File Exchange Format

for Vital Signs, ENV 14271 and its use in Electronic Interchange of Polysomnography Data

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ENV 14271, Background

- work began in 1994 in CEN/TC251/PT-21
- vision: one format for all biosignals in the world
- work could not be finished before ENV 13734 Vital Signs Information Representation was frozen (now an ISO 11073 series standard)
- project team CEN/TC251/PT-40 established in 1998
- final version delivered to CEN in 2002

Contents of the FEF specification

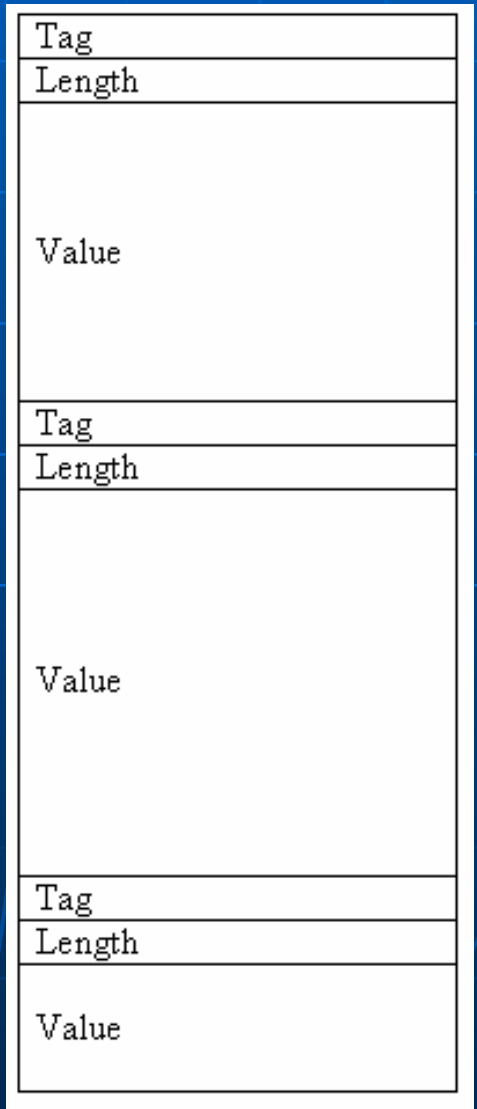
- Scope statement
- References to ENV 13734 and others
- Object model
- Section and attribute definitions
- Info for conformance statements
- Encoding rules (ASN.1)
- Nomenclature of measurements, units, body sites, events etc.
- Example defined byte by byte


Preamble
FEF File
When cardinality is not assigned 1 is assumed
SessionArchiveSection
ManufacturerSpecificSection
HealthcareProviderSection
(from HealthcareProvider -6.3.5)
DemographicsSection
SessionTestSection
(from SessionTest - 6.3.8)
SessionNotesSection
Healthcare ProfessionalSection
(from HealthcareProvider -6.3.5)
MedicalDeviceSystemSection
(from MedicalDeviceSystem - 6.3.9)
MultimediaSection
(from SessionTest - 6.3.8)
SimpleMedicalDeviceSystemSection
(from MedicalDeviceSystem - 6.3.9)
CompositeMedicalDeviceSystemSection
(from MedicalDeviceSystem - 6.3.9)
HydraMedicalDeviceSystemSection
(from MedicalDeviceSystem - 6.3.9)
VirtualMedicalDeviceSection
(from MedicalDeviceSystem - 6.3.9)
SessionPhaseSection
(from SessionPhase - 6.3.15)
AllertSection
(from SessionPhase - 6.3.15)
DescriptiveDataSection
(from SessionPhase - 6.3.15)
MeasuredDataSection
(from SessionPhase - 6.3.15)
DynamicAttributeChangeSection
(from SessionPhase - 6.3.15)
RealTimeSampleArrayDDS
(from SessionPhase - 6.3.15)
RealTimeSampleArrayMDS
(from SessionPhase - 6.3.15)
TimeSampleArrayDDS
(from SessionPhase - 6.3.15)
TimeSampleArrayMDS
(from SessionPhase - 6.3.15)
EnumerationDDS
(from SessionPhase - 6.3.15)
EnumerationMDS
(from SessionPhase - 6.3.15)
DistributionSampleArrayDDS
(from SessionPhase - 6.3.15)
DistributionSampleArrayMDS
(from SessionPhase - 6.3.15)
NumericDDS
(from SessionPhase - 6.3.15)
NumericMDS
(from SessionPhase - 6.3.15)

