Instructions for Use
femSense Fertility

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What is femSense?

Please read the instructions for Use and the safety instructions carefully before using femSense and adhere to them.

femSense is a medical device used to determine a woman's fertility on a given day. femSense Fertility consists of a wearable temperature measurement patch, the femSense sensor patch, and the supporting smartphone app for iOS and Android.

The femSense Patch is a disposable product that is worn under the arm for a period of up to 7 days when a woman is most fertile. During this time it continuously measures, records and analyzes body temperature data to determine the current fertility status.

femSense can be used to determine the fertile and infertile phases of a woman's menstrual cycle, either to support natural family planning methods or to plan a pregnancy. The femSense app communicates with the sensor patch, guides the user through the system and shows the user a calendar view of her fertility during her menstrual cycle. The femSense app can be used as a period diary without a patch. The user can choose which app function they wish to use – Cycle Tracking or Get Pregnant.

- **Get Pregnant mode**: the app gives you information about your cycle, your most fertile days (when you are most likely to get pregnant) and if and when ovulation could be detected.
- **Cycle Tracking mode**: the app gives you a calendar overview of your daily fertility status, shows you the days of high fertility and if and when ovulation could be detected.

The femSense patch is a non-invasive product that must only be applied to healthy skin. It provides information about a woman's fertile days based on body temperature measurements. It is not intended for diagnostic or therapeutic use. femSense does not display temperature values. The femSense patch is hypoallergenic and uses medical grade adhesives.

femSense Fertility is not a form of contraception and does not protect against sexually transmitted diseases.

Contraindications

femSense Fertility is not intended to be used as a contraceptive method. It shall not be used with the following conditions:

- Serious, acute or chronic diseases
- Nicotine or alcohol abuse
- Amenorrhea
- Oligomenorrhea
- Polycystic ovary syndrome (PCOS)
- Obesity (BMI > 30)*
- Hirsutism
- Known allergy to components of plasters or adhesive
- Wounds, skin diseases or abrasions in the application area
- Medication that can influence your body temperature
- Hormone treatments (e.g. pill, hormone injections, hormon spiral etc.) may affect body temperature

*Extreme weight conditions can affect the reliability of femSense. If you are not sure whether femSense is suitable for you, please consult your doctor before beginning use.

You can download these instructions for use at www.femsense.com/en/instructions-for-use/. If you would like to have these instructions for use sent to you in paper form, please contact support@femsense.com. The manual will be mailed to you within seven calendar days, free of charge.

Download the femSense app

Download on the App Store

iPhone 7 and higher

ANDROID APP ON Google Play

Android OS 6 with NFC

femSense operating modes

femSense offers two modes of operation:

- **Get Pregnant mode**: for women who are planning a pregnancy.
- **Cycle Tracking mode**: for women who want to track their fertility.

When you register in the femSense app, you must choose one of the two functions. You can change the function in the femSense app menu if you want to use the other mode. Depending on the selected mode of operation, the display of the "Today" screen and the calender will differ slightly.

Measures for IT Safety

- Choose a secure password when you create an account in the femSense app.
- You can change your password at any time by logging out of the app and clicking "Forgot Password" on the login screen.
- Do not give your smartphone to anyone else if you do not want other people to insight on your femSense app.
- Once you have created your femSense account, all of your data and cycle information is stored in the femSense backend.
    - If you change your phone, you can log in with your existing account sign in and password to access your data.
- If necessary, you can delete your user account in the femSense app menu. This will anonymize your data and it can no longer be associated with you. If you would like to physically delete your data, please contact us via email: support@femsense.com
- Keep the femSense app up to date if possible.

Data protection

We collect and process personal data in our app only to the extent described here and in accordance with the regulations of the GDPR.
The femSense App interacts with the Patch via NFC to read continuously recorded body temperature. This data is transmitted securely to our backend servers for analysis. Our system processes the data to detect ovulation and sends the results back to your device.

When you create an account, we collect and store the following information on our servers:

- Username
- Email address
- Date of birth
- Temperature data from the Patch
- Any entries you make in the femSense App (such as period, symptoms etc.)

How we use your data:

- To provide detection analysis and cycle insights for you in the app
- For anonymized research, studies, and internal analyses to improve our services

- We will never sell your data to third parties
- We use Firebase Analytics to understand app usage and improve functionality. This analytics data does not include temperature data or any personal information and cannot be linked to an identifiable person.

