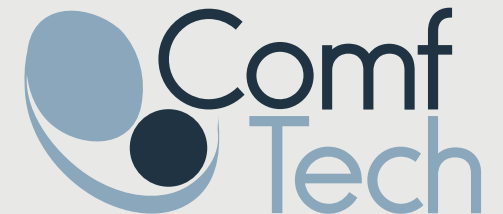


Wearable monitoring systems

Smart Textiles & Wearable Technologies

ComfTech srl
Società Benefit

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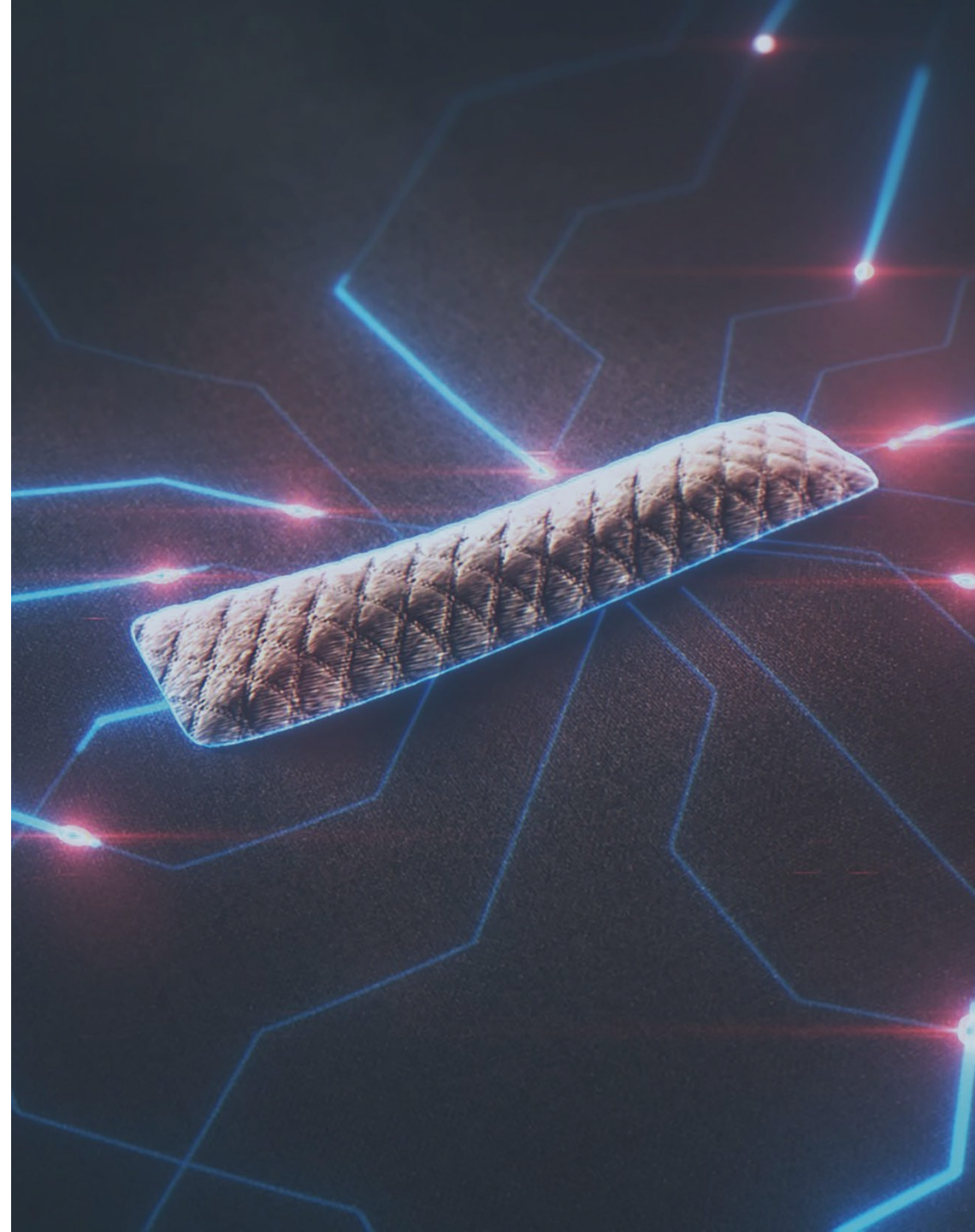