PREAMBLE	= 1
MANUFACTURER SPECIFIC SECTION	≤ 1
HEALTH CARE PROVIDER SECTION	≤ 1
PATIENT DEMOGRAPHICS SECTION	= 1
SESSION TEST SECTION	≥ 1
MEDICAL DEVICE SYSTEM SECTION	= 1
MULTIMEDIA SECTION	≤ 1
SESSION PHASE SECTION	≥ 1
DESCRIPTIVE DATA SECTION	= 1
MEASURED DATA SECTION	≥ 1
Real Time Sample Array Measured Data section	≥ 0
Time Sample Array Measured Data section	≥ 0
Distribution Sample Array Measured Data section	≥ 0
Numeric Measured Data section	≥ 0
Enumeration Measured Data section	≥ 0
Alert section	≥ 0
Dynamic Attribute change section	≥ 0
SESSION NOTES SECTION	≥ 0

FEF does not always need a full implementation

- sections are coded in TLV style (tag, length, value)
- sections not needed by the reader can be skipped with the help of the length field to the beginning of the next section



ENV 14271 support for polysomnography

- all what is needed for general biosignal storage (except compression)
- measurement codes for all physiological signals and numeric measurements which CEN/TC251/WGIV & IEEE 1073 could think of
- event codes, all which were identified by CEN/TC251/WGIV & IEEE 1073 and a possibility for private extensions

Responses to questions

1) What mechanism is used to insure integrity of multiple files (if they exist)?

A: The format specification does not define any. It is considered as an implementation issue.

