

# Machine-readable Data Export Specification for M-sense Migräne

Version 1.0

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## Revision history

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# 1 Introduction

## 1.1 Scope of this document and interoperability standards used

This document describes the interoperable data export of the DiGA M-sense Migräne. It is based on the FHIR<sup>1</sup> standard published by HL7, more specifically the FHIR Specification v4.0.1: R4 without custom profiles or extensions. The FHIR<sup>®</sup> data export is done in the non-proprietary JSON (JavaScript Object Notation) standard<sup>2</sup> and encoded in the ISO 10646 (Unicode<sup>3</sup>) *UTF-8* format. Please note that this document does not constitute an implementation guide for FHIR.

## 1.2 Target audience

This document is aimed at the various stakeholders in the public health sector (regulators, manufacturers, physicians and patients).

## 1.3 Purpose of the data export

The purpose of the data export is to provide the patient's data in an interoperable and internationally recognized standard format to enable the patient to have the captured data processed by others in the healthcare system. Please note that the focus of the data export lies on machine readability, not human readability.

The *DiGA Leitfaden* states that digital health applications should communicate with other services and thus be integrated into the national e-health infrastructure. The possibility of machine-readable data transfers should enable added value in patient care<sup>4</sup>.

# 2 Data Export

## 2.1 Export specification

The settings view of the M-sense Migräne app contains an option that allows the user to export the entered data. The data will then be exported as a FHIR bundle file (in JSON format) as seen exemplary in the table in section [2.2 Example data export](#).

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<sup>1</sup>FHIR<sup>®</sup> is the registered trademark of HL7 and is used with the permission of HL7. The Flame Design mark is the registered trademark of HL7 and is used with the permission of HL7.

<sup>2</sup>The specification can be found here: <https://www.json.org/json-en.html>

<sup>3</sup>See <https://home.unicode.org/>

<sup>4</sup>[https://www.bfarm.de/SharedDocs/Downloads/DE/Service/Beratungsverfahren/DiGA-Leitfaden.pdf?\\_\\_blob=publicationFile&v=1](https://www.bfarm.de/SharedDocs/Downloads/DE/Service/Beratungsverfahren/DiGA-Leitfaden.pdf?__blob=publicationFile&v=1)

The `Bundle` element allows to form a collection of self-contained data being packed inside the exported document. The bundled document then starts with the core elements representing the patient data.

The bundle contains a data entry structured according to the FHIR `Patient` resource that includes information on the data subject. Each patient is assigned a unique identifier (UUID) that is generated by the system. It also includes the nickname as a human readable identifier as well as the provided email that is used for the M-sense user account. Furthermore, the user's gender is included as well. For data economy reasons we do not ask for the exact date of birth in the app, so no other identifiable information is added here.

Data entered by the user is represented as FHIR `Observation` resources. Entries there are categorized as `Survey` data based on HL7's `Observation` category code<sup>5</sup>. The entries there differ depending on the respective diary survey in the app. If possible, they are identified via the associated `LOINC`<sup>6</sup> code (e.g. 8990-4 for fluid intake per day, or 95606-0 for the stress level per day). Where no matching `LOINC` code is available, the generic `LOINC` code for patient reported outcomes is used and a text description is provided for additional interpretation about the context and its values.

An exemplary dataset is found in section [2.2 Example data export](#).

FHIR resource	Type	Cardinality	Description
Bundle	collection	1..1	A bundle is a unique resource that can be used to store a collection of other resources.
Patient	subject	1..1	Base resource that is used to store patient's contact data such as self-reported username and email address.
Observation	survey	0..*	Entries consisting of patient reported outcomes with scores calculated by the system based on responses to diary surveys in the app.

