1. Indications for Use

Please read these instructions before you start using Nala.

Nala is indicated for use by pregnant individuals aged 18 years and over, from initial conception up to 8 weeks postpartum, to track pregnancy progress, record patient-reported outcomes, and integrate wearable device data.

Nala is not a substitute for professional medical advice. See Warnings and Contraindications.

2. Intended Use

Nala is a user-facing digital health software application developed to support pregnancy management through the secure collection, integration and visualisation of patient-reported, contextual and physiological data, and by providing educational content. It is for use by pregnant individuals aged 18 and over, from initial conception up to 8 weeks postpartum, to track pregnancy progress, log patient-reported data and view metrics synced from a wearable device. Nala does not diagnose, treat, or provide medical interpretation of the data it collects or presents.

Nala includes an AI-assisted educational content feature (the "AI librarian"). It answers questions using a curated knowledge base reviewed by clinicians. It does not give personalised clinical advice.

Nala, including the AI librarian, is available in English only.

Nala has no clinician-facing interface. Where a healthcare professional sees information from Nala, it is because the user has chosen to show it to them on her own device.

Nala also supports a research use: historical, aggregated data is transferred to the governing study's contract research organisation. This takes place outside the app.

3. Device Description

Nala is a mobile software application (Software as a Medical Device in the UK) for iOS and Android. It is intended for use by pregnant individuals within routine antenatal care. Nala is software only and has no physical contact with the user.

Main functions: pregnancy progress tracking and symptom and context logging; standard self-report questionnaires (Nala records your answers and does not give you a score or result); display of data synced from your own consumer wearable or phone health source; and educational content, including the AI librarian.

Regulatory status: In the UK, Nala is a Class I medical device under the UK Medical Devices Regulations 2002. In the US, Nala is not a medical device. Daiser Ltd is the manufacturer in both markets.

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Device identification: Manufacturer: Daiser Ltd, 45a Marine Ave, Newcastle upon Tyne, NE26 1LZ. Application: Nala.

Software version: V.1.1

AI librarian model identifier (UK):
Model: nala-ai-uk-locked-gemini-3-5-flash

ID: 7063333065577201664

AI librarian model identifier (US):
Model: nala-ai-usa-locked-gemini-3-5-flash

ID: 5068379168140427264

Technical assistance: contact Daiser support through the Zendesk support service.

Performance: Nala records the information you enter and shows data that your connected wearable or phone health source provides. It does not check, interpret or score that information, and it cannot confirm that it is accurate. The AI librarian answers questions from a curated educational knowledge base reviewed by clinicians. Its answers are for education only.

4. Contraindications

Nala is not intended for use:

- as a diagnostic or therapeutic tool, or as a substitute for professional medical advice or clinical decision-making;
- as the basis for diagnosis, treatment or management of pregnancy-related conditions;
- in an emergency;
- by anyone under 18, or by anyone who is not pregnant;
- more than 8 weeks after birth or the end of pregnancy. Nala is not supported after that point and closes active tracking;
- in emergency departments, labour and delivery units, or other emergency obstetric or critical care settings, or anywhere real-time clinical monitoring or intervention is needed;
- in a language other than English. Nala and the AI librarian support English only;
- in situations that need intensive monitoring.

Nala may not be right for you if:

- you want an app that monitors you or alerts you to urgent symptoms. Nala does not monitor you or detect emergencies;

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- you want a score, result or diagnosis from your answers or your wearable data. Nala does not give these;
- you want advice on what to do about your own health. Nala, including the AI librarian, is for education only and does not give personalised clinical advice.

5. Warnings

⚠ **In an emergency, do not use Nala.** Follow the guidance your maternity care team has given you about symptoms that need urgent attention and who to contact. In the UK this includes NHS 111 and 999. In the US, call 911. Nala does not provide this guidance and does not alert you to urgent symptoms. Nala does not monitor you or detect emergencies. Opening Nala first, instead of getting help, could delay the care you need.

⚠ **Always speak to a qualified healthcare professional** for a diagnosis, treatment or urgent care, and if anything you record or see in Nala worries you. Nala does not replace the judgement of a healthcare professional.

⚠ **Nala does not interpret your information.** Nala does not give you a score or result from your answers. Wearable values are shown as they are recorded. Nothing in Nala is a diagnosis or an assessment of your health, and a value shown without a label, colour or warning does not mean it is normal.