We care with Comfortable Technology

ComfTech

ComfTech is an Italian company specializing in the design and production of **wearable monitoring systems** based on an innovative **textile sensors** technology fully integrated into smart garments, classified as **medical devices**. These systems allow to **collect unique health data** from patients in a comfortable way.

- ComfTech is a **Benefit Corporation**
- Our products are **designed** and **manufactured in Italy**
- ComfTech has obtained CE certification according to the **MDR regulation**. Our products are **class IIb and class I medical devices**



Our vision

Enabling **anyone, anywhere**, at **any time** to monitor their **vital parameters** for **prevention, prediction** and **treatment support** purposes.

Our mission

Offering systems that **integrate unobtrusively** into **people's daily lives**, for continuous, non-invasive **monitoring of vital parameters**.



Our history

ComfTech was **founded in 2010 as a non-participated spin-off of the Politecnico di Milano** and the innovation branch of the **textile manufacturing company New Sirvip S.r.l.** The project was launched in the intensive neonatal unit of Lecco Hospital, with **the aim of using wearable technology to improve the quality of life of premature babies.**

- 2010** ● Development of textile sensors and circuits
 - **1st patent** for a wearable textile sensor system for premature babies and newborns
 - **2nd patent** for a textile sensor with innovative features capable of detecting an individual's vital signs
- 2012** ● ComfTech is invited to join the **EIT ICT Lab European Institute of Innovation & Technology community**
- 2013** ● Development of the **HOWDY Baby electronic monitoring system for newborns** in the delivery room
Participation in a **pregnancy monitoring project**
- 2014** ●
 - **1st trial at Lecco Hospital** of the monitoring system for newborns in the first two hours of life
- 2015** ●
 - Application filed for a **3rd patent** relating to a sensor for measuring physiological electrical signals
 - **Collaborations with Italian and foreign research institutions** on projects involving continuous monitoring using wearable systems
 - **Awarded Horizon 2020 SME phase 1**
 - Partnerships launched for the development of new sensors (breathing, sweat, printed electronics)
- 2016** ●
 - **ISO 13485 certification**
- 2017** ●
 - **2nd clinical trial**
- 2018** ●
 - Winner of the '**Somnus**' and '**Smart living & design**' calls for proposals

- 2019** ● Closing with **Principia SGR**, hiring of R&D and production staff
- 2020** ●
2021 ●
- During the two years of COVID, hospital wards and especially neonatal units have been closed to commercial initiatives
 - Certification of the **HOWDY Senior** adult medical device
 - **Cloud setup and analysis tools**
- 2022** ●
2023 ●
- Analysis of **privacy and security** issues, appointment of DPO
 - ComfTech becomes a **Benefit Corporation** and obtains **B Corp** certification
 - Repurchase of shares by the **founders**
 - Resumption of commercial activities and development of the Italian market, testing in Belgium
 - Start of **transition to MDR**
- 2024** ●
2025 ●
- **Usage trials in hospital wards**
 - **Data collection on newborns**
 - Development of HBHTA analysis with the Politecnico di Milano
 - **Cloud development and data analysis services**
 - Obtaining **MDR certification**
 - Extension of the **HOWDY Baby** product to **paediatric use**
 - Participation in the *ThrombUS+* project (2024-2027), funded by Horizon Europe
 - Participation in the *GESTUS* project (2024-2027), funded by Horizon Europe
 - Participation in the *SFIDA* project, funded by the Regional Innovation Fund
 - Participation in the *NASC-ITA* project, funded by MIMIT
 - Participation in the *VIPPSTAR* project (2025-2028), funded by Horizon Europe
 - Participation in the *HOWDY Edge* project, funded by the Regional Innovation Fund
 - Participation in *HPC4wearable*, funded by Sapienza University - PNRR