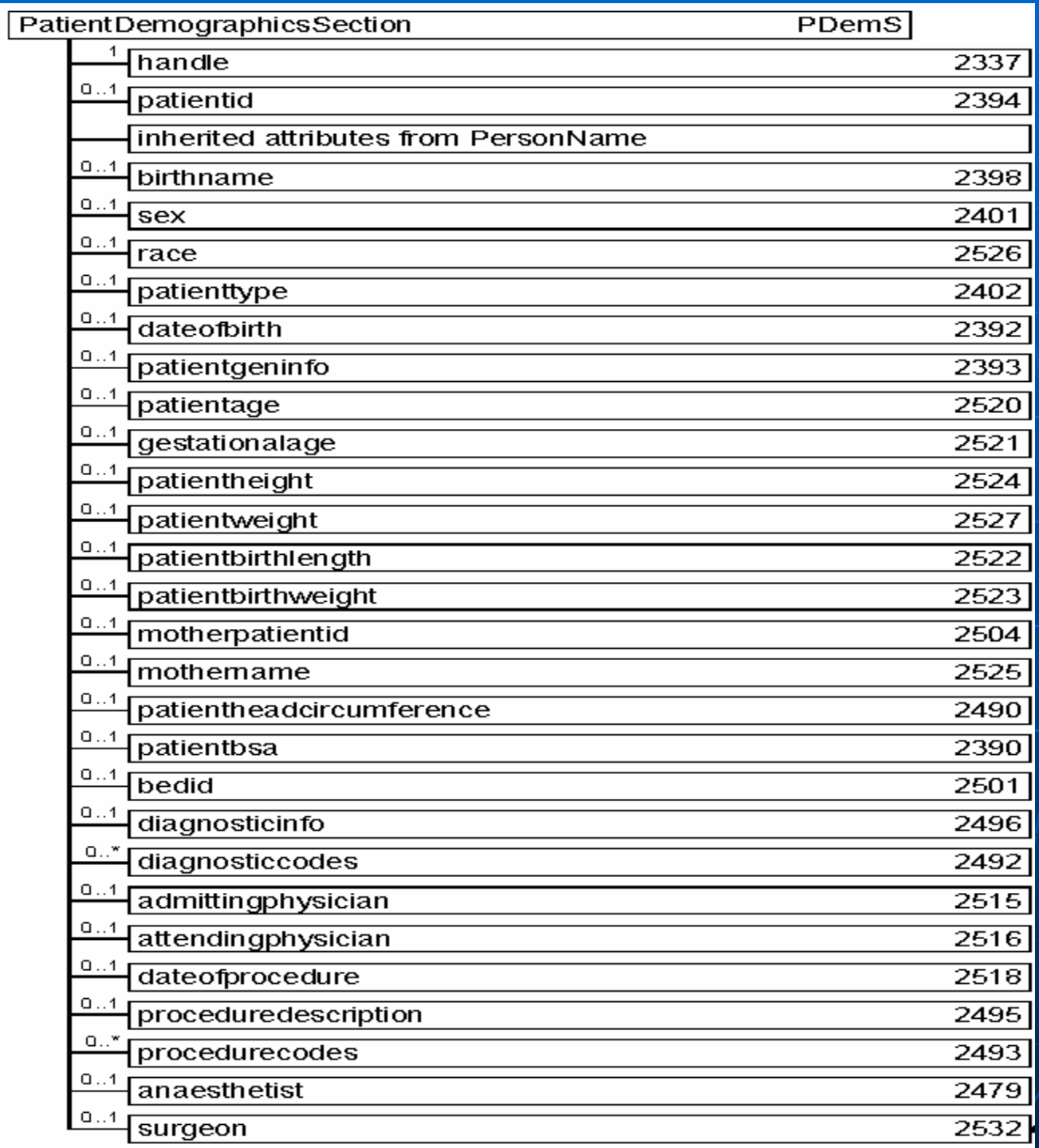
Respones to questions

2 a) Is patient information extensible or definable

A: Demographic information is fixed but the ”Diagnostic Info” field can contain free form text

2 b) Can a file be easily deidentified

A: Overwriting all text fields with spaces (ASCII 32) and removing all optional attributes from the demographic section deidentifies the file


PatientDemographicsSection PDemS
1 handle 2337
0..1 patientid 2394
inherited attributes from PersonName
0..1 birthname 2398
0..1 sex 2401
0..1 race 2526
0..1 patienttype 2402
0..1 dateofbirth 2392
0..1 patientgeninfo 2393
0..1 patientage 2520
0..1 gestationalage 2521
0..1 patientheight 2524
0..1 patientweight 2527
0..1 patientbirthlength 2522
0..1 patientbirthweight 2523
0..1 motherpatientid 2504
0..1 mothername 2525
0..1 patientheadcircumference 2490
0..1 patientbsa 2390
0..1 bedid 2501
0..1 diagnosticinfo 2496
0..* diagnosticcodes 2492
0..1 admittingphysician 2515
0..1 attendingphysician 2516
0..1 dateofprocedure 2518
0..1 proceduredescription 2495
0..* procedurecodes 2493
0..1 anaesthetist 2479
0..1 surgeon 2532

B.1.15 Person name

The PersonName type is used to express a person name as five component group as in DICOM or HL7. For the purpose of writing names in ideographic characters and in phonetic characters up to three groups of components may be used.

In a section referring to one person COMPONENTS-OF PersonNameGroup shall be used.

ASN.1 source defining the PersonName type

```
PersonNameGroup ::= SEQUENCE {
    familyname              [1] FEFString,
    givenname               [2] FEFString,
    middlename              [3] FEFString,
    prefix                  [4] FEFString,
    suffix                  [5] FEFString,
    degree                  [6] FEFString
}



PersonName ::= SEQUENCE {
    ungroupedname           [APPLICATION 6001] FEFString OPTIONAL,
    characternamegroup      [APPLICATION 6002] PersonNameGroup OPTIONAL,
    ideographicnamegroup    [APPLICATION 6003] PersonNameGroup OPTIONAL,
    phoneticnamegroup       [APPLICATION 6004] PersonNameGroup OPTIONAL
    -- at least one of the groups must be present
    -- this will be the characternamegroup for European names
}
```

Responses to questions

3) How is the raw data stored:

A: For signals EDF style blocks are possible but it is possible to interlace all channels sample by sample (requires the same sampling frequency to all channels) or store all channel 1 samples first, then channel 2 etc.