Your data rights:

You maintain control over your data. You can request deletion of your account and all associated data at any time by deleting your account in the femSense app settings (My Account – Delete my Account). Uninstalling the app does not delete data stored on our servers; you must request account deletion separately.

For more details, please refer to https://www.femsense.com/en/privacy-policy-app/.

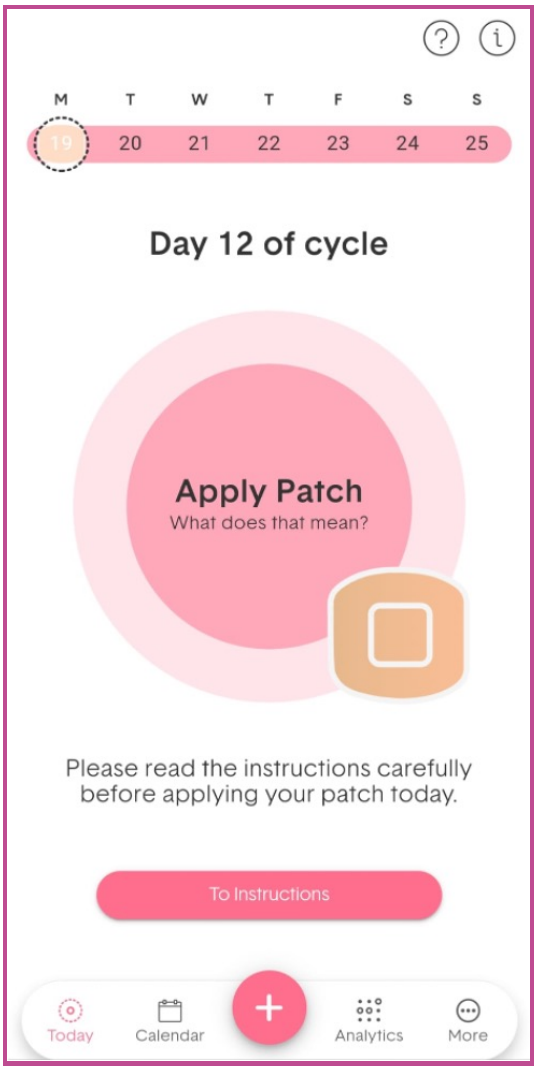
Contact of the data protection officer: gdpr@steadysense.at | Tel: +43 316 232 004

Application and use

Instruction

Once you have successfully registered and entered your cycle details, femSense can calculate your individual cycle profile and show you in the calendar when you are likely to be most fertile. The "Today" screen tells you when you can apply the patch.

Only apply the patch when the app instructs you to do so. Once you have reached your patch application day (which is marked by a patch symbol in your calendar), you have 48h to apply and activate your patch.



Disclaimer: this screen might vary slightly depending on the selected operating mode

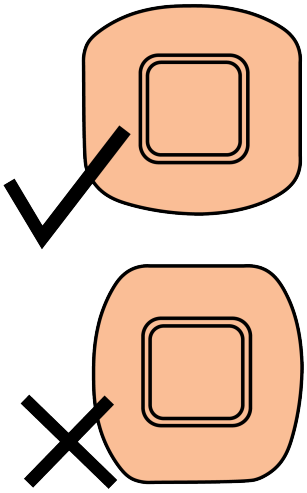
On the day you are instructed by the app to apply the patch, please follow the below steps:

1. Preparation

The patch must be applied on clean, dry skin (without cream/deodorant). It is recommended to apply the patch after showering. The adhesive area can also be cleaned with a suitable alcohol swab. However, make sure your skin is dry before applying. Apply the patch only on intact skin.

2. Find position

The correct position of the patch is important to achieve accurate measurements. Place your hand on your hip and relax your shoulder. The correct position of the patch is three finger widths under the armpit, centered between the back and chest.



Note: Place the patch so that the rounded sides face up and down.

3. Attach patch

Remove the small part of the backing, make sure you are relaxed, and apply the patch to the previously determined location. Once again, make sure that your shoulder is relaxed and that your skin does not have strong wrinkles here. Then remove the rest of the backing and press the patch firmly on all sides.