⚠ **The AI librarian is an AI tool, not a person, and is not medical advice.** It answers questions from a curated educational knowledge base. It is for education only, can be incomplete, and cannot tell you what to do about your own health. Its answers do not replace advice from your maternity care team.

⚠ **The AI librarian works in English only.** If you write to it in another language, it replies: "I'm sorry, I am currently only able to assist in English." It does not answer your question. If you need urgent help, do not use Nala; follow the emergency guidance above.

⚠ **Remaining risks with the AI librarian.** Even with the safeguards built into Nala, the AI librarian can:

- give an answer that is wrong, misleading or different from earlier answers;
- give an answer that sounds like a diagnosis or a treatment plan;
- fail to tell you to seek medical attention when your symptoms need it, or fail to recognise that a question describes an emergency;
- sound more reassuring, or more alarming, than your situation deserves;
- fail to give you an answer. If this happens, Nala shows a message telling you to contact a clinician.

⚠ **Do not rely on the AI librarian to decide whether you need care.** If you are worried about your health or your baby, contact your healthcare professional or emergency services, whatever

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the AI librarian says. If you notice an answer that seems wrong, use **Report a problem** in the chat.

⚠ **Telling your healthcare professional.** If you read or are told something in Nala that concerns you, or something you recorded in Nala seems wrong, tell your midwife, doctor or other healthcare professional.

⚠ **Do not service or modify Nala.** There is nothing for you to service or maintain. Keep the app updated through your app store.

⚠ **Reporting a problem.** If something goes wrong with Nala, contact Daiser using the contact details above. In the UK, if a serious incident has occurred in relation to this device, please report it to Daiser.

6. Cautions

- **Where to use Nala.** Nala is for home and everyday use, and can be used during antenatal visits. It has no separate clinician login.
- **Check what you record.** Information you enter may be inaccurate or incomplete if entered wrongly. Check what you record.
- **Wearable and phone health data.** This data is supplied by those devices. Nala does not control them and only shows what each device makes available. If a connection stops, or you gave only some permissions, Nala may keep showing the last value it received or show less data than you expect. Check when each value was last synced.
- **Save and finish later needs an internet connection.** If your connection is lost before you save or submit, answers you have not saved may be lost. A questionnaire you do not finish is not submitted and later shows as expired. Finish and submit a questionnaire when you have a connection.
- **Keep Nala up to date.** Keep the app and your phone software up to date. If an update is mandatory, Daiser will tell you.
- **Protect your phone and your sign-in.** Do not leave the app signed in on a device other people use.

7. Storage

Not applicable. Nala is software only and needs no special storage or transport conditions.

Device requirements: Nala runs on the iOS and Android operating system versions declared by the released build. Nala supports the current major OS version (N) plus one previous version (N-1), on both iOS and Android

8. Directions for Use

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Before you start

To get started with Nala you will need:

1. **A Nala account.** Install Nala on your iPhone or Android phone from your app store, then sign in with Google, Apple or SMS. Your account is personal. Do not leave Nala signed in on a device other people use.
2. **To be pregnant and aged 18 or over.** Nala supports you from initial conception up to 8 weeks after birth.
3. **A wearable or health app (optional).** Oura, Fitbit, Apple Health (iPhone) or Google Health Connect (Android). You can connect later from Settings.

1. Opening Nala and signing in

1. Open Nala. A start screen with the Nala logo shows while the app loads.
2. Choose how to get started: **Continue with Google**, **Continue with Apple** or **Continue with SMS**. The same screens are used whether you are new or returning.
3. If you choose SMS, enter your phone number and tap **Send code**. You have 5 attempts to enter the code. Enter the 6-digit code from your text message within 5 minutes and tap **Continue**. If no code arrives you can ask for another after 30 seconds; too many requests will stop new codes for a while. If your number is rejected too many times you will be asked to sign in another way.
4. If you are returning you go to Home. If you are new you see **Welcome to Nala** and tap **Continue** to start setup.

