Daysy Clinical Evaluation

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Change History

Date	Edition	Author	Modifications	Pages
	0.01	B. Kratochvil	First draft of document	All
	1.00	B. Kratochvil	Added PMCF, Released	All

Distribution List

Company	Function
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List of Review / Approval

Company	Name	Function	Date	Signature
Valley Electronics AG	N. Rechberg	CEO		
Valley Electronics AG	B. Kratochvil	CTO		
		Reviewer		

References

- MEDDEV 2.7.1, 2009
- 2014-02-16_EN_ISO_10993-1_MDRS_Declaration_of_Confomity

1. Purpose/Scope

This document is the clinical evaluation report for Daysy version 1.0 and DaysyView 1.0 as produced by Valley Electronics AG. Daysy is functionally equivalent to the LadyComp and Pearly, and the core technology has been on the market for over 25 years. The method is one based on natural family planning, and uses Daysy as a way to reduce user error in measurement and interpretation. Daysy is not a contraceptive device, and has no way of controlling conception. This technology has been subjected to multiple clinical studies, which are directly applicable to evaluate the efficacy Daysy. Daysy has been found suitable for the task of a fertility monitor and risk analysis has found that there are no unacceptable risks with the final product.

This document follows the guidelines as provided by MEDDEV 2.7.1, 2009, and in particular the report format as laid out in Appendix E.

2. Description of the device and its intended application

Daysy is intended for measuring and recording basal body temperature (BBT) as an aid in ovulation prediction to facilitate conception and contraception. **Daysy does not control contraception**. It is only able to advise users as to whether or not contraception should be used to prevent pregnancy or when it is advisable for the user to have sex to increase the likelihood of conception. If contraception is required, it must be provided through other means such as a barrier method (condom, diaphragm, etc.).

The user interface for Daysy is designed to be simple and easy to use. It consists of a temperature sensor for orally taking measurements, a single button, a buzzer, a communication jack, and a series of colored LEDs. The fertility status and device state are displayed to the user through the LEDs. Daysy does not display the user's temperature.

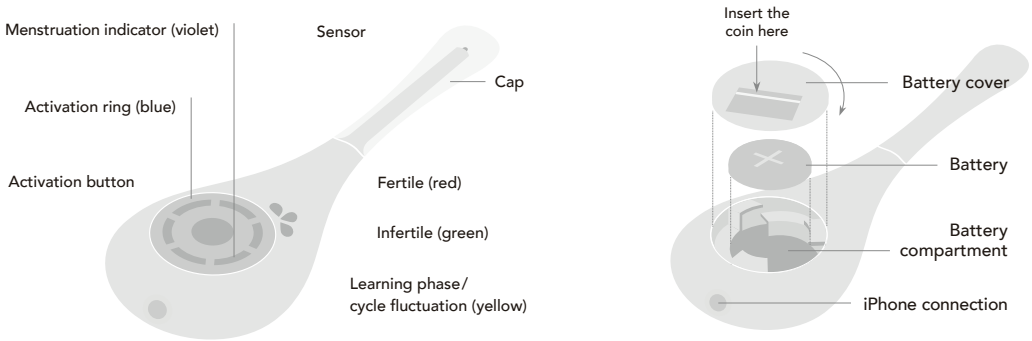


Figure 1: Daysy User Interface Diagram

Depending if the user wishes to conceive or prevent a pregnancy, the color LEDs on Daysy can be acted upon in different ways.

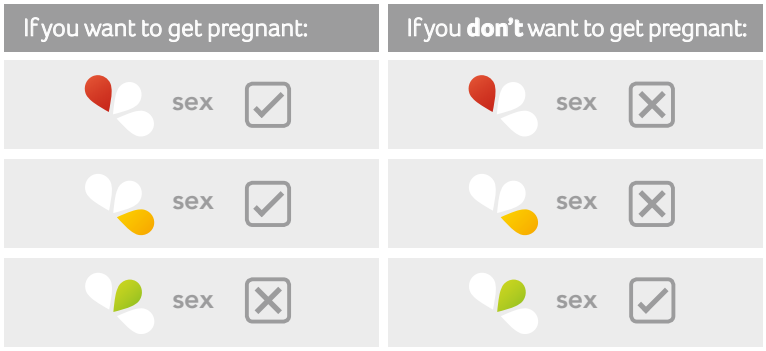


Figure 2: Daysy Quick Reference Card

Daysy and DaysyView are designed to be used in multiple languages, and accompanying documentation is currently available in English and German.