4. Activate patch

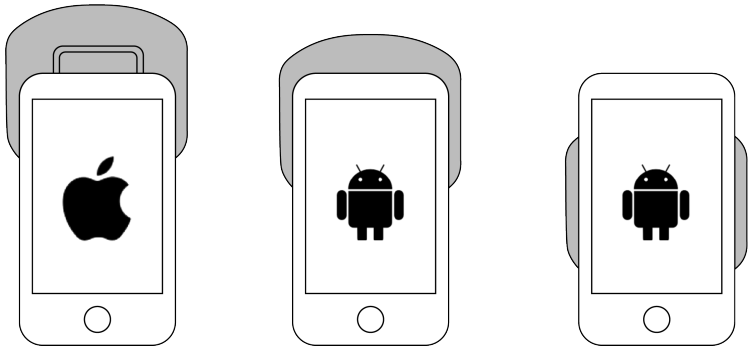
After you have applied the patch correctly, it can be activated. To do so, tap on "Read patch" in the femSense app and hold the back of your smartphone calmly on the center of the patch for a few seconds to activate it. A vibration will confirm successful activation. Once activated, the patch will continuously measure your temperature.

Position for NFC Communication

Depending on your device manufacturer and operating system (Apple iOS or Android) the smartphone has to be held differently against the patch in order to read it correctly.

iPhone: Hold the top edge of the backside of your phone, at an slight angle, to the middle of the patch.

Android: On an Android phone the NFC antenna can be located in different positions. Hold either the area around the camera or the back of the smartphone against the middle of the patch. Please make sure that NFC is switched on. NFC can be switched on in the quick menu or in the settings.



5. Read out patch

After startup, you should read the patch at least once a day. Twice a day is recommended to get regular updates on whether ovulation has been detected. To do this, go to the "Cycle" screen of the femSense app. Tap on "Read patch" and hold the smartphone on the patch as described in point 4 (Activate patch). Your temperature data will be read from the patch and you will see if ovulation has been detected. You can also read out the patch several times a day.

6. Remove patch

The maximum wearing time of the femSense patch is 7 days. The app will inform you when it is time to remove the patch.

To remove the patch, it is helpful to moisten the patch with warm water to soften the adhesive (e.g. when showering or using a washcloth). Then you can carefully remove the patch.

If the patch feels uncomfortable to wear, or if you feel itching or a burning sensation, please remove the patch.

Disposal

Patch:

- The patch is powered by a button cell battery. Therefore, it should not be thrown out in the regular household waste but disposed according to the local waste regulations for batteries and electrical goods.
- The femSense packaging is recyclable and can be disposed in the paper bin.

App:

- If the femSense App is no longer used, it can be removed from the mobile device by uninstalling the application using the standard uninstallation procedure of the respective operating system (e.g. iOS or Android). Ensure that the application and locally stored application data is completely removed from the device.
- Deinstallation of the app does not automatically delete data stored on femSense servers. For information on data storage duration and deletion rights, please refer to femSense's Privacy Policy.
- To permanently delete your user account and associated data, follow the instructions in the app settings or contact support@femsense.com.

The calendar

The calendar function in the femSense app is a cycle tracker (period diary) which predicts future periods and fertile days. You can also enter personal data and dates relevant to your cycle. The calendar also shows the date you will be advised to apply the patch.

If you tap on a date in the calendar, you will get to the detailed view of that day. By tapping on the (+) button you can enter more details like period, illness or sporting activities. All data entered by you will be treated confidentially and will not be passed on to third parties.

Change/ delete entry

To change or delete an entry, select the corresponding day in the calendar and then select the specific entry you want to change or delete. Click on the three dots on the right. Here you can select whether you want to change or delete the entry.

If you want to delete all entries for a day, you can do this for all individual entries as described above. Or scroll down to the bottom of the respective day and click on "Delete all entries".

Please be aware that changing or deleting entries is permanent, they cannot be restored.

Explanation of symbols

Period (predicted) – For these days your period is predicted.

Periode (entered) – You had your period on these days.

Ovulation – The femSense patch detected your ovulation on this day.

Next Patch – Day, on which you can apply your next patch.

Applied Patch – You have applied a patch on this day.

Missed Patch – You have not applied a patch within the application window of this cycle.

Low Fertility – Your fertility is low.

High Fertility – Your fertility is high. Unprotected intercourse might lead to a pregnancy.

Fertility uncertain – Your fertility is uncertain, when no patch was used or no ovulation could be detected.

Today – This cycle represents today.

Entry – On this day you have entered additional entries.

Analytics

In the analytics screen you will find a summary of all your cycles tracked with femSense, average cycle lengths and period days as well as an overview of the data entered in the cycle.

