

Monolithic Product (demo)

1.0

System Requirements Specification

KXDOC0VNS4BEJPR83JSD4Z87SMDGT70

Generated by Ketryx Lifecycle Management on 2024-02-26 19:10Z

Ketryx Demo

Document version control

Release date

2024-02-26 19:10Z

Document version

System Requirements Specification 1.0

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1. User/Marketing

RQ-KT-22-#24

Dose selection menu

KXREC6DVM5QH4059Q5TRRERQVXDWGCQ

Controlled at: 2024-02-26 18:13Z

The user interface shall have a pre-defined set of possible dose levels the patient can select from.

Some of the key elements that could be included in the interface are:

1. Dose entry field: A simple numeric input field where users can enter the amount of insulin they wish to take. The field could be accompanied by a unit of measurement, such as "units.
2. Timing options: An option allowing users to indicate when they plan to take their insulin. This could be in the form of a drop-down menu or toggle buttons, such as "before meal," "after meal," "bedtime," "as needed," etc.
3. Recent doses: A list of the user's recent insulin doses, including the date, time, and amount of insulin, allowing them to easily repeat a previous dose or make small adjustments.
4. Safety warnings: A warning system that alerts users if they are trying to take an insulin dose that is outside of their normal range or if there are any other safety concerns.
5. Clear and simple layout: The interface should be designed with a clear and simple layout, making it easy for users to understand and navigate. The buttons and fields should be large enough to be easily tapped or selected, and the font should be easy to read.

Introduced in version 1.0.0

Parent requirements

RQ-KT-21-#78

Drug product dosing

Requirement type

User/Marketing

2. Security/Privacy

RQ-KT-18-#33

Cybersecurity

KXREC0XJP4Y766J9A196HG1N76SGY52

Controlled at: 2024-02-26 18:12Z

The application shall be secure from cybersecurity harm and conform to ISO 27001 and the requirement detailed in SI-5.

Introduced in version 1.0.0

Parent requirements

RQ-KT-101-#10 Provider Reviews Patient Data

Requirement type Security/Privacy

Context Security

Children

RQ-KT-17-#16 Application running on approved iOS versions

RQ-KT-27-#16 Client cybersecurity

RQ-KT-28-#16 Server cybersecurity

RQ-KT-29-#21 User authentication

Risk control for

RISK-KT-42-#22 Loss of data integrity

3. Performance

RQ-KT-4-#66

Reliability

KXREC3DWGPA09HB9ZHBS4T8HF7GGS7H

Controlled at: 2024-02-26 19:08Z

Reliability in terms of:

- End-to-end data traceability
- 99.5% availability
- Regular database backups
- Connection to data storage system
- Infusion limitations

Also requirements described in <https://ketryx-sb8.atlassian.net/browse/SI-4>

Introduced in version 1.0.0

Parent requirements

RQ-KT-99-#24 Daily Insulin Dose Calculation

RQ-KT-100-#10	Adjusting for Exercise
RQ-KT-101-#10	Provider Reviews Patient Data
Requirement type	Performance
Children	
RQ-KT-10-#18	Availability of at least 99.5%

4. Usability

RQ-KT-12-#32

Usability

KXREC71Q6WG9JNB9DYSJAX4H5VKMM5Z

Controlled at: 2024-02-26 18:13Z

The application must be easy to learn to operate and use continuously for the patients.

The application is easy enough to use while at the same time, automatize key decisions for the patient in order to remove any misuse possibility of the medical device itself. Key warnings for the user should be promptly displayed and clearly give a call to action for the patient.

Key information such as analytics of treatment is easily accessible and easy to use independently of patient technological know-how or for their care givers.

Introduced in version 1.0.0

Parent requirements

RQ-KT-100-#10	Adjusting for Exercise
Requirement type	Usability
Context	Clinical

Children

RQ-KT-13-#19	Design for dashboard GUI
RQ-KT-14-#15	Dashboard with predefined analytics
RQ-KT-15-#14	Manual input of dose
RQ-KT-16-#22	Mobile app support
RQ-KT-20-#14	Warning indication

Risk control for

RISK-KT-39-#32	Patient can not use the product, and does not get treatment on time
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5. Use case

RQ-KT-99-#24

Daily Insulin Dose Calculation

KXREC4WTMC7QC4X9ASR7YWMH73D5K4G

Controlled at: 2024-02-26 17:31Z

Persona: A 35-year-old woman with Type 1 Diabetes.

Preconditions:

- The user has registered on the app and entered her medical data.
- The user's blood glucose monitor is compatible with the app and connected.
- The user's weight, age, and daily activity level have been recorded.

