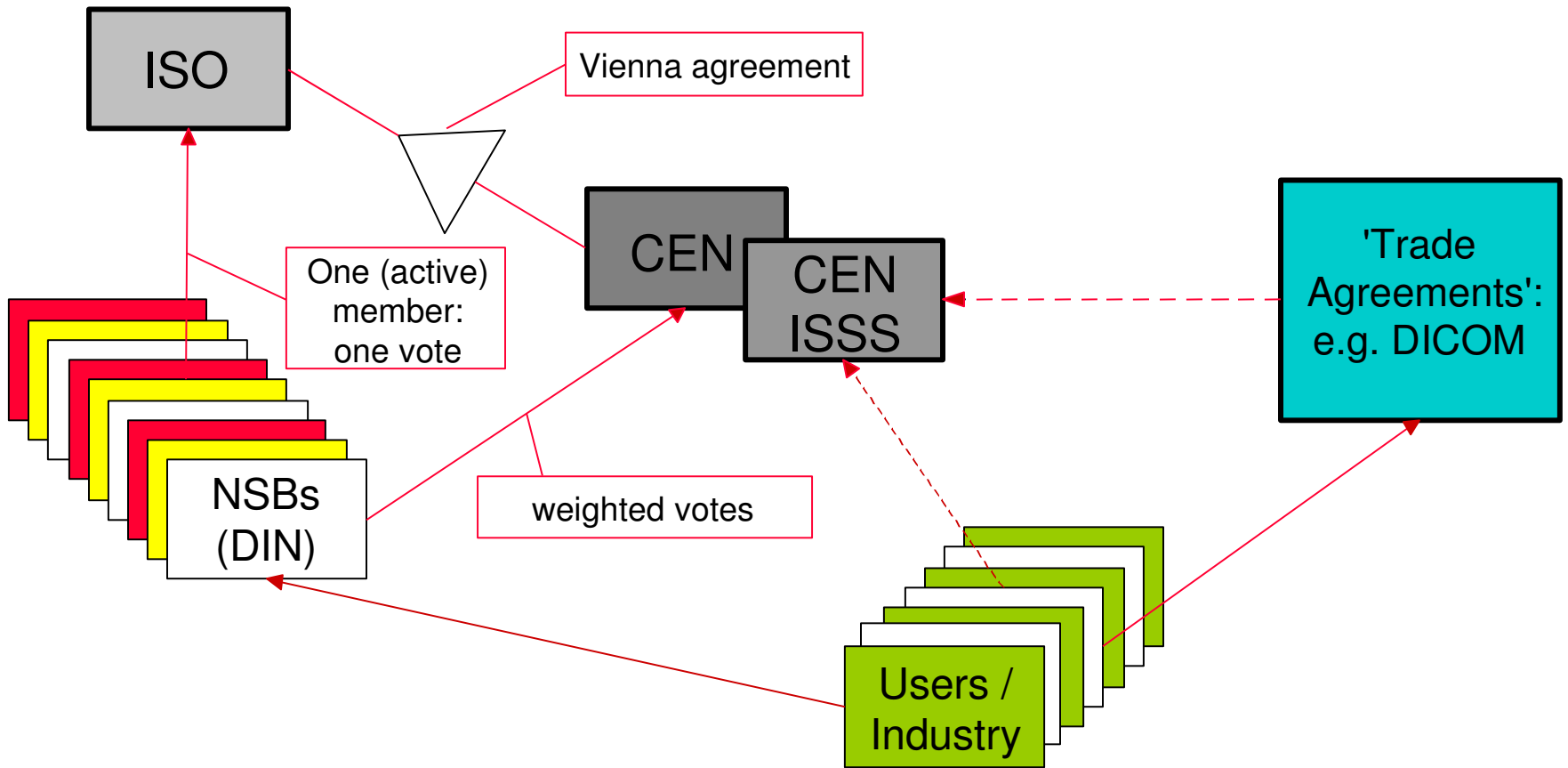


Point of care medical device communication and data storage

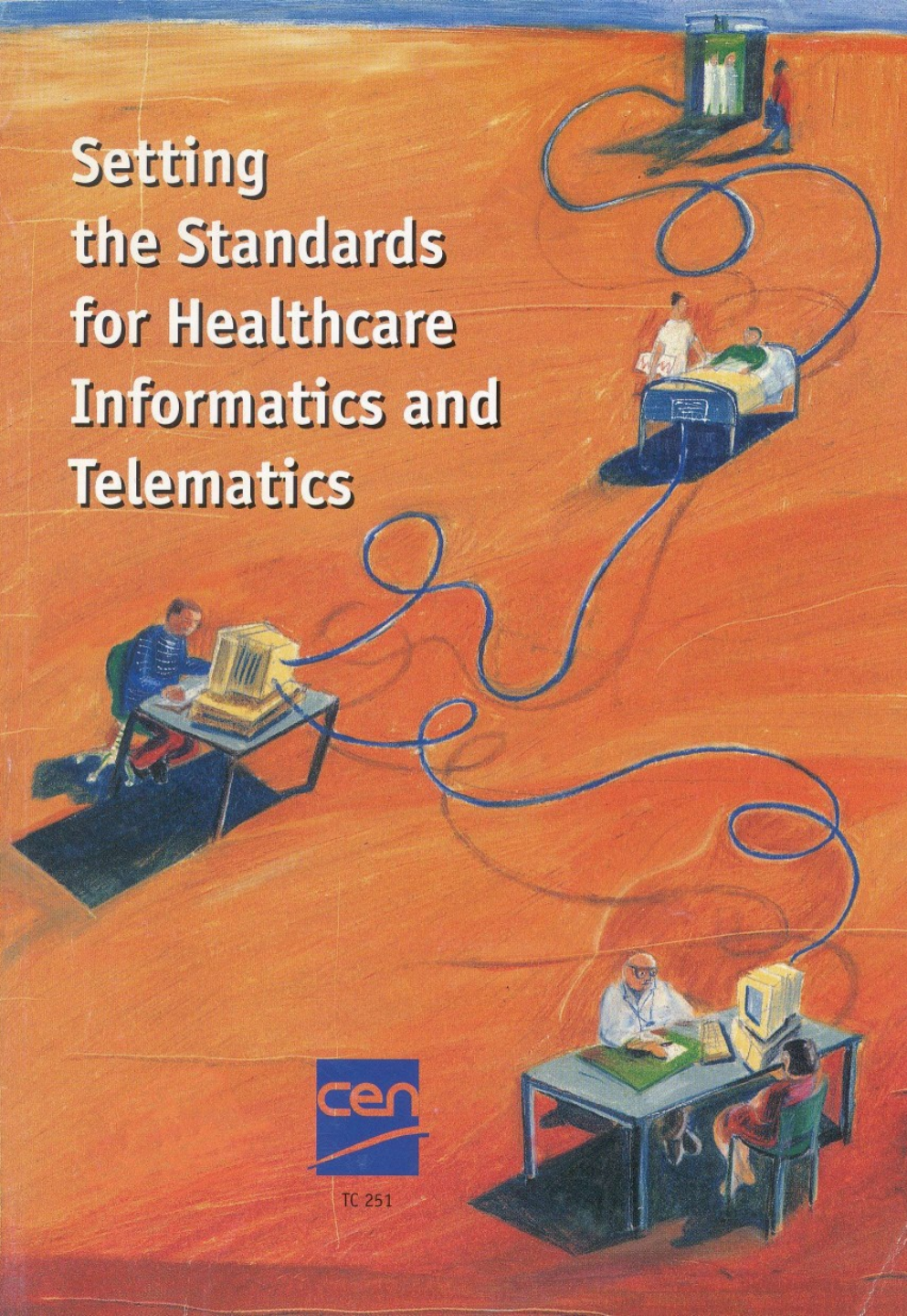
# „Metric“-Spezialisierungen (Vererbung)



# International Standardization bodies



# Setting the Standards for Healthcare Informatics and Telematics



TC 251