2. Setting up Nala (new users)

1. **Consent to use Nala.** Read the Intended use and Limitations of Use. You can open the Privacy policy and the Terms and conditions from this screen. Tick both boxes (that you have read and understood the intended use, limitations and privacy policy, and that you consent to Nala processing your health and biometric data) and tap **Continue**. You cannot continue until both are ticked.
2. **About you.** Enter the name you want Nala to use (up to 30 characters), your date of birth (confirm it on the next screen; you can edit it), and your postcode (UK) or zip code (US). If you are under 18, Nala tells you it is for people aged 18 and over, points you to support organisations, and lets you delete your account.
3. **App permissions.** Nala asks whether to allow location access (**Enable location access** or **Skip for now**) and notifications. You can finish with **Go to Dashboard**.
4. **Your pregnancy.** Answer whether your healthcare professional has established your due date with you. If yes, enter your estimated due date and confirm it. If no, enter when

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your last period started and confirm it. If you are not sure, Nala asks how many weeks pregnant you think you are.

5. **Preferences.** Answer the diet question, then choose measurement units (US customary: lbs, ft/in, °F; or Metric: kg, cm). Nala then creates your profile.
6. **About Nala.** Five short screens explain how Nala works, tasks, how often tasks come, connected apps, and that your information is stored safely.
7. **Connect a wearable (optional).** Choose Oura or Fitbit, or tap **Skip for now**. You can also connect Apple Health (iPhone) or Google Health Connect (Android). See section 7. You can connect later from Settings.

3. Home, menu and navigation

- Home shows your pregnancy week and trimester, the weeks and days until your due date, the tasks assigned to you (the tasks area does not appear when no tasks are assigned), and a health summary with a **Log my health** button. You can change your due date from Home. You can also change it from Profile.
- The bottom bar has **Home**, **Tasks**, **My data** and **Articles**, and a **+** button. The menu (three lines, top left) also lists AI Librarian, FAQs, Support, Profile, Settings and About.

4. Tasks and questionnaires

1. Open **Tasks** (or tap a task on Home). **To do** lists tasks available now and tasks coming soon; **Done** lists completed and expired tasks and cannot be edited.
2. Tap **Start** (or **Resume**). Answer each question and tap **Continue**. Use the back arrow to go to the previous question.
3. To stop and come back, tap **Save and finish later**. You need an internet connection to do this. The task shows **In progress** with a **Resume** button. A questionnaire you do not finish is not submitted and later shows as expired.
4. At **Ready to submit?** You can go back to check your answers. Once you submit, your answers cannot be changed. Tap **Submit**. Nala confirms your answers are saved to your record and you can look back on them. Nala does not give you a score or result. Tap **Done**. If submitting fails, tap **Try again** or **Save and finish later**.

5. Logging your health

1. Tap **+** and choose **Log my health**, **Log blood pressure**, **Log blood glucose** or **Ask AI librarian**.

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2. In **Log my health** choose Vitals (blood glucose, blood pressure, weight), Symptoms (blurred vision, cramping, headache, itching, nausea, swelling, vomiting) or Well-being (energy, mood, stress).
3. Enter the value or choose an option, check the date and time, review and tap **Log**. A message confirms it was logged. Values are shown in the units you chose.

6. Viewing your data

- **My data** shows cards for active minutes, blood glucose, blood pressure, body temperature, resting heart rate, sleep, steps, symptoms, weight and well-being, each with when it was last synced or logged. Tap a card for past entries. Nala does not read blood glucose or blood pressure from Apple Health or Google Health Connect; you enter them yourself.
- Nala shows this on the screen: *"Nala does not assess these values and cannot confirm they are accurate. If you're worried about a reading or how you feel, speak to your care team or dial 999."*

7. Connecting and disconnecting a wearable or health app

1. From a banner on Home or My data, or from **Settings > Device connections**, tap **Connect** beside Apple Health (iPhone) or Google Fit / Google Health Connect (Android), or beside Oura or Fitbit.
2. **Oura:** install the Oura app, sign in to Oura (email, then a single-use code) in the window Nala opens, and wait for the success message. **Fitbit:** your Fitbit must be linked to a Google account; sign in to Google and grant access. **Apple Health / Google Health Connect:** follow the steps, then choose which data to share in the phone's permission sheet. Nala then shows that a request was sent. Nala cannot tell whether you allowed access.
3. You can connect one wearable at a time. To switch, disconnect the first (**Disconnect**, then **Yes, disconnect**) and connect the other.
4. Syncing can take a few minutes. If a connection fails, tap **Try again** or **Skip for now**.