Postconditions:

- The user receives the recommended insulin dose for the day.
- The app logs the insulin recommendation for the day.

Steps:

1. The user opens the insulin dosing app.
2. The user syncs the app with her blood glucose monitor.
3. The app retrieves the latest blood glucose reading.
4. The user inputs any carbohydrate intake planned for her next meal.
5. The app calculates the required insulin dose based on the user's blood glucose level, carbohydrate intake, weight, age, and activity.
6. The app displays the recommended insulin dose.
7. The user administers the insulin as recommended.

Introduced in version

1.0.0

Requirement type

Use case

Rationale

Rationale

Children

RQ-KT-4-#66

Reliability

RQ-KT-5-#34	Infusion Limitations
RQ-KT-10-#18	Availability of at least 99.5%
RQ-KT-19-#21	Patient app UI
RQ-KT-21-#78	Drug product dosing
RQ-KT-104-#9	Infusion Pump Connects to iOS
RQ- KXREC13A7QRB8FP900TY SB0P3YFDYF8-#11	Patient app UI (Android)

RQ-KT-100-#10

Adjusting for Exercise

KXREC0JWPP7Z9AW8E484DX8B91XN0PF

Controlled at: 2024-02-26 18:12Z

Persona: A user with diabetes who relies on insulin injections for glucose management.

Preconditions:

- The user has registered on the app and entered relevant medical data.
- The user's insulin pump or smart injection device is compatible with the app and connected via Bluetooth or another wireless connection.
- The app has been updated with the most recent insulin dosing recommendations based on the user's profile, glucose readings, and any other pertinent data.

Postconditions:

- The correct insulin dose has been administered to the user via their connected device.
- The app logs the time, date, and amount of the administered insulin dose.
- The user's glucose levels remain within a safe range following the administered dose.

Steps:

1. The user opens the insulin dosing app.
2. The app syncs with the connected insulin pump or smart injection device to ensure compatibility.
3. The user selects the option to administer the recommended dose from within the app.
4. The app displays a confirmation prompt, ensuring the user wants to proceed with the dose.
5. Upon user confirmation, the app sends a signal to the connected device to administer the recommended dose of insulin.

6. The insulin pump or smart injection device delivers the precise dose as instructed by the app.
7. A notification or sound is given to confirm that the dose has been successfully administered.
8. The app records the date, time, and amount of the administered dose for tracking purposes.
9. The user continues to monitor their glucose levels as usual and reports any discrepancies or issues to their healthcare provider.

Introduced in version

1.0.0

Requirement type

Use case

Children

RQ-KT-4-#66

Reliability

RQ-KT-8-#24

Connect to Sensor

RQ-KT-12-#32

Usability

RQ-KT-101-#10

Provider Reviews Patient Data

KXREC4SYNSAH9EK8K3VH0RT429CRQRH

Controlled at:

2024-02-26 18:14Z

Persona: An endocrinologist who specializes in diabetes management.

Preconditions:

- The endocrinologist has registered on the insulin dosing app with a provider account and has been verified as a medical professional.
- The patient has granted permission to the endocrinologist to access their medical data on the app.
- The endocrinologist has a secure and stable internet connection to access the cloud-based patient data.

Postconditions:

- The endocrinologist has reviewed the patient's insulin dosing, blood glucose readings, carbohydrate intake, and any other pertinent data.
- The endocrinologist can make informed recommendations or modifications to the patient's treatment plan based on the reviewed data.

Steps:

1. The endocrinologist logs into the insulin dosing app using provider credentials.

2. They navigate to the "Patient List" section where they can view all patients who have granted them access.
3. The endocrinologist selects the specific patient whose data they wish to review.
4. The app displays a comprehensive dashboard of the patient's data, including recent blood glucose readings, insulin doses administered, carbohydrate intake, activity levels, and any notes or concerns flagged by the patient.
5. The endocrinologist reviews the data, paying particular attention to any patterns or anomalies, such as frequent hypoglycemia events or consistently elevated glucose readings.
6. If needed, the endocrinologist uses the app to chart trends over time, comparing data from various dates to get a clearer picture of the patient's overall glucose management.
7. After reviewing, the endocrinologist can annotate specific data points, leave comments, or add recommendations directly within the app.
8. If immediate intervention is necessary, the endocrinologist contacts the patient directly to discuss the findings and recommend any changes to the treatment plan.
9. For routine reviews, the endocrinologist saves their notes and schedules a follow-up appointment or telemedicine session to discuss findings with the patient.