Daysy can be connected to a mobile phone and the data read out of it with DaysyView. This information can then be viewed graphically by the user in a more convenient form. DaysyView is not needed for the appraisal of the female cycle by Daysy.

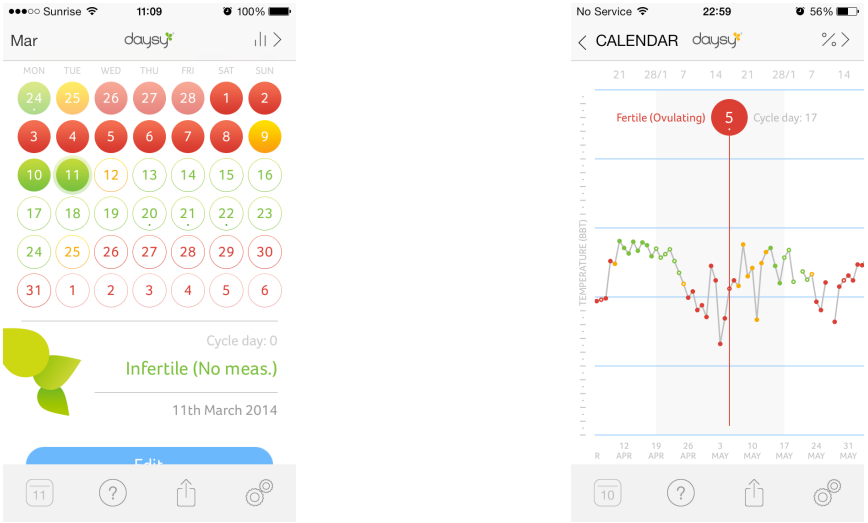


Figure 3: DaysyView Calendar and Fertility Chart Views

Daysy is intended to be used by a single user, aged 25-45, over a period of several years.

3. Intended therapeutic and/or diagnostic indications and claims

Daysy is intended for measuring and recording basal body temperature (BBT) as an aid in ovulation prediction to facilitate conception and contraception.

DaysyView is a program for displaying data related to a woman's menstrual cycle to aid in ovulation prediction. It can be used stand-alone to log and display a graphical representation of this data, or in conjunction with Daysy to display the fertility status as well.

Daysy is a tool of the so-called "natural family planning". These type of tools are not contraception, but rather aid the users to be aware of the fertile days. During these days,

one has to use some kind of a contraceptive to avoid pregnancy or avoid sexual intercourse at all, to avoid pregnancy.

Since Daysy is based on the fertility algorithm of Lady-Comp and Pearly from Valley Electronics GmbH, it is claimed that Daysy has a similar Pearl Index, a method for measuring the effectiveness of a family planning method, to these products that are ultimately bounded by the natural family planning method itself.

4. Device classification

In Europe, Daysy is classified as a class I medical device according to the Council Directive 93/42/EEC of 14 June 1993 according to Rule 5 of Annex IX.

In the USA, Daysy would be regulated under the heading of *Device, Fertility Diagnostic, Proceptive*, Product Code LHD. These are "unclassified" devices: they are considered to be pre-amendment devices since they were in commercial distribution prior to May 28, 1976 (when the Medical Device Amendments became effective).

According to EN ISO 62304:2006, the software in Daysy is classified as Class A: No injury or damage to health is possible. This is based upon the risk assessment in 61_Risk_Management_File.

5. Context of the evaluation and choice of clinical data types

The core technology for Daysy is based upon that of LadyComp and Pearly as developed by Valley Electronics GmbH. This technology has been on the market for well over 25 years, and Valley Electronics AG has been selling products with the algorithm for well over 15 years.

The conformance to the Essential Requirements has been met as listed in 10_Essential_Principles_Conformity_Checklist. Since it is an invasive device, key among these are the biocompatibility which has been assessed via EN ISO 10993-1 as documented in 2014-02-16_EN_ISO_10993-1_MDRS_Declaration_of_Confomity.