Responses to questions

3 a) Can it handle differing frequencies for various channels?

A: Yes, as EDF or even better

3 b) Can it handle differing byte resolutions for various channels?

A: Yes, Allowed combinations of storagedatatype and storagedatasize are: unsigned 8, unsigned 16, unsigned 32, signed 8, signed 16, signed 32, ieee754float 32, ieee754float 64.

Responses to questions

3 c) Can it handle irregularly spaced measures (RR intervals etc.)?

A: There is a section in the file which can store numeric measurement values with time stamps: NumericMeasuredDataSection

B.11.7 NumericMeasuredDataSection (NMDS)

The NumericMeasuredDataSection stores observed attributes of the of one object of ENV13734 class Numeric.

ASN.1 source defining NumericMeasuredDataSection

```
NumericMeasuredDataSection ::= SEQUENCE {
    metricref [APPLICATION 6050] HandleRef, -- reference to
                                            -- NumericDescriptiveDataSection
    nuobservedvalue       ChoiceOfNuObsValue,
                          -- simple or compound
    timestamp             ObservationTime
}
```

ASN.1 source defining types referenced in NumericMeasuredDataSection

```
ChoiceOfNuObsValue ::= CHOICE {
    nuobservedvalue         [APPLICATION 2384] NuObsValue,
                             -- e.g. measurement value, should also contain
                             -- validity information to be useful!
    compoundnuobservedvalue  [APPLICATION 2379] SEQUENCE-OF
                             NuObsValue
                             SIZE (2..*)
                             -- used when multiple values are represented
                             -- in a single NU object (Structure is compound)
}

NuObsValue ::= SEQUENCE {
    metricid                [1] MetricsCode OPTIONAL,
    state                   [2] MeasurementStatus DEFAULT {},
    unitcode                [3] UnitsOfMeasurementCode OPTIONAL,
    value                   [4] FEFFloat
}
```

Responses to questions

4) How are ”events” defined and stored?

A: They are stored in EnumerationMeasuredDataSection:

```
EnumerationMeasuredDataSection ::= SEQUENCE {
    metricref [APPLICATION 6050] HandleRef, -- reference to
                                            -- EnumerationDescriptiveDataSection
    enumobservedvalue     ChoiceOfEnumObsValue,
                          -- simple or compound
    enumadditionaldata    [APPLICATION 2498] ANY-DEFINED-BY enumobservedvalue
                          OPTIONAL,
                          -- additional non normative event specific
                          -- information can be provided (e.g. pacer
                          -- parameters of pace pulse detect). Requires
                          -- use of enum-obj-id in observed value!
    enumtimestamp         ChoiceOfEnumTimeStamp,
                          -- one or more timestamps
}
```

```
ChoiceOfEnumObsValue ::= CHOICE {
    enumobservedvalue           [APPLICATION 2462] EnumObsValue,
    compoundenumobservedvalue   [APPLICATION 2463] SEQUENCE-OF
                                EnumObsValue SIZE (1..*)
}

EnumObsValue ::= SEQUENCE {
    metric-id               [1] MetricsCode OPTIONAL,
    state                   [2] MeasurementStatus DEFAULT {},
    value                   [3] EnumVal
}

EnumVal ::= CHOICE {
  enum-obj-id           [1] MetricsCode,  -- id of the metric
  enum-text-string      [2] FEFString,    -- free text
  enum-external-code    [8] ExtNomenRef,  -- code defined in other coding system
  enum-bit-str          [16] BITS-32,         -- bit string
  enum-record           [33] EnumRecordMetric -- record type defined Metric ID
  enum-record-oo        [34] EnumRecordOO     -- record type defined OO ID
}

EnumRecordMetric ::= SEQUENCE {
  record-type-code MetricsCode
  record-data ANY DEFINED BY record-type-code
}

EnumRecordOO ::= SEQUENCE {
  record-type-code OID-Type -- from OO Partition
  record-data ANY DEFINED BY record-type-code
}
```