Introduced in version

1.0.0

Requirement type

Use case

Children

RQ-KT-4-#66

Reliability

RQ-KT-7-#25

Connection to data storage system

RQ-KT-9-#23

Regular database backups

RQ-KT-11-#18

End-to-end traceable data reliability

RQ-KT-18-#33

Cybersecurity

6. Other requirements

RQ-KT-5-#34

Infusion Limitations

KXREC1FBK189JAE9KR80TSFVGWSDYT3

Controlled at:

2024-02-26 18:12Z

The pump should never deliver more than 1ml of drug substance at a time.

Introduced in version 1.0.0

Parent requirements

RQ-KT-99-#24 Daily Insulin Dose Calculation

Rationale

This is a risk control for <https://ketryx-sb8.atlassian.net/browse/SAMD-6>

Risk control for

RISK-KT-6-#49 Insulin Dosage Risk

RISK-KT-40-#34 Unauthorized Access

RQ-KT-7-#25

Connection to data storage system

KXREC2K075SK6NQ86TTXYXBX0ZS8MD2

Controlled at: 2024-02-26 18:12Z

The application needs to connect to existing data storage systems across the enterprise.

If the system is unreachable, either because it is unavailable or the device is not currently connected to the internet, data needs to be stored locally until a full data sync can happen again. This should be retried automatically.

Introduced in version 1.0.0

Parent requirements

RQ-KT-101-#10 Provider Reviews Patient Data

Children

RQ-KT-8-#24 Connect to Sensor

RQ-KT-8-#24

Connect to Sensor

KXREC5GZ1EE6DG48RATD0DTJFQ69AFC

Controlled at: 2024-02-26 18:13Z

The SaMD shall connect to a glucose monitor sensor and have continuous synchronization. Glucose levels must be monitored continuously and the device needs up-to-date real time patient information in order to properly function with the treatment calibration and administration.

Introduced in version 1.0.0

Parent requirements

RQ-KT-7-#25

Connection to data storage system

RQ-KT-100-#10

Adjusting for Exercise

RQ-KT-9-#23

Regular database backups

KXREC015007BFFX9HQVW2HPF6SF3P8E

Controlled at: 2024-02-26 18:13Z

The database shall be backed up automatically every day. Backups shall be stored for at least 30 days in a separate datacenter in a different geographic region from the primary database.

Introduced in version

1.0.0

Parent requirements

RQ-KT-101-#10

Provider Reviews Patient Data

Rationale

Database backups mitigate the risk of data loss in case of failures of the primary database server.

Risk control for

RISK-KT-42-#22

Loss of data integrity

RQ-KT-10-#18

Availability of at least 99.5%

KXREC7V6TD6SCJF8XGRV8Z5F9NQF5MK

Controlled at: 2024-02-26 18:13Z

The application should have at least 99.5% uptime. In other words, it can be down or unavailable for a maximum of 0.5% of the time. This means that over the course of a year, the application can be down for a maximum of 1.8 days (0.5% of 365 days).

It is important to note that this uptime percentage is calculated based on the total time, not just the time when it is being used. It also doesn't take into account any scheduled maintenance or updates.

Introduced in version

1.0.0

Parent requirements

RQ-KT-4-#66

Reliability

RQ-KT-99-#24

Daily Insulin Dose Calculation

Risk control for

RISK-KT-41-#29

Application is not available

RQ-KT-11-#18

End-to-end traceable data reliability

KXREC2B22R6M4HN9CET0J132W88TZCJ

Controlled at: 2024-02-26 18:13Z

The application should store a record for each transformation it does to the data following 21 CFR Part 11. Each of these data transformations shall contain the following information: what the change was, when the change was done, and who implemented the change.

Introduced in version 1.0.0

Parent requirements

RQ-KT-101-#10 Provider Reviews Patient Data

Risk control for

RISK-KT-42-#22 Loss of data integrity

RQ-KT-13-#19

Design for dashboard GUI

KXREC6CJRZK2JNX8RJVEVMA6NHVPGW2

Controlled at: 2024-02-26 18:13Z

The dashboard shall have the following GUI:

- A summary of the meal times, logged by the patient
- A summary of the recent insulin administration
 - Time
 - Amount
- A graph depicting the blood sugar levels with the option for daily, weekly, monthly, and yearly view, if the data exists. This shall displayed by blood sugar levels (mmol/L) over time.
- A graph depicting the insulin administered. This shall displayed by insulin amount (units) over time

Introduced in version 1.0.0

Parent requirements

RQ-KT-12-#32 Usability

RQ-KT-14-#15

Dashboard with predefined analytics

KXREC73QBAJWGTW8ZMSA0ND177Q599M

Controlled at: 2024-02-26 18:12Z

Patients, doctors and caretakers would like to view predefined analytics on a dashboard.