Compliance and Certification



ComfTech is **UNI CEI EN ISO 13485:2016** certified



ComfTech obtained **CE certification according to the MDR Regulation**
Our products are **class IIb medical device** and **class I medical device**



Patented
Intellectual
Property

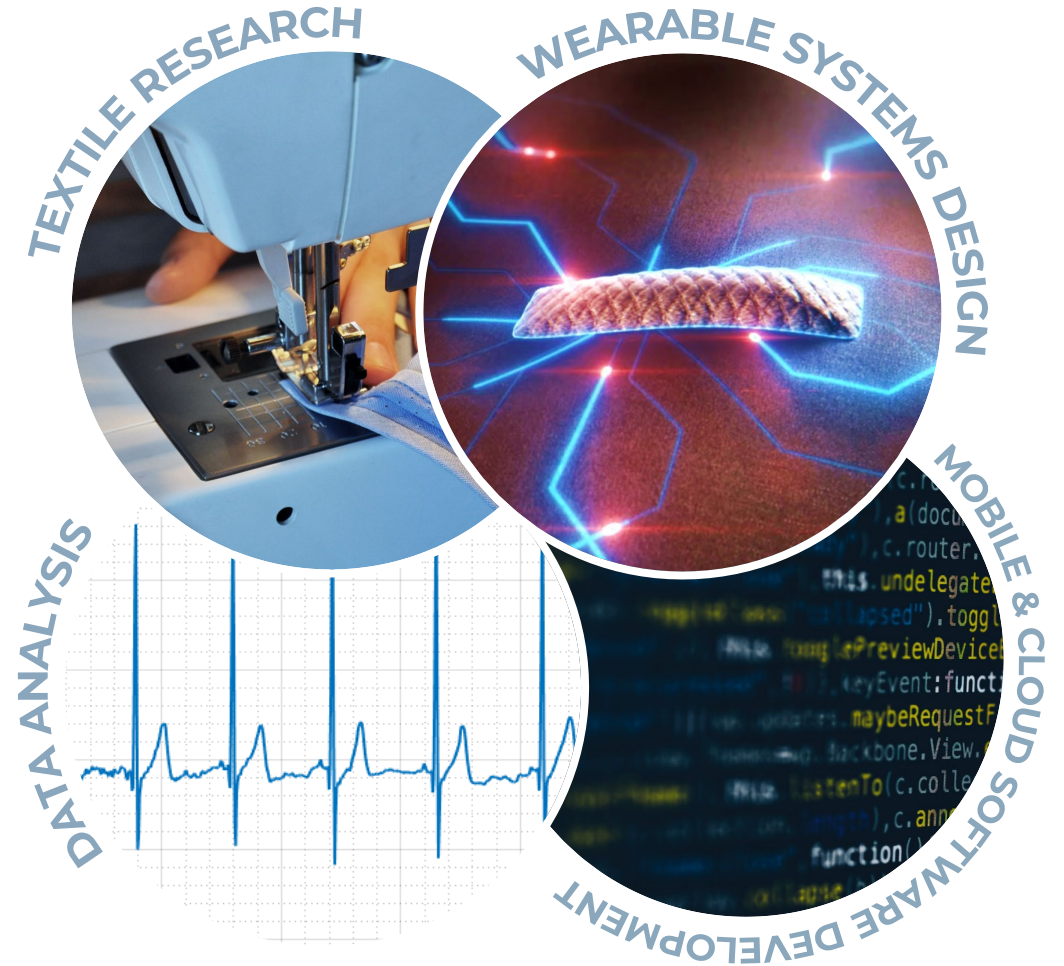
ComfTech
registered
8 international patents

Our team

ComfTech team **oversees** and **manages** every aspect of the product we bring to market **in-house**.