Systematic Name	Common Term	Acronym	Description/ Definition	Code
Pattern|Background, Unspecified|Cortex, EEG|CNS	Background activity		Background activity description, unspecified	23560
Pattern|Background, BetaActivity|Cortex, EEG|CNS	Background activity beta		Background activity description, Beta activity	23568
Pattern|Background, SigmaActivity|Cortex, EEG|CNS	Background activity sigma		Background activity description, Sigma activity	23576
Pattern|Background, GammaActivity|Cortex, EEG|CNS	Background activity gamma		Background activity description, Gamma activity	23584
Pattern|Background, AlphaActivity|Cortex, EEG|CNS	Background activity alpha		Background activity description, Alpha activity	23592
Pattern|Background, MuActivity|Cortex, EEG|CNS	Background Mu activity		Background activity, Mu activity	23600
Pattern|Background, ThetaActivity|Cortex, EEG|CNS	Background activity theta		Background activity, Theta activity	23608
Pattern|Background, BisynchronousThetaActivity|Cortex, EEG|CNS	Background activity bisynchronous theta		Background activity, Bisynchronous theta activity	23616
Pattern|Background, DeltaActivity|Cortex, EEG|CNS	Background activity delta		Background activity description, Delta activity	23624
Pattern|Background, BisynchronousDeltaActivity|Cortex, EEG|CNS	Background activity bisynchronous delta		Background activity description, Bisynchronous delta activity	23632
Pattern|Background, ArrhythmicDeltaActivity|Cortex, EEG|CNS	Background activity arrhythmic delta		Background activity description, Arrhythmic delta activity	23640
Pattern|Background, SlowFusedTransients|Cortex, EEG|CNS	Background activity slow fused transients		Background activity description, Slow fused transients	23648
Pattern|Classification, UnspecifiedSleepStage|Cortex, EEG|CNS	Sleep stage unspecified		Sleep state description, Unspecified	23656
Pattern|Classification, Unstageable|Cortex, EEG|CNS	Sleep stage unstageable		Sleep state description, Unstageable, Movement time	23664
Pattern|Classification, StageWake,|Cortex, EEG|CNS	Sleep stage wake		Sleep state description, Stage wake	23672
Pattern|Classification, REMsleep|Cortex, EEG|CNS	Sleep stage REM		Sleep state description, REM sleep	23680
Pattern|Classification, REMspindleSleep|Cortex, EEG|CNS	Sleep stage REM with sleep spindle		Sleep state description, REM-spindle sleep	23688
Pattern|Classification, SleepStageI|Cortex, EEG|CNS	Sleep stage I		Sleep state description, Stage I sleep	23696
Pattern|Classification, SleepStageII|Cortex, EEG|CNS	Sleep stage II		Sleep state description, Stage II sleep	23704
Pattern|Classification, SleepStageIII|Cortex, EEG|CNS	Sleep stage III		Sleep state description, Stage III sleep	23712
Pattern|Classification, SleepStageIV|Cortex, EEG|CNS	Sleep stage IV		Sleep state description, Stage IV sleep	23720
Pattern|Classification AlphaDeltaSleep|Cortex, EEG|CNS	Alphadelta Sleep		Sleep state description, Alpha-delta sleep	23728
Pattern|Classification, SleepActivity|Cortex, EEG|CNS	Sleep activity and event		Sleep activity and event description, Sleep activity	23736
Pattern|Classification, SleepSpindle|Cortex, EEG|CNS	Sleep spindle		Sleep activity and event description, Sleep spindle	23744
Pattern|Classification, V_Wave|Cortex, EEG|CNS	Sleep V wave		Sleep activity and event description, V waves	23752
Pattern|Classification, F_Wave|Cortex, EEG|CNS	Sleep F wave		Sleep activity and event description, F waves	23760
Pattern|Classification, K_Complex|Cortex, EEG|CNS	Sleep K complex		Sleep activity and event description, K complexes	23768
Pattern|Classification, PostOccipitalSharpTransient|Cortex, EEG|CNS	Sleep post occipital sharp transient		Sleep activity and event, Post occipital sharp transients	23776
Pattern|Classification, SawToothWave|Cortex, EEG|CNS	Sleep saw tooth wave		Sleep activity and event description, Saw tooth waves	23784
Pattern|Classification, SleepStageShift|Cortex, EEG|CNS	Sleep stage shift		Sleep activity and event description, Sleep stage shifts	23792

