

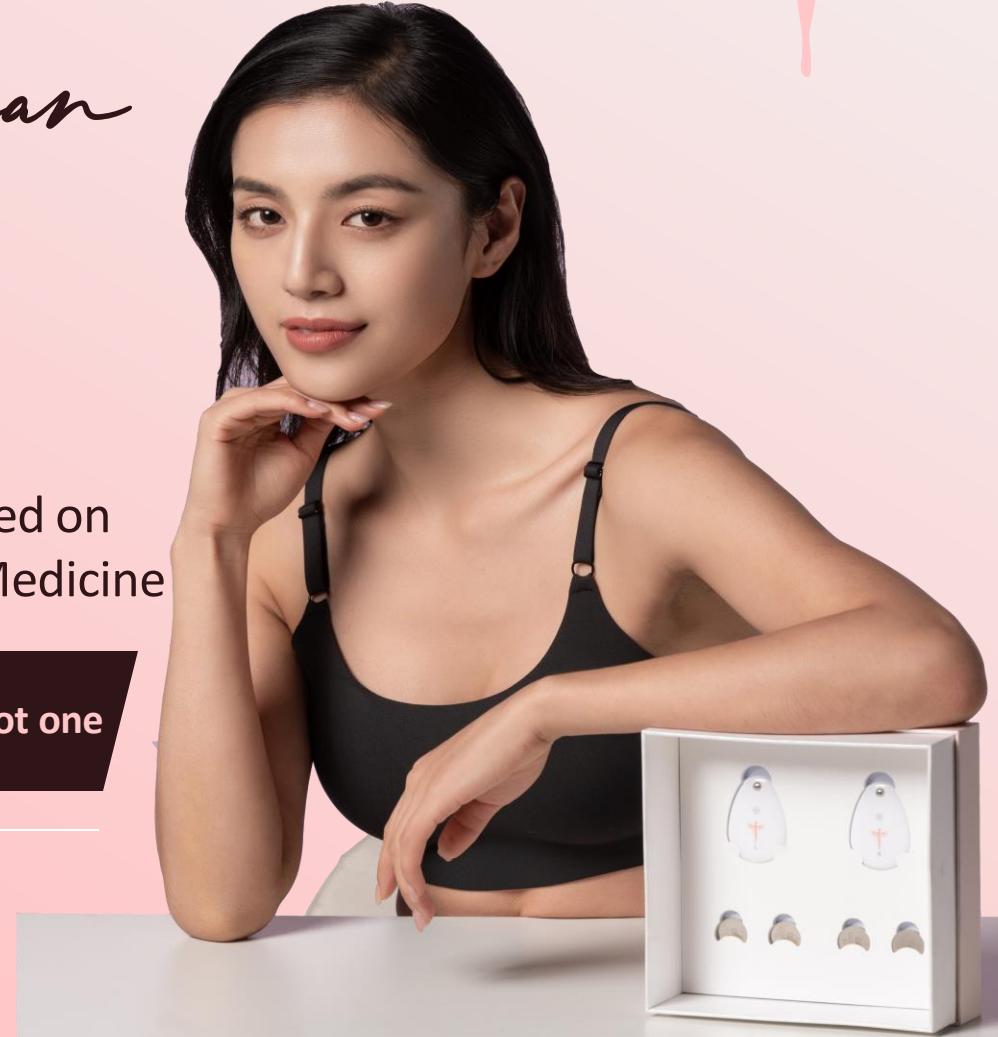
# Breast Guardian



Intelligent devices developed based on  
the Nobel Prize in Physiology or Medicine

All women who are health-conscious got one

*On March 8, 2021, the World Health Organization launched the  
"Global First Cancer - Breast Cancer Response Initiative"*