Skills

- Algorithms development
- Data analysis
- Mobile and Cloud software development
- Signal optimization
- Textile research and prototyping
- Wearable systems design



Textile sensors



Patented
Intellectual
Property

ComfTech textile sensors are patented, safe, and efficient:

- **HIGH SIGNAL QUALITY**
- **SOFT AND FLEXIBLE**
- **HYPOALLERGENIC**
- **COMFORTABLE**

- They do not hinder movement and do **not interfere** with activities.
- The sensors **do not need to be placed** on the body, as they are integrated into the garment.
- **They reduce the perception of medical devices**
- They enable **continuous, non-invasive monitoring**.
- They feature **tested** textile sensors and circuits.

Health data monitoring, from newborn to elderly



Neonatal & Paediatric



**Rehabilitation,
Geriatric, daily life**



Sport & Wellness

Wearable monitoring systems

HOWDY
baby



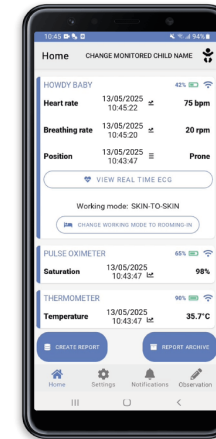
Electronic unit

+



Textile unit

+



Howdy Baby App



*From birth to
adolescence*

0-16yo

HOWDY
senior



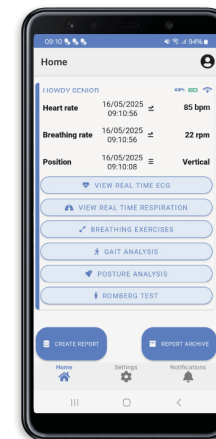
Electronic unit

+



Textile unit

+



Howdy Senior App

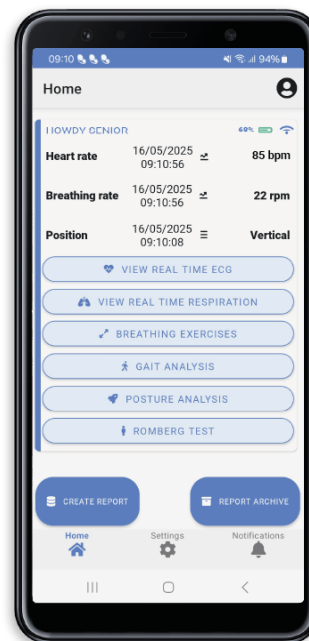


*From healthcare
to wellbeing*

>16yo

Howdy App

- **Real-time** parameters display and **exercises**
- Monitoring **report** generation
- Data sent to **Web App** for data consultation, both on the patient side and on the operator side
- Data sent to **Central Monitor** to real-time parameters display of different patients



App



Web App

Report

Howdy app - Report	
20/01/2023 12:23	
Paziente monitorato: Paziente	
Operatore: Operatore	
Inizio monitoraggio: 18/01/2023 12:19:00 Fine monitoraggio: 20/01/2023 12:22:54 Durata monitoraggio: 48 Ore 3 Minuti 54 s Dispositivo: HOWDY SENIOR (fw v. 2.0.58) (B4:DF:DA:45:D7:C8) Versione App: 1.1.0	Note:
Statistica Generale	
Howdy Senior (B4:DF:DA:45:D7:C8)	
QRS totali	23995
Frequenza cardiaca massima [bpm]	196 (19/01/2023 12:16)
Frequenza cardiaca minima [bpm]	35 (18/01/2023 23:46)
Frequenza cardiaca media [bpm]	52
Battiti sottosoglia (FC < 30 bpm)	0
Battiti sopra soglia (FC > 120 bpm)	22
Valori non validi *	9866
Atti respiratori totali	15591
Frequenza respiratoria massima [rpm]	49 (18/01/2023 19:08)
Frequenza respiratoria minima [rpm]	0 (18/01/2023 19:36)
Frequenza respiratoria media [rpm]	25
Respiri sottosoglia (FR < 4 rpm)	80
Respiri sopra soglia (FR > 50 rpm)	0
Valori non validi **	0
Tempo in pos. supina [h:m:s]	06:22:39 - 32.8 % del tempo totale
Tempo in pos. prona [h:m:s]	00:18:36 - 1.6 % del tempo totale
Tempo in pos. verticale [h:m:s]	10:19:29 - 53.2 % del tempo totale
Tempo in pos. capovolta [h:m:s]	00:05:26 - 0.5 % del tempo totale
Tempo in pos. lato destro [h:m:s]	02:17:22 - 11.8 % del tempo totale
Tempo in pos. lato sinistro [h:m:s]	00:01:21 - 0.1 % del tempo totale
Cambio di Posizione totali	70