Exclude cycle

In the "Analytics" screen, you also have the option to exclude cycles from the cycle calculation. Exceptionally long or short cycles can, for example, distort the cycle calculation and thus the calculation of your patch application day. If such cycles are "outliers", you can exclude them from the cycle calculation. The reasons for such atypical cycles can be different: illness, pregnancy, miscarriage, emergency contraception or abortion, for example.

To do this, select the relevant cycle under "Analytics" and open it (by clicking on the arrow on the right). At the bottom you will find the option "Exclude cycle from analysis". If you have inadvertently excluded a cycle, you can easily undo this in the same way.

More

Under "More" you will find the menu of the femSense app. This is divided into several areas where you can manage your account and find additional functions and information.

At the top under "**Mode selection**" you can choose between the two operating modes.

Under "**My account**" you can view your account data, log out, change your password or delete your account.

Under "**My Body**" you can view and edit your user data. You also have the option of activating the app's pregnancy mode. In this mode, the "Today" screen changes and you receive information about your pregnancy progress.

Under "**Settings**" you can switch between the metric and Anglo-American measurement systems, change your region and activate or deactivate notifications.

Under "**Help & Support**" you will find the instructions for use as well as explanatory videos and tutorials for the femSense app. The "FAQs" button takes you to the frequently asked questions. By tapping on "Support team", you can contact technical support if you have any problems.

Under "**Legal matters**" you will find the privacy policy, the terms and conditions and the legal notice. You can also view the version of your femSense app here.

Troubleshooting

If the femSense app displays an error message, please take a screenshot. If you are not able to solve the problem on your own, please contact our support team with the screenshot directly in the app via "Contact support" or via email to support@femsense.com.

In order to be able to correct errors as quickly as possible, you can find the most common error messages here:

- "**READ_FAILED** Read failed, please try again. If this issue persists, please contact support."
- "**ACTIVATION_FAILED** The activation process failed, please try again. If this issue persists, please contact support."
- "**NFC_NOT_ENABLED_ANDROID** The NFC function on this device is disabled. Click OK to activate NFC in the settings."
- "**NFC_NOT_AVAILABLE_ANDROID** Your device does not support NFC. You cannot read femSense patches with this device."
- "**NFC_TAG_UNSUPPORTED** This patch is not compatible with the femSense app. Please contact support. Do not throw away your patch or its packaging."
- "**DID_INVALIDATE_WITH_ERROR** The read-out failed, please try again. Try holding your phone at a different angle or closer to the patch. If this issue persists, please contact support."
- "**PatchSwError** A unexpected software error occurred on your patch, please take off the patch but do not dispose of it. Contact support. Do not use another patch."
- "**PatchBatteryLow** The battery of your patch is empty, please take off the patch but do not dispose of it. Contact support. Do not use another patch."

Help

If questions or problems with the product occur, please contact our support:
support@femsense.com or tap “Contact support” in the femSense app menu.
Go to femsense.freshdesk.com/en/support for more support.

Safety Instructions

- The patch should only be worn by those in the specific femSense user group.
- The patch is a disposable product, use it only once and not longer than 7 days. In the event of reuse, the adhesive strength of the patch is no longer ensured and the patch may become detached. Furthermore, reuse may cause skin irritation due to contamination.
- Do not use the patch if you are sick.
- Do not apply the patch on injured skin.
- Do not use the patch if you are allergic to adhesives.
- Do not use the patch if it has been damaged or contaminated.
- Do not attempt to disassemble or open the patch. Do not fold or twist the patch.
- Do not apply successive patches on the same body side.
- femSense does not interfere with other electronic devices. femSense is not affected in normal use.
- For users with pacemakers: Wear the patch only on the side of the body away from the heart, as the smartphone may interact with the pacemaker. If you are unsure, ask your doctor.
- femSense may react unpredictably in combination with strong magnetic fields. Please remove the patch before MR or CT examinations.
- The patch is a small electronic device and should not be disposed in regular household waste.
- Do not throw the patch into the fire, the battery could explode.
- Keep the patch out of the reach of people with disabilities, children and animals.
- Store the patch in a dry place and protect it from sunlight.
- Do not take extended baths or go swimming while wearing the patch.
- If the patch becomes uncomfortable, please remove it immediately.
- Use the patch only under the specified environmental conditions.
- The patch should not be permanently exposed to an NFC field.
- When applied, the patch can cause local and temporary skin irritations.
- Increased immune system activity (for example due to a vaccination) can promote temporary skin reactions in the patch application areas. Remove the patch immediately if the patch feels uncomfortable.