# New Technology for Breast Health Monitoring



Breast  
Guardian

Breast Holter  
intelligent early  
warning system



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# 「 Introduction 」

## The Global Status of Female Breast Cancer

## International Agency for Research on Cancer



World Health  
Organization

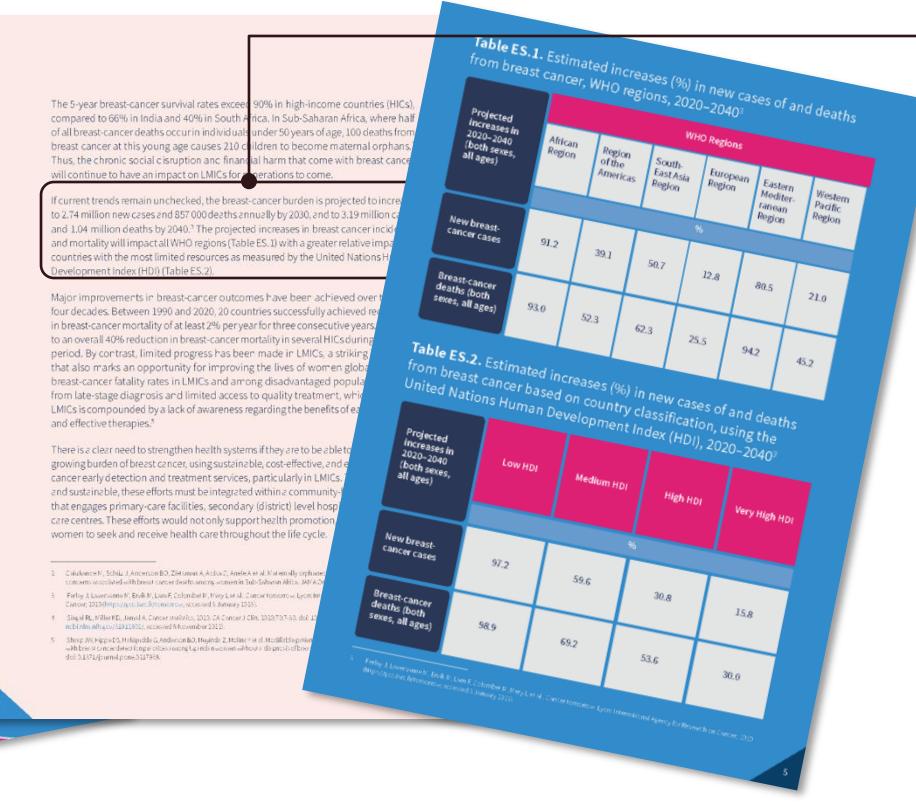
Breast Cancer is now the most commonly diagnosed cancer in women worldwide, and it is also the leading cause of cancer-related deaths among women<sup>1</sup>.

According to a research report released by the International Agency for Research on Cancer (IARC), a part of the World Health Organization (WHO), in 2022, during the year 2020, 2.3 million women were diagnosed with breast cancer globally, and 685,000 died from the disease. It has surpassed lung cancer to become the leading cancer globally<sup>1</sup>.

### Reference:

1. International Agency for Research on Cancer (IARC) November 21, 2022 News : Guida F, Kidman R, Ferlay J, Schüz J, Soerjomataram I, Kithaka B, et al.

Link: <https://www.iarc.who.int/news-events/global-and-regional-estimates-of-maternal-orphans-attributed-to-cancer-mortality-in-2020/>



The global trend of breast cancer is growing rapidly.

If current trends remain unchecked, the breast-cancer burden is projected to increase to 2.74 million new cases and 857 000 deaths annually by 2030, and to 3.19 million cases and 1.04 million deaths by 2040<sup>2</sup>.



Global breast cancer initiative implementation framework: assessing, strengthening and scaling up of services for the early detection and management of breast cancer: executive summary - 2023

## Reference:

2. Ferlay J, Laversanne M, Ervik M, Lam F, Colombet M, Mery L et al.. Cancer tomorrow. Lyon: International Agency for Research on Cancer; 2020  
 Link: (<https://gco.iarc.fr/tomorrow>, accessed 3 January 2023).