## 2.2 Example data export

```
{
  "resourceType": "Bundle",
  "identifier": {
    "use": "official",
    "value": "1cf0a65a-de9e-11eb-af38-03a59af5d253",
    "period": {
      "start": "2020-07-07T12:00:00.000000Z",
      "end": "2021-07-07T15:30:00.000000Z"
    }
  }
}
```

<sup>5</sup> <https://www.hl7.org/fhir/observation.html>

<sup>6</sup> <https://loinc.org>

```

    },
    "type": "collection",
    "timestamp": "2021-07-07T15:30:00.000000Z",
    "entry": [
      {
        "fullUrl": "52c75fe3-ee22-45ce-b9a8-338d1551ca1a",
        "resource": {
          "resourceType": "Patient",
          "id": "52c75fe3-ee22-45ce-b9a8-338d1551ca1a",
          "language": "de",
          "name": [
            {
              "use": "nickname",
              "text": "Clara"
            }
          ],
          "telecom": [
            {
              "system": "email",
              "value": "example@email.com"
            }
          ],
          "gender": "female"
        }
      },
      {
        "fullUrl": "92363989238923632984",
        "resource": {
          "resourceType": "Observation",
          "id": "92363989238923632984",
          "category": [
            {
              "coding": [
                {
                  "system": "http://terminology.hl7.org/CodeSystem/observation-category",
                  "code": "survey"
                }
              ]
            }
          ],
          "code": {
            "coding": [
              {
                "system": "http://loinc.org",
                "code": "8990-4"
              }
            ]
          },
          "text": "Wie viel hast du getrunken?",
          "status": "final",
          "subject": {
            "reference": "Patient/52c75fe3-ee22-45ce-b9a8-338d1551ca1a"
          },
          "effectivePeriod": {
            "start": "2020-07-05T00:00:00.000000Z",
            "end": "2020-07-05T23:59:59.999999Z"
          },
          "valueInteger": 1200
        }
      },
      {
        "fullUrl": "92363989238923632931",
        "resource": {
          "resourceType": "Observation",
          "id": "92363989238923632931",
          "category": [

```

```

        "coding": [
          {
            "system": "http://terminology.hl7.org/CodeSystem/observation-category",
            "code": "survey"
          }
        ]
      },
    ],
    "code": {
      "coding": [
        {
          "system": "http://loinc.org",
          "code": "95606-0"
        }
      ]
    },
    "text": "Wie gestresst warst du?"
  },
  "status": "final",
  "subject": {
    "reference": "Patient/52c75fe3-ee22-45ce-b9a8-338d1551ca1a"
  },
  "effectivePeriod": {
    "start": "2020-07-06T00:00:00.000000Z",
    "end": "2020-07-06T23:59:59.999999Z"
  },
  "valueInteger": 5
},
{
  "fullUrl": "92363989238923632947",
  "resource": {
    "resourceType": "Observation",
    "id": "92363989238923632947",
    "category": [
      {
        "coding": [
          {
            "system": "http://terminology.hl7.org/CodeSystem/observation-category",
            "code": "survey"
          }
        ]
      }
    ]
  }
},
{
  "code": {
    "coding": [
      {
        "system": "http://loinc.org",
        "code": "89196-0"
      }
    ]
  },
  "text": "Wie war dein Energielevel?"
},
{
  "status": "final",
  "subject": {
    "reference": "Patient/52c75fe3-ee22-45ce-b9a8-338d1551ca1a"
  },
  "effectivePeriod": {
    "start": "2020-07-06T00:00:00.000000Z",
    "end": "2020-07-06T23:59:59.000000Z"
  },
  "valueInteger": 6,
  "interpretation": [
    {
      "coding": [
        {
          "system": "http://loinc.org",
          "code": "89193-7"
        }
      ]
    }
  ]
}

```

```

        ],
        "text": "Scores range between 0-10 with higher values representing
higher energy levels."
    }
}
},
{
  "fullUrl": "92363989238923632929",
  "resource": {
    "resourceType": "Observation",
    "id": "92363989238923632929",
    "category": [
      {
        "coding": [
          {
            "system": "http://terminology.hl7.org/CodeSystem/observation-category",
            "code": "survey"
          }
        ]
      }
    ],
    "code": {
      "coding": [
        {
          "system": "http://loinc.org",
          "code": "72514-3"
        }
      ]
    },
    "text": "Wie stark ist dein Kopfschmerz?"
  },
  "status": "final",
  "subject": {
    "reference": "Patient/52c75fe3-ee22-45ce-b9a8-338d1551ca1a"
  },
  "effectivePeriod": {
    "start": "2020-07-06T09:59:00.000000Z",
    "end": "2020-07-06T15:30:00.000000Z"
  },
  "valueInteger": 7
}
]
}

```