The following items highlight the similarities and differences between Pearly, the latest generation in the fertility monitors from Valley Electronics GmbH, and Daysy.

Electronics	The core measurement circuitry and processor have been reused in Daysy. Improvements have been made in noise rejection. Along with technical verification, this means that the measurement performance is the same or better with Daysy. More information can be found in 20_System_Architecture_Description.
User Interface and Form Factor	The user interface has been greatly simplified with Daysy to reduce the chance for User Error. This mainly takes the form of the fertility status being reduced from a LCD to a set of colored LEDs. Also, the number of buttons on the device has been reduced to a single one. This has been evaluated and found to be suitable as documented in

	the 50_Daysy_Usability_File.
Modeling Algorithm	The fertility algorithm has been ported from Pearly, and is functionally equivalent as documented in 20_Pearly_Comparison.
Accompanying Documents	The accompanying documentation has been simplified and extended from a traditional user manual to include a step-by-step interactive guide that teaches users how to use the device. In addition, video tutorials have been created to reach users that do not like traditional manuals.

Table 1: Comparison between Pearly and Daysy.

For clinical evaluation purposes, Daysy can be considered functionally equivalent to Lady-Comp and Pearly which have been validated through years of experience on the market and multiple clinical studies. Therefore, an examination of fertility awareness methods has been performed with the performance statistics of LadyComp being used as analogies to Daysy.

6. Summary of the clinical data and appraisal

A summary of the clinical data has been done in the form of a literature review as documented in 30_Literature_Review.

7. Data analysis

7.1. Performance

The existing fertility awareness methods were examined as to their efficacy in facilitating or preventing pregnancy. There was significantly more literature available in the prevention category.

As an aid in conception, fertility awareness methods were shown to qualitatively be beneficial, but without strong statistical backing. This is in part due to limited studies being performed and in some cases controls being omitted. For all results reported though, fertility awareness methods were viewed as beneficial in increasing the cumulative probability of conception, and thus reduce the amount of time to conception.

As an aid in pregnancy prevention, a number of different studies presented results. In the table below, it can be seen the that digital fertility monitors based on the LadyComp technology, have a method safety of 0.7% over 12-months placing it at the lower end of natural family planning methods. The usage safety also displays similar good performance, and has been shown to be lower than the oral contraceptive pill.

Method	**Brand/Common Name**	**Typical Use (Usage Safety)**	**Perfect Use (Method Safety)**
Vasectomy[1]	male sterilization	0.15	0.10
IUD with Progestogen[1]	Mirena	0.2	0.2
IUD with Copper[1]	ParaGard, Copper T, the coil	0.8	0.6
BBT[3]	**LadyComp**	**3.8**	**0.7**
BBT[4]	**LadyComp**	**5.3**	
Oral Contraceptive Pill[1]	the pill	9	0.3
NuvaRing[1]	the ring	9	0.3
Diaphragm and Spermicide[1]		12	6
Symptothermal Method[2]		13-20	2
Ovulation Method[2]		22	3
Male latex Condom[1]	condom	21	5
No Method[1]		85	85

Table 2: Comparison of different methods of avoiding pregnancy.
1 data from [Trussell 2011]
2 data from [Hatcher 2007]
3 data from [Bachhofer 1997]
4 data from [Freundl 1998]

7.2. Safety

The concept of natural family planning is based on observation of the female menstruation cycle and some statistical properties of it. Digital fertility monitors, like Daysy, are using the same methods, while reducing the risk of wrongly interpreting data (as it is done by a machine) and wrongly reading or noting measurement results (as it is done by a machine). If the device is used correctly, its level safety cannot exceed the particular value of the natural family planning applied properly, but it can approach it closely. If users decide to have sex during their fertile periods, they must use some form of contraception to avoid pregnancy.

It must be noted, that an unwanted pregnancy is not a harm arising from the application of the device. It is a risk of the natural family planning per se. Using natural family planning means accepting this risk. Digital fertility monitors are a way to mitigate the risk down to a significantly lower level, and have been shown to approach that of forms of contraception such as the pill or sterilization. Daysy accomplishes this through reducing the risk of user error through miscalculation, user bias, and being able to use more advanced statistical methods than the paper and pencil methods.