8. Using the AI librarian

1. Tap **Ask AI librarian** (from **+** or the menu). The first time, read the three introduction screens: how it works, privacy (it does not remember previous chats), and Using AI safely.
2. On the last screen read that the app does not replace medical advice, tick the box, and tap **Start chat**. You can read the introduction again from the information icon.

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3. Type your question in English (up to 1,000 characters). The AI librarian works in English only. If you write in another language, it replies "I'm sorry, I am currently only able to assist in English." and does not answer. Answers may include related articles. Nala does not save your chat history. Under the text box Nala shows: *"Nala does not provide medical advice. Consult your provider."*
4. If an answer seems wrong, tap **Report a problem**, which opens a support form. If you leave a conversation you are asked to confirm.

9. Articles and weekly insights

- **Articles** has "What to expect this week" and categories to browse. Weekly insights follow your pregnancy week.

10. Settings and your profile

- **Settings** has Notifications (switches for new task, task due and check-in reminder; changes apply straight away), App preferences (measurement units), Device connections, Account and data, Privacy policy, Terms and conditions, and **Sign out**.
- **Profile** shows preferred name, date of birth, pregnancy status and due date. You can edit your preferred name and due date; changing the due date updates your pregnancy timeline, weekly milestones and tasks. You edit one item at a time. You can also change your due date from Home.
- **Account and data: Request my data** opens an email. **Delete my account** first offers to manage notifications or sign out instead; if you continue you re-confirm with your sign-in method (text code, Google or Apple), are told that data may be kept for research purposes, and confirm.

11. When your pregnancy changes or ends

1. You can update your status from **Profile > Pregnancy status > Edit**. At 42 weeks of pregnancy, if you have not updated your pregnancy status, Nala also shows a sheet. Tap **Review my pregnancy status**. Choose **My baby has arrived**, **I'm still pregnant** (confirm or change your due date) or **I've experienced a loss**.
2. **Baby has arrived:** choose how things are going, enter your baby's birth date and birth weight, and your profile moves to postpartum. **Loss:** Nala explains how it will support you, you can enter the date, and you confirm that the pregnancy has ended. Confirming cannot be undone. Nala pauses notifications and shows helpful resources from support organisations.

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3. Nala can be used up to 8 weeks after birth. In the last 14 days a banner shows how many days are left. When support ends Nala explains what happens to your data (used for research, private and secure) and shows resources.
4. **Starting a new pregnancy** deletes your current data and cannot be undone. Nala warns you and asks you to tap **I understand** before you continue.

12. Getting help and troubleshooting

- If Nala is not working as you expect, open **Support** from the menu. **App support** answers common problems (syncing, verification codes, notifications, crashes, updates, loading screens). **Still need help?** offers: Report a health or safety concern, Make a complaint, Report a problem with the app, Share feedback or an idea, and Ask a question. These go to Daiser support (Zendesk). **FAQs** cover getting started, using Nala and your data. The Support page and the FAQs page each have a link to these instructions.
- ⚠ For urgent health concerns do not use Nala. Call your care team or emergency services: 999 (UK) or 911 (US).

13. Finding these instructions

- You can open these instructions in the app at any time: open the menu, then **About** (Regulatory Information). About shows the manufacturer, software version and UDI-DI, regulatory status (UK), and the intended use, with links to **Instructions for use**, Privacy policy and Terms and conditions.
- You can also open these instructions from the link on the Support page or the FAQs page.
- The instructions are stored in the app, so you can read them without an internet connection. When you are online, Nala checks for a newer version and shows it, so corrections reach you without a new app release. The version shown tells you which copy you are reading.
- The instructions are also available as a PDF to download, on the Daiser website and from the app. To get a printed copy, print the PDF yourself.

Functions: there are no functions in Nala that a lay user cannot safely use.

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9. Attachments

Symbol	Reference	Meaning	Where shown
⚠ Caution	ISO 15223-1:2021, 5.4.4	Caution. Consult these instructions for important cautionary information, such as warnings and precautions.	These instructions: Warnings, and Getting help
UKCA	UK Medical Devices Regulations 2002 (not an ISO 15223-1 symbol)	The UKCA mark shows that Daiser has declared that Nala meets the requirements of the UK Medical Devices Regulations 2002 for a Class I medical device.	About > Regulatory status (UK)

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