* I valori disturbati della frequenza cardiaca si riferiscono a quei valori che si discostano significativamente dal valore medio dell'intervallo. Sono principalmente riscontrabili a battiti elevati in condizioni di angustia nervosa.
 ** I valori disturbati del respiro si riferiscono ad atti respiratori la cui ampiezza è inferiore ad una soglia predefinita. Sono principalmente riscontrabili ad atti respiratori registrati mentre il soggetto parla.

Central Monitor



HOWDY
baby

Wearable monitoring system for newborns, infants and children

Newborn safety

Support for healthcare personnel

Peace of mind for parents



HOWDY baby

Howdy Baby is a wearable device for **monitoring vital signs from the very first hours of life.**

It facilitates **safe Skin-to-Skin contact** and supports staff by enabling Zero Separation.

Howdy Baby easily integrates into care routines, allowing reliable and non-invasive monitoring, benefiting newborns, parents and healthcare professionals.

Howdy Baby can follow the patients **from birth to adolescence**, both in the **hospital** and at **home**.

The system allows for **multi-parameter monitoring**.



Heart Rate



Real-time ECG trace



Breathing Rate



Body position



Oxygen saturation *



Body temperature*





HOWDY baby

from Birth to Adolescence



Delivery Room and Wards

Skin-to-Skin Care, Rooming-in, Paediatrics



Continuous monitoring at home

Childhood and Adolescence



HOWDY

senior

Wearable monitoring system for adults

Daily monitoring
Motor rehabilitation
Breathing exercises



HOWDY senior

Howdy Senior is a wearable monitoring device for adults that **continuously and non-invasively detects cardiac, respiratory and motor parameters.**

Howdy Senior is a **safe and comfortable** product that allows monitoring without interfering with normal daily activities.



CARDIAC PARAMETERS

-  Heart Rate
-  Real-time ECG trace
-  HRV analysis

RESPIRATORY PARAMETERS

-  Breathing Rate
-  Respiratory trace
-  Biofeedback breathing exercises

MOTION PARAMETERS

-  Body position
-  Gait analysis
-  Postural analysis
Romberg test

INTEGRATED PARAMETERS

-  Oxygen saturation
-  Body temperature



HOWDY senior

From healthcare ...



Monitoring in the facility
Vital & motion parameters, Rehabilitation,
Biofeedback breathing exercises



Monitoring at home
Vital & motion parameters, Rehabilitation,
Biofeedback breathing exercises