Digital fertility monitors do not prevent from the transmission of HIV and STDs.

Due to the minimally invasive nature of digital fertility monitors, no other adverse affects were found in the examination of the literature.

In all methods examine, the usage safety rate was significantly worse than the method safety. This implies that usability plays a key role in a fertility-monitoring device and it's safe effective use.

7.3. Design Verification and Validation (V&V)

Daysy has been subject to a rigorous verification and validation program as guided by P09_02_Verification_and_Validation_Sample_Size_Selection from the Valley Electronics AG Quality Management System. This V&V program is summarized in 50_Report_V_and_V_Summary and encompasses both internal and external testing.

External testing is used for the following items:

- DIN EN 60601-1 ed 3 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-8:2006 - Medical electrical equipment General requirements for basic safety and essential performance. Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- EN 60601-1-11:2010 - Medical electrical equipment General requirements for basic safety and essential performance. Collateral standard. Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- ISO 10993-1:2009 - Biological evaluation of medical devices Evaluation and testing within a risk management process

7.4. Post Market Clinical Follow Up Plan (PMCF)

The PMCF plan is based on the residual risks inherent in the subject device, collected complaints and adverse events, and devices considered equivalent. **A PMCF Study is not warranted at this time due to the established safety and clinical performance and significant clinical experience on the equivalent devices (i.e., Lady-Comp and other companies similar devices), which have demonstrated a clear history of long-term clinical performance and a favorable risk/benefit ratio.**

Valley Electronics AG has documented and organized methods and procedures in place to collect post-market surveillance data based on the use of the device. Post-market surveillance data as part of the quality system is continually compiled by the manufacturer through the quality management system. Device-related adverse events and complaints are recorded to identify and investigate any residual risks associated with the use of the device.

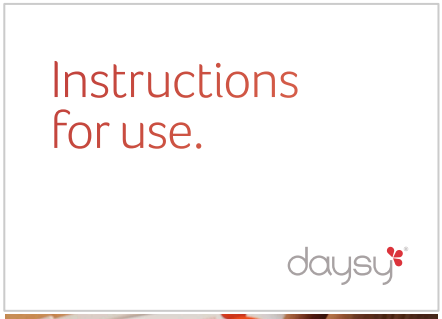
Continued post-production controls, including clinical and commercial compliant procedures and processes, post-market surveillance activities, recall procedures and control of technical documentation will provide sufficient data and controls to adequately address clinical risks, and detect any newly emerging risks on the basis of evidence.

Furthermore, this clinical evaluation report will be actively updated and the need for device specific PMCF studies will be continuously evaluated and considered as part of post-market surveillance plan.

7.5. Product Literature and Instructions for Use

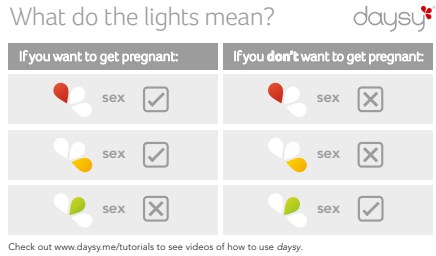
Daysy is marketed and documented as a fertility monitor. The user experience has been designed to be 'easy to use, accurate, trustable, fun.' One of the key goals of the accompanying documentation has been to increase the usage safety to that of the method safety. This goal has been implemented and monitored as guided by IEC 62366:2007. This process, as documented in 50_Daysy_Usability_File, has found that users are very comfortable with their ability to learn, use, and understand Daysy with the help of the accompanying documentation.

The accompanying documentation for Daysy uses multiple forms of media to approach users with different learning preferences, and consists of the following items:

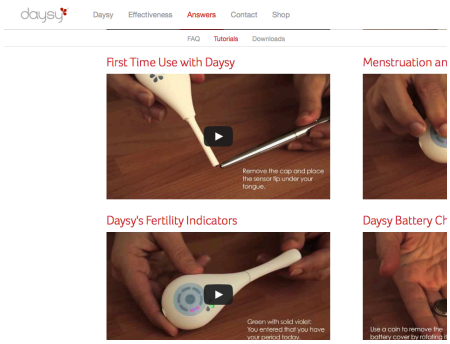


The Instructions for Use (IFU, 10_IFU_Daysy_EN) are the traditional user manual for Daysy. The IFU clearly states that daysy does not protect against HIV and STDs.