Systematic Name	Common Term	Acronym	Description/Definition	Code
Pattern|Classification, Arousal|Cortex, EEG|CNS	Sleep arousal		Sleep activity and event description, Arousals	23800
Pattern|Classification, Awakening|Cortex, EEG|CNS	Sleep awakening		Sleep activity and event description, Awakenings	23808
Pattern|ParoxismalActivity, UnspecifiedEpileptiformDischarge|Cortex, EEG|CNS	Sharp appearing or epileptiform activity		Sharp appearing or epileptiform activity, Unspecified eliptiform discharges	23816
Pattern|ParoxismalActivity, SharpTransient|Cortex, EEG|CNS	Sharp transient		Sharp appearing or epileptiform activity, Sharp transients	23824
Pattern|ParoxismalActivity, Wicket|Cortex, EEG|CNS	Wicket		Sharp appearing or epileptiform activity, Wickets	23832
Pattern|ParoxismalActivity, SmallSharpSpike|Cortex, EEG|CNS	Small sharp spike		Sharp appearing or epileptiform, Small sharp spikes	23840
Pattern|ParoxismalActivity, ZetaWave|Cortex, EEG|CNS	Zeta wave		Sharp appearing or epileptiform, Zeta waves	23848
Pattern|ParoxismalActivity, TriphasicWave|Cortex, EEG|CNS	Triphasic wave		Sharp appearing or epileptiform activity, Triphasic waves	23856
Pattern|ParoxismalActivity, PhantomSpikeAndWaveActivity|Cortex, EEG|CNS	Phantom spike and wave activity		Sharp appearing or epileptiform activity, Phantom spike and wave activity	23864
Pattern|ParoxismalActivity, 14And6HzPositiveBursts|Cortex, EEG|CNS	14 and 6 Hz positive bursts		Sharp appearing or epileptiform activity, 14 and 6 Hz positive bursts	23872
Pattern|ParoxismalActivity, LambdaWave|Cortex, EEG|CNS	Lambda wave		Sharp appearing or epileptiform activity,	23880
Pattern|ParoxismalActivity, UnspecificIctalDischarge|Cortex, EEG|CNS	Epileptic or potentially epileptogenic activity		Epileptic or potentially epileptogenic activity identifiers, Unspecific ictal discharges	23888
Pattern|ParoxismalActivity, SharpWave|Cortex, EEG|CNS	Epileptic or potentially epileptogenic sharp wave		Epileptic or potentially epileptogenic activity identifiers, Sharp waves	23896
Pattern|ParoxismalActivity, Spike|Cortex, EEG|CNS	Epileptic or potentially epileptogenic spike		Epileptic or potentially epileptogenic activity identifiers, Spikes	23904
Pattern|ParoxismalActivity, MultipleSpikes|Cortex, EEG|CNS	Multiple spike		Epileptic or potentially epileptogenic activity identifiers, Multiple spikes	23912
Pattern|ParoxismalActivity, SpikeAndWaveComplex|Cortex, EEG|CNS	Spike and wave complex		Epileptic or potentially epileptogenic activity identifiers, Spike and wave complexes	23920
Pattern|ParoxismalActivity, AtypicalSpikeAndWaveComplex|Cortex, EEG|CNS	Atypical spike and wave complex		Epileptic or potentially epileptogenic activity identifiers, Atypical spike and wave complexes	23928
Pattern|ParoxismalActivity, SharpAndSlowWaveComplex|Cortex, EEG|CNS	Sharp and slow wave complex		Epileptic or potentially epileptogenic activity identifiers, Sharp and slow wave complexes	23936
Pattern|ParoxismalActivity, RhythmicSharpWaves|Cortex, EEG|CNS	Rhythmic sharp waves		Epileptic or potentially epileptogenic activity identifiers, Rhythmic sharp waves	23944
Pattern|ParoxismalActivity, BurstSuppression|Cortex, EEG|CNS	Burst suppression		Epileptic or potentially epileptogenic activity identifiers, burst suppression	23952
Pattern|ParoxismalActivity, MultipleIndependentSpikesAndAsynchronousSlow|Cortex, EEG|CNS	Multiple independent spikes and asynchronous slow waves		Epileptic or potentially epileptogenic activity identifiers, Multiple independent spikes and asynchronous slow (hypsarrhytmia)	23960
Pattern|ParoxismalActivity, UnspecifiedPeriodicCerebralActivity|Cortex, EEG|CNS	Periodic and Quasiperiodic Cerebral Activity		cont. moderate frequency periodic epileptiform discharges, Unspecified periodic cerebral activity	23968
Pattern|ParoxismalActivity, QuasiperiodicTriphasicWaves|Cortex, EEG|CNS	Quasiperiodic triphasic waves		cont. moderate frequency periodic epileptiform discharges, Quasiperiodic triphasic waves	23976