- A very high BMI (>30) may affect the accuracy of femSense. It may also cause discomfort, skin irritation, non-detection of ovulation and damage to the sensor.

Usage Informations

- femSense is designed for ovulation detection and does not show temperature curves.
- The patch can only be read via NFC.
- You need the femSense app to be able to use a patch.
- The patch should only be worn as instructed in the app.
- Only one patch can be used per cycle.
- Large cycle length variations can reduce the reliability of femSense.
- The patch must be worn in the correct position under the arm to ensure reliable ovulation determination.
- Do not apply the patch until the app instructs you to do so.
- Only apply the patch as described in the instructions for use.
- Wash and thoroughly dry the skin under the arm before applying the patch. The area can also be cleaned unsing a suitable alcohol pad.
- Do not use deodorants or lotions beforehand.
- When applying the patch, remove the small part of the carrier foil first.
- Do not touch the adhesive side of the patch, this could reduce the overall adhesiveness.
- Do not overstretch patch during application as this may cause skin irritation.
- After applying the patch, smooth it out gently on all sides to fix it in place.
- Do not wear tight bras while wearing the patch as this can cause pressure points and can also affect the reliability of femSense.
- The patch should be read via NFC at least once a day. For best results, it is recommended to read the patch twice everday, once in the morning and once in evening.
- Hold your smartphone as still as possible while activating and reading the patch.
- Remove the patch immediately if it feels uncomfortable or causes skin irritation.
- Avoid high intensity sports or other activities that cause excessive perspiring (sauna/steam/bath) while wearing the patch as it can lead to skin irritations and decrease the adhesive strength.

- Prolonged sunbathing and environments that can significantly affect your surface temperature during use should be avoided.
- Everyday activities such as personal hygiene, work or light physical activity will not affect the patch.
- After showering, make sure that you dry the patch carefully (dabbing is best) so that the patch does not come off unintentionally.
- After contact with water (e.g. shower), make sure you pat the patch firmly and allow the patch to dry well.

Reporting obligation

Report all serious incidents (damage, injuries, infections, etc.) that occurred in connection with the product to the manufacturer (via e-mail to: support@femsense.com) and the competent authority of the EU member state in which you reside. In Austria, the competent authority is the BASG. Their current contact information can be found on the website: www.basg.gv.at/en/

Further information

- Terms and Conditions: https://www.femsense.com/en/general-terms-and-conditions/
- Privacy policy: https://www.femsense.com/en/privacy-policy-app/
- Revocation: https://www.femsense.com/en/right-of-cancellation/
- Imprint: https://www.femsense.com/en/imprint/

Follow us on social media

Legal

©SteadySense GmbH,

Johann-Schreiner-Straße 3,

8074 Raaba-Grambach, Austria

Symbols

Manufacturer

Green Dot

Type BF

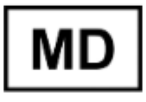
Information

CE marked

Single Use Product

NFC required

Safety advice



Medical Device

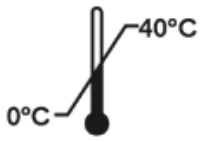
Do not dispose in household waste

Expiration Date

Observe electric operating instruction

LOT Number

Protect from sun and heat



Storage temperature

MR unsafe

Intended Use

femSense Fertility is an information system intended for women in their fertile phase delivering information about the fertility status. femSense Fertility provides the probability of the fertility of a user each day.

femSense Fertility is a temperature measuring medical device, capable to detect ovulation-based changes in body temperature in the sub-degree range (<1°C) by measuring axillary temperature. A cloud-based backend for data storage and processing and the corresponding mobile application serves as accessory to the femSense Fertility.

The temperature data measured by the femSense Fertility is transmitted via Near-Field-Communication (NFC) to the backend, where it is processed and evaluated. After evaluation, the fertility information is then transmitted to the App, which is used to inform the user about their fertility status. femSense Fertility is intended to be used in home environments.

femSense Fertility is not a method of contraception.

Safety and Performance Claims, Clinical Benefit of femSense Fertility

- **Clinical Safety:** CS-SYS-001: Safe use of the combined system: achieved through the collective safety measures of all system components (Patch, App, Backend), summative usability validation per EN 62366-1, and system-level risk management per ISO 14971.
- **Clinical Performance:** CP-SYS-001: Provision of daily fertility status throughout the menstrual cycle based on cycle prediction (cycle-tracking algorithm) and, during the fertile window, temperature-based ovulation detection (ovulation detection algorithm).
- **Clinical Benefit:**
    - CB-SYS-001: Comprehensive fertility awareness by combining continuous temperature monitoring, validated algorithmic analysis, and user-entered cycle data — delivering daily fertility status throughout the full menstrual cycle.
    - CB-SYS-002: Supports conception planning by identifying the fertile window and confirming ovulation, without the need for hormone-based methods or manual basal body temperature charting.