HOWDY

senior

... to wellbeing



Wellness

**Vital & motion parameters, HRV analysis,
Rehabilitation, Biofeedback breathing exercises**



Performance

**Vital & motion parameters, HRV analysis,
Rehabilitation, Biofeedback breathing exercises**

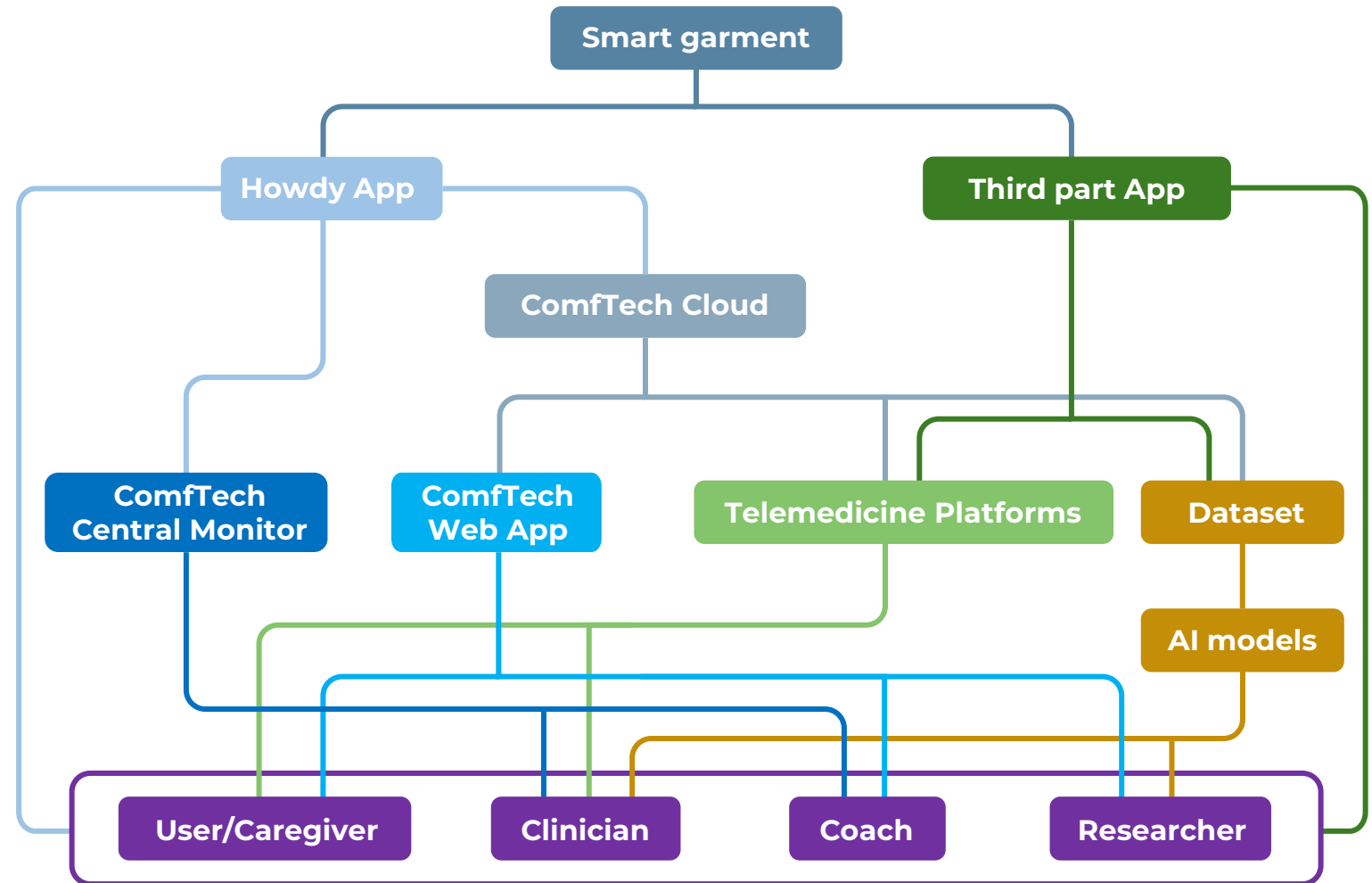


Flexible solution

Our products can be used:

- as a **self-standing solution**
- to **centralize** the data of **several patients** to facilitate monitoring and collecting data
- as a **link in the chain of e-health**, thanks to easy integration
- as **data sources** for **AI models**

These possibilities make our solution extremely **versatile and flexible**.





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 COMFTECH srl

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