A Quick Start Guide (10_IFU_Quick_Start_Daysy_EN) has been developed to guide users through their first-time use of Daysy. As users flip through the booklet, it slowly exposes different features of Daysy, and instructs them on usage.



A portable Quick Reference Card (10_Quick_Reference_EN) is included in the packaging with the key device information.



No matter how friendly the printed documentation is, some users will not read it. In an effort to better serve these users, video tutorials have been developed and posted online for them to download at https://www.daysy.ch/en/answers/tutorials/, along with additional frequently asked questions about Daysy.

8. Conclusions

Daysy is intended for measuring and recording basal body temperature (BBT) as an aid in ovulation prediction to facilitate conception and contraception. DaysyView is an alternate way of viewing this data. As such, Daysy and DaysyView are suitable for placement on the market for the following reasons.

- The evidence investigated demonstrates conformity with the relevant Essential Requirements.
- Daysy is functionally equivalent to LadyComp, BabyComp, and Pearly, and the core technology from Valley Electronics GmbH has been validated through clinical studies and over 25 years on the market. These devices have been shown to have a method failure rate of 0.7% in 12-months, which demonstrates their efficacy as a family planning tool. Daysy has been bench tested against Pearly and found to be functionally equivalent.
- Natural fertility methods have a higher risk than hormonal methods, but some users choose to accept these for different personal, medical, or religious beliefs. Digital fertility monitors, such as daysy, provide users with a safer way to implement these methods because they help reduce user error. After mitigation, no risks were identified, which are classified as "unacceptable."

9. Appendix

9.1. Daysy Instructions for Use (IFU)

The following items from the Daysy IFU have been listed here for convenience.

9.1.1. Precautions

- Please read this manual before you start using *daysy*. Additional information about *daysy* and your cycle can be found on www.daysy.me.
- Please stop taking hormonal contraceptives before starting with *daysy*. – *Daysy* does not provide protection against sexually transmitted diseases in any way. – *Daysy* can only be used by women with menstrual cycles lasting between 19 – 39 days.
- You should not use *daysy* while you are experiencing symptoms of menopause, or taking hormonal treatments and/or birth control hormones.
- *Daysy* may be less effective in identifying fertile days if you experience irregular menstrual cycles.

9.1.2. Technical Details

Principle of operation: *Daysy* uses your daily basal body temperature to track your menstrual cycle. Once it has enough data from you, it calculates your fertility status based on a proven statistical algorithm. The fertility status of the current day will be presented by one of three indicator lights.

Intended user profile: Users are expected to be 15 years or older with 9+ years of public school, capable of reading and understanding this document.

Significant performance characteristics: Measurement of basal body temperature, estimation of fertility status, display of fertility status.

9.1.3. Warnings

- Do not read today's fertility status in the App.
- The most accurate reading is always on *daysy*.
- Do not measure while the cable is connected.
- Do not connect to anything but the iPhone.
- Do not connect to the iPhone while it is connected to anything else.
- Do not use when the housing is broken.
- Do not chew on the sensor.
- Do not bite/swallow housing or parts of it.
- Do not use with irregular menstrual cycles.
- Do not open the housing.
- Do not modify this device.
- Do not expose to high temperatures (i.e. boiling water)
- Do not expose to direct sunlight for extended periods of time.
- Measure only in your mouth.
- Do not over-insert the sensor into your mouth.

9.1.4. Indications/Contraindications

Indications: *Daysy* fertility monitor can be used by women with regular menstrual cycles with a length between 19 and 39 days.

Contraindication: *Daysy* shall not be used if you are experiencing symptoms of menopause, or taking hormonal treatments and/or birth control hormones.

Purposes: *Daysy* is a fertility monitor presenting your daily fertility status based on the regular measurement of the basal body temperature taken orally every morning. The device uses a statistical program to estimate the fertile and non-fertile days in your individual cycle.

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