The dashboard should include useful metrics as well as highlight metrics that are out of predefined limits.

Historical data should be charted to get a quick overview of glucose levels as well as times when drugs were administered.

Introduced in version 1.0.0

Parent requirements

RQ-KT-12-#32

Usability

Risk control for

RISK-KT-41-#29

Application is not available

RQ-KT-15-#14

Manual input of dose

KXREC2XG74RKATQ8SJB574KRS0EDK7V

Controlled at: 2024-02-26 18:13Z

Users shall be able to input dose information manually.

Introduced in version 1.0.0

Parent requirements

RQ-KT-12-#32

Usability

Rationale

Allowing users to input insulin doses manually is important for a few reasons:

1. **Flexibility:** Users should have the option to manually input their insulin doses in case the device's suggestions are not accurate or appropriate for their specific needs. For example, the device may not account for unexpected changes in activity levels or food intake.
2. **Safety:** Users may need to override the device's suggestions in order to avoid potentially dangerous situations, such as hypoglycemia (low blood sugar). By allowing users to manually input their insulin doses, they have more control over their treatment and can make adjustments as needed to keep their blood sugar levels within a safe range.

3. **User engagement:** Allowing users to manually input their insulin doses can help increase their engagement with the device and their overall diabetes management. It encourages users to take an active role in monitoring their blood sugar levels and managing their insulin doses.
4. **Customization:** Each person has different needs and response to insulin, manually inputting their doses allows them to make adjustments and customize their treatment according to their own needs.

Risk control for

RISK-KT-43-#16

Slow application response

RQ-KT-16-#22

Mobile app support

KXREC61CSERN4V58XRB7Y4R38YKBBAR

Controlled at: 2024-02-26 18:13Z

Users need to interact with the application on a standard-issue iPhone (iPhone 12 or later) running iOS 15 or later.

Introduced in version 1.0.0

Parent requirements

RQ-KT-12-#32

Usability

Children

RQ-KT-17-#16

Application running on approved iOS versions

Risk control for

RISK-KT-41-#29

Application is not available

RQ-KT-17-#16

Application running on approved iOS versions

KXREC1B6BBB5SEH8D5TT052DKWPK3ZJ

Controlled at: 2024-02-26 18:14Z

The application needs to run on the most recently approved iOS version.

Currently, iOS 15.4+ and 16.0+ are supported.

Introduced in version 1.0.0

Parent requirements

RQ-KT-16-#22

Mobile app support

RQ-KT-18-#33

Cybersecurity

Rationale

To leverage the newest HealthKit APIs and remove potentially insecure OS versions there needs to be a tight requirement on OS versions. It might even be the case that certain minor versions will be required, e.g. iOS 15.4 and above instead of 15.0 and above.

RQ-KT-19-#21

Patient app UI

KXREC6YHNQ4C5G58S2BTX64DMG7XRD3

Controlled at: 2024-02-26 18:13Z

In the patient iOS app, patients will be able to:

- Review their dosage history
- Message their provider
- Provide dosage instructions to the infusion pump
- Read sensory readings from their glucose monitor
- View the version of the infusion pump being used
- See prescriptions from the provider

Introduced in version 1.0.0

Parent requirements

RQ-KT-99-#24 Daily Insulin Dose Calculation

RQ-KT-20-#14

Warning indication

KXREC2EW3M9CBSX8QS8TKTZ1VZZE59R

Controlled at: 2024-02-26 18:12Z

When the recommended insulin dose is above the defined limits, or the glucose readings are outdated, warn the user.

Introduced in version 1.0.0

Parent requirements

RQ-KT-12-#32 Usability

Risk control for

RISK-KT-43-#16

Slow application response

RISK-KT-44-#19

Recorded glucose value is not correct

RQ-KT-21-#78

Drug product dosing

KXREC5BPHJTHKCW8XVAK6X80PJ81BM8

Controlled at: 2024-02-26 18:13Z

Patients can select the size of a drug product dose based suggestions from the AI/ML model and provider treatment. They are able to trigger the dose to execute or stop the dose administration if needed.

Manual triggering of the drug product still needs to be enabled for the patient or caregiver. In this case it will be recorded in the history tracking as “patient-administrated”.