Intended user group

Women in their fertile age who want to be informed about their fertility status and gain deeper understanding of their menstrual cycles, or who wish to determine the exact time of ovulation.

The smartphone application is reusable and can be downloaded from the respective app store (Apple App Store and Google Play Store). It is suitable for continuous use and is updated on a regular basis. To confirm ovulation, femSense requires temperature time-series data (timestamp & temperature) measured at predefined intervals of 10 minutes.

Product Shelf life & Package Contents

Sensor patch:

- GTIN (Global Trade Item Number):
    - EU:
        - 1 piece: 09120095900519
        - 3 pieces: 09120095900502
    - US:
        - 1 piece (flatpack): 09120095900274
        - 1 piece (clutch): 09120095900243
- The patch is supplied in product packs of 1 or 3 patches.
- The patch is a single use product and has a shelf life of 2 years.
- Batch number and expiration date can be found on the bottom of the product package.
- The patch is worn for a period of up to 7 days after application.
- The patch is a microelectronic device and should be disposed off according to local disposal regulations or returned to the manufacturer for recycling. See the **Disposal** section for more information.

femSense app:

- The femSense app is available in the App Store (Apple App Store & Google Play Store) and is updated regularly.
- The femSense app is compatible with all patches distributed in the EU (except Ireland).

Package Contents

- **Patch**: each product package includes one or three patches (for one or three cycles); patches are individually packaged
- **Quick Guide:** each package contains a Quick Guide. This is to remind you how to use the

patch. Using femSense for the first time? Then check out our **instructions** further down.

- **femSense Fertility app:** the femSense app can be downloaded for free from the App Store. You need it to use the patch.
- **femSense Instructions for Use:** the electronic instruction manual is available in paper form upon request. Please contact support at support@femsense.com. The instructions for use will be sent to you by mail free of charge within a maximum of seven calendar days.

ⓘ Technical Specifications

- Type of measuring device: temperature sensor for ovulation detection
- Measurement site: Axilla
- Type of use: Single use product
- Typical application duration: 7 days
- Operating conditions:
    - Environmental temperature: +15 to +40°C (+86 to +104°F)
    - Humidity: 15 to 95%
    - Air pressure: 86 to 106 kPA
- Transport- und storage conditions:
    - Environmental temperature: 0 to +40°C (32 to 104°F)
    - Humidity: 15 to 95%, non-condensing
    - Air pressure: 86 to 106 kPa
- System requirements:
    - iPhone: iOS 13 or higher on iPhone 7 or newer models
    - Android: Android OS 6.0 Marshmallow or later on an NFC-enabled smartphone
- Internet connection at least 3G or WIFI
- Warranty: 2 years after production
- Dimensions patch: 65 x 60 x 3 mm (2.56 x 2.36 x0.12 in)
- Weight: 3 g (0.11 oz)
- Power source: 3 V lithium button cell battery (not replaceable)
- IP-classification: IPX5: Protection against waterjets from any direction
- UDI-DI App Store (iOS): 09120095900137
- UDI-DI Play Store (Android): 09120095900144

EMC

Guidance and manufacturer's declaration – electromagnetic emissions			
The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.			
Emission test	**Frequency Range**	**Compliance**	**Compliance Level**
EN 55011B/ EN 55032B RF Interference field	30-1000 MHz	Class B	PASS

Guidance and manufacturer's declaration – electromagnetic immunity			
The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.			
Immunity Test	**IEC 60601-1 test level**	**Compliance level**	**NOTE**
EN 61000-4-2: Electrostatic discharge	Contact discharge: ±8 kV	not applicable	Contact discharge is to be applied according to EN 61000-4-2 due to conducting surfaces of the DUT
	Coupler plate: ± 8kV	PASS	-
	Air discharge: ± 2kV ±4kV ±8kV ±15kV	PASS	-
EN 61000-4-3: Electromagnetic fields	10 V/m 80MHz to 2,7 GHz	PASS	-
EN 61000-4-8: Magnetic fields	-	not applicable	Device is not sensitive against power frequency magnetic fields. It has no magnetic field senstive components.