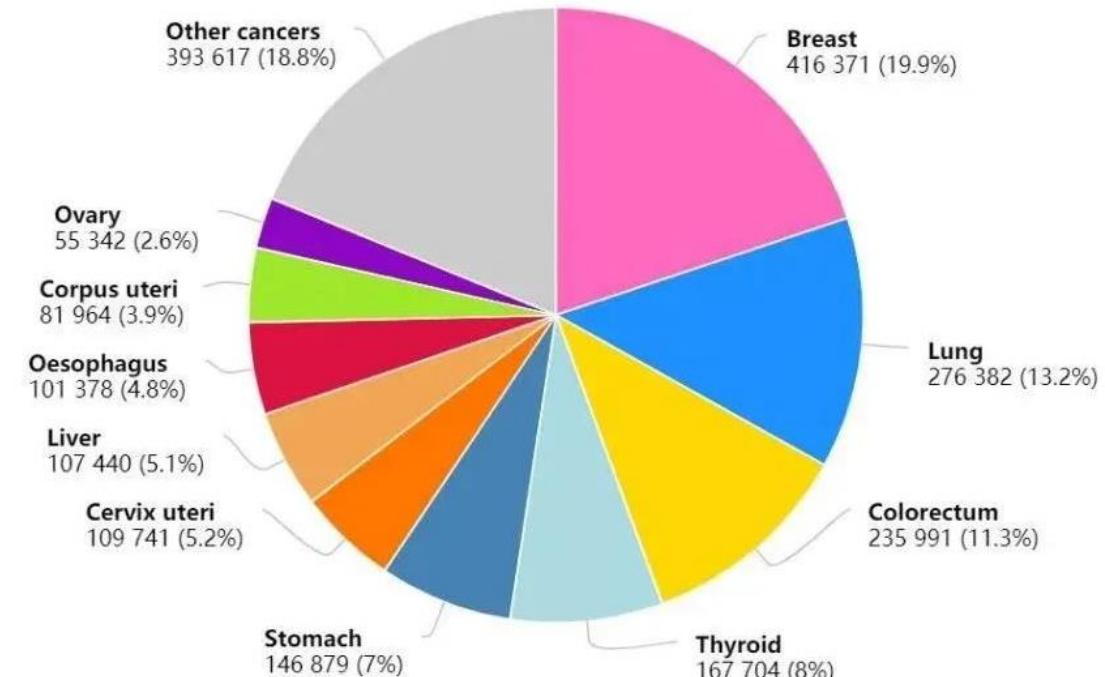
## National Cancer Center of China : National Cancer Report 2022

Top ten incidence of new cancer cases in Chinese women in 2020

乳腺癌 Breast Cancer	42 0000
肺癌 Lung Cancer	28 0000
结直肠癌 Colorectal Cancer	24 0000
甲状腺癌 Thyroid Cancer	17 0000
胃癌 Stomach Cancer	15 0000
宫颈癌 Cervical Cancer	11 0000
肝癌 Liver Cancer	11 0000
食管癌 Esophageal Cancer	10 0000
子宫内膜癌 Endometrial Cancer	8 0000
卵巢癌 Ovarian Cancer	6 0000
These ten types of cancer account for the incidence of new cancer cases in women	81%

The overall crude incidence rate of cancer in China continues to rise, reflecting a heavy burden of cancer in the country. The leading cancer for men is lung cancer, while for women it is **breast cancer**. The incidence rate is higher in urban areas than in rural areas.