Introduced in version 1.0.0

Parent requirements

RQ-KT-99-#24

Daily Insulin Dose Calculation

Context

Clinical

Children

RQ-KT-22-#24

Dose selection menu

RQ-KT-23-#24

Continuous recording of blood glucose levels

RQ-KT-24-#15

Dose history

RQ-KT-25-#13

Dose administration from the app

RQ-KT-23-#24

Continuous recording of blood glucose levels

KXREC4PV8W7FQM88AR8KN71BDGG1A69

Controlled at: 2024-02-26 18:13Z

Blood glucose levels should be recorded in 5-minute intervals to ensure that the insulin can be administered as soon as blood sugar levels rise considerably.

Introduced in version 1.0.0

Parent requirements

RQ-KT-21-#78

Drug product dosing

RQ-KT-24-#15

Dose history

KXREC5D9E6ZER039RD9R9M6E2HRATXM

Controlled at: 2024-02-26 18:13Z

Patients need to be able to store information about doses they have taken. This history is required to have proper documentation for dosage tracking and effectiveness of treatment.

The whole history of patient taken doses should be stored and include detailed information about which product was injected, when the dose was administered and in which dose (size).

Introduced in version 1.0.0

Parent requirements

RQ-KT-21-#78 Drug product dosing

Risk control for

RISK-KT-42-#22 Loss of data integrity

RQ-KT-25-#13

Dose administration from the app

KXREC4F8H8FAXND8Z29TD93HYEGNJ1W

Controlled at: 2024-02-26 18:12Z

In addition to suggesting a dose level to the user, the user shall also be able to administer a user-selected dose directly from the app.

Introduced in version 1.0.0

Parent requirements

RQ-KT-21-#78 Drug product dosing

RQ-KT-27-#16

Client cybersecurity

KXREC4XXVMXSDMM8T1RPF72DRFEBWK

Controlled at: 2024-02-26 18:12Z

Client shall be secure and comply with SOC 2 and ISO 27001.

The client should not make unencrypted connections to untrusted endpoints.

For encryption no known weak ciphers should be used and for transfers protocol downgrades should be prevented.

Introduced in version 1.0.0

Parent requirements

RQ-KT-18-#33

Cybersecurity

RQ-KT-28-#16

Server cybersecurity

KXREC1MQDXSJST69QJ9DGB7CW0A82V3

Controlled at: 2024-02-26 18:13Z

Server infrastructure shall be secure and comply with SOC 2 and ISO 27001.

Additionally:

- Internal services shall not be exposed to the internet unless absolutely necessary
- Interfaces to the outside shall be clearly defined and as narrow as possible
- Regular scanning for vulnerabilities should be done as well as port scanning to verify only defined ports are open
- No unencrypted transfer of data should happen
- HTTP requests should be redirected to HTTPS before data would be exposed
- HSTS with a `max-age` of at least 1 year should be set
- Remote access should be limited and use strong authentication

Introduced in version 1.0.0

Parent requirements

RQ-KT-18-#33

Cybersecurity

RQ-KT-29-#21

User authentication

KXREC256Z1FXQ098WQRW17883RS51TZ

Controlled at: 2024-02-26 18:12Z

Each patient must authenticate using a private key based on elliptic curve cryptography (ECC) using one of the curves recommended by FIPS 186-3 Appendix D with a bit length of at least 256.

FIPS 186-3: https://csrc.nist.gov/csrc/media/publications/fips/186/3/archive/2009-06-25/documents/fips_186-3.pdf

Introduced in version 1.0.0

Parent requirements

RQ-KT-18-#33 Cybersecurity

Risk control for

RISK-KT-40-#34 Unauthorized Access

RISK-KT-42-#22 Loss of data integrity

RQ-KT-104-#9

Infusion Pump Connects to iOS

KXREC4ZCF104K5Z8H083FM1Y8AXCWV1

Controlled at: 2024-02-26 19:09Z

As a user, I want the infusion pump to be able to connect to iOS devices so that I can control and monitor the pump's operation through my iOS device.

Parent requirements

RQ-KT-99-#24 Daily Insulin Dose Calculation

RQ-KXREC13A7QRB8FP900TYSB0P3YFDYF8-#11

Patient app UI (Android)

KXREC13A7QRB8FP900TYSB0P3YFDYF8

Controlled at: 2024-02-26 18:12Z

In the patient Android app, patients will be able to:

- Review their dosage history
- Message their provider
- Provide dosage instructions to the infusion pump
- Read sensory readings from their glucose monitor
- View the version of the infusion pump being used
- See prescriptions from the provider

Parent requirements

RQ-KT-99-#24 Daily Insulin Dose Calculation

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