Responses to questions

4a) Does the event storage method allow expansion to new event types (without programming)?

A: Yes, the default event code table can be extended through ISO/TC215/WG7 or one can even define an event coding scheme of one's own and refer to that in the events section

Responses to questions

4b) Can new information be added to an event definition (without programming)?

A: Yes, throuhg the use of one's own nomenclature (= coding scheme).

Alternatively, if standard event codes are used, one can use compound enumerations and add free text to accompany an event code

Responses to questions

4c) Are events fixed to a channel?

A: They are linked either to a channel or to the medical device used in the activity. Environmental events exist, too:

Loff¤	Lights·in·the·(sleep·measurement)·room·are·switched·off¤	484¤
Lon¤	Lights·in·the·(sleep·measurement)·room·are·switched·on¤	6260¤

Responses to questions

4d) Can events overlap?

A: Yes, there is no limit to the amount of time-stamped events there can be within one second. Events can also be compound linking > 1 event codes to a single time stamp.

Responses to questions

4e) Can events reference (link to) other events?

A: Compound enumerations are events occuring at the same time, i.e. they are time-linked. An arbitrary event cannot refer to any arbitrary event in general but one can always add a textual annotation to an event saying that ”this event is related to another one which occurred some 15 seconds ago”.

Responses to questions

5a) How are measurements of channels handled, eg. saturation?

A: If a channel saturates, an Alert event can be stored to mark it in the file

5b) CPAP pressure (regularly spaced)?

A: Either as a signal like EEG or as separate time-stamped numeric measurements

5c) RR interval or HR (irregularly spaced)?

A: As time-stamped numeric measurements (metric codes 16168 and 16770)

Responses to questions

6) Are tabulations of information stored in the format (eg. AHI, TST)?

A: A FEF file stores data of a single subject. A FEF file can contain data from different Session Tests, eg. different nights of which the whole multitude of signals and measurements are stored. One may decide to store only the TST of all nights into a FEF file, too (but FEF would be overkill for the purpose). However, the coding scheme does not contain codes for all derived measures such as AHI or TST and private codes need to be used for those until they are incorporated into the formal standard

Future of ENV 14271, FEF

- **Possibility:**
  ISO Technical Specification "Health informatics – Point-of-care medical device communication – Application profile – File exchange format for electrophysiology (or polysomnographic?) studies“,
  ISO 11073.20401
- As a world standard implemented to medical recording devices and EHCR systems worldwide