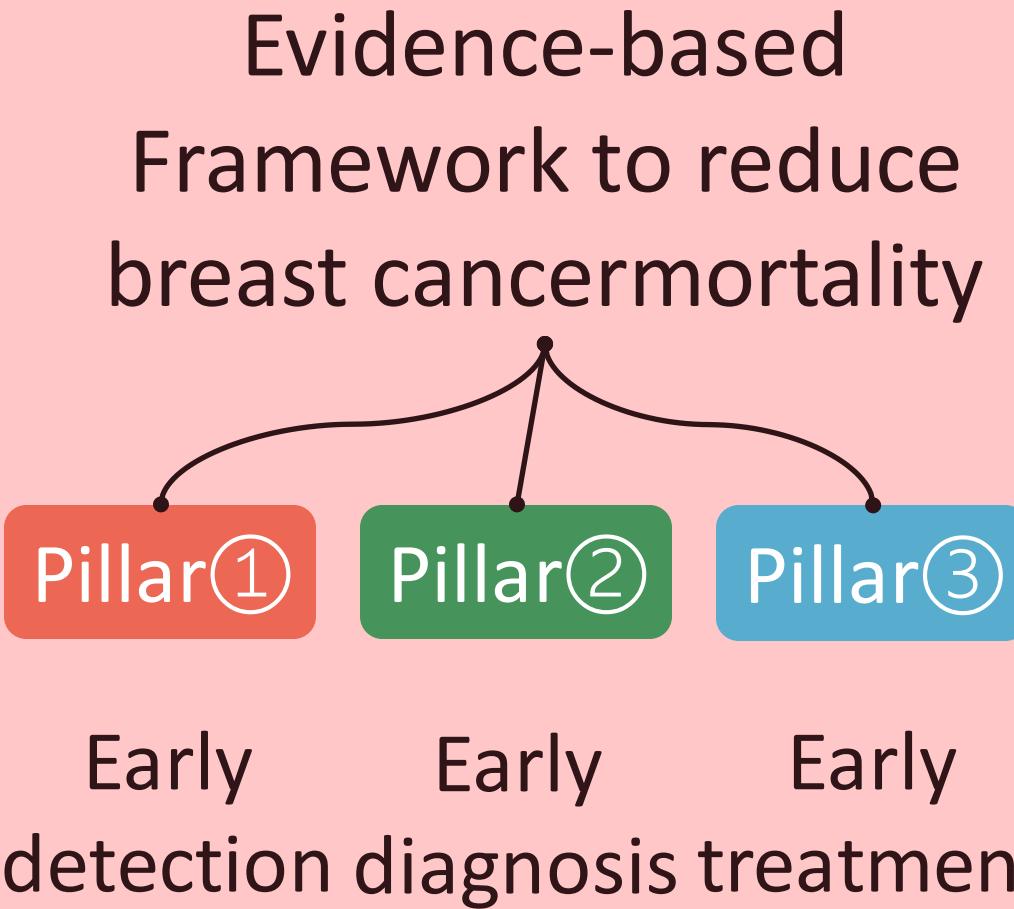
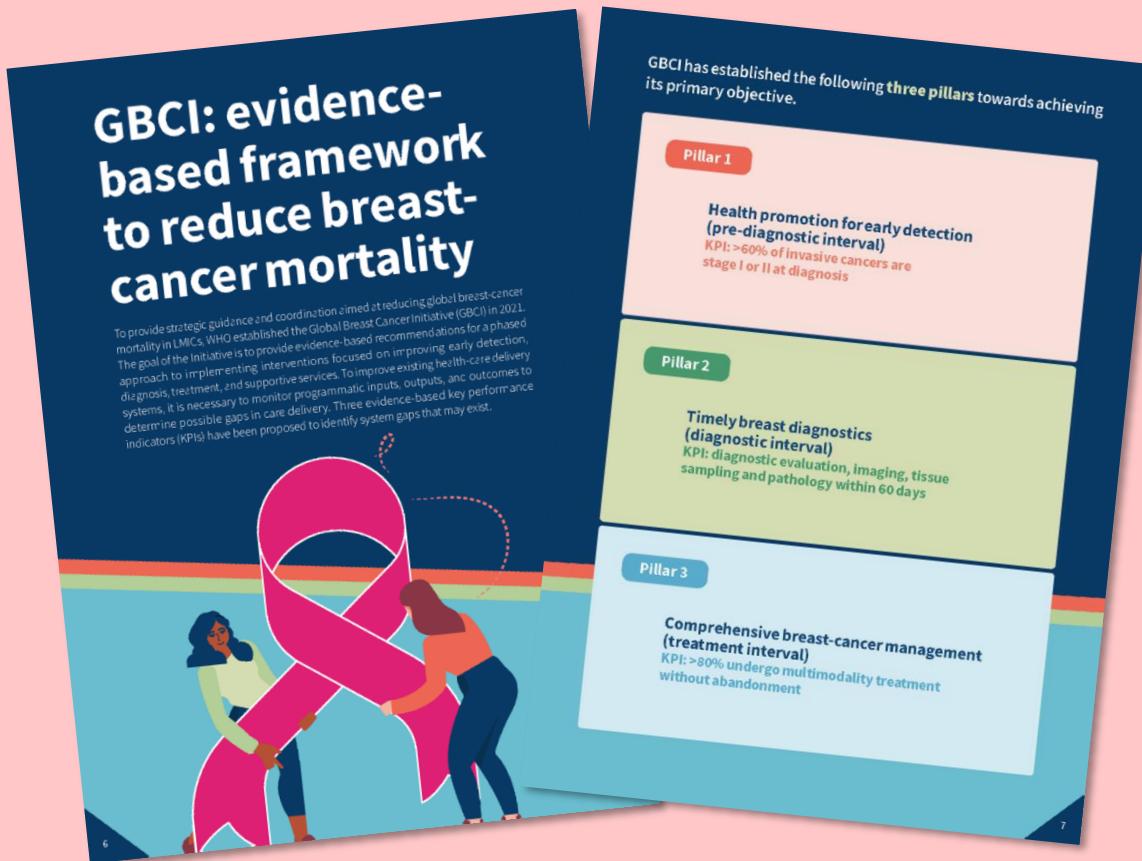
The crude mortality rate of cancer in China is also on the rise, but after adjusting for the age structure of the population, the standardized mortality rate shows a decreasing trend, reflecting the initial success of comprehensive cancer prevention and control in China in recent years; *Source: Cancer incidence and mortality in China, 2016 / Published in February 2022*



**In Chinese women, the incidence of new cases of breast cancer has surpassed lung cancer, taking the top spot.**

# 「Analysis of Market Demand」

Challenges in breast cancer detection and prevention

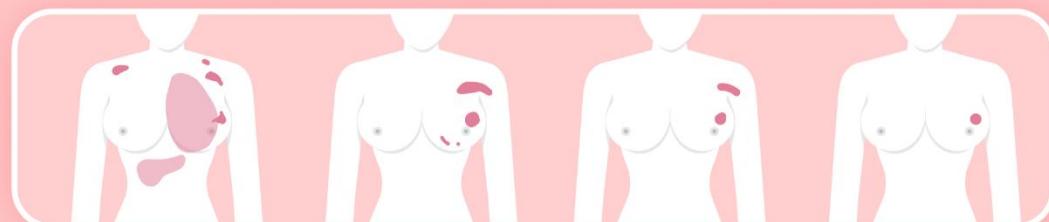
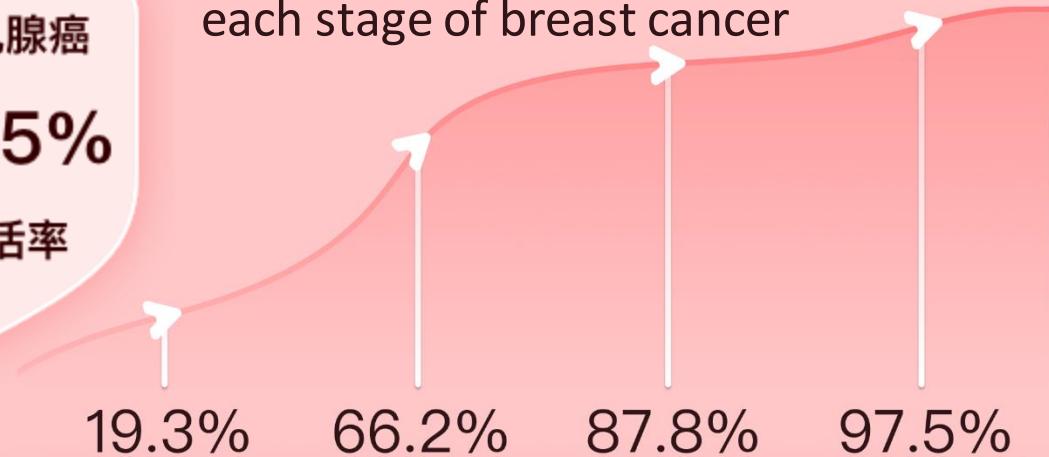


Global breast cancer initiative implementation framework: assessing, strengthening and scaling up of services for the early detection and management of breast cancer: executive summary – 2023 P6-P7



Therefore, countries need to focus on breast-cancer early-detection programmes so that at least 60% of breast cancers are diagnosed and treated early in their progression (stages I or II), when treatment is most effective, best tolerated and least costly.

## The five-year survival rates for each stage of breast cancer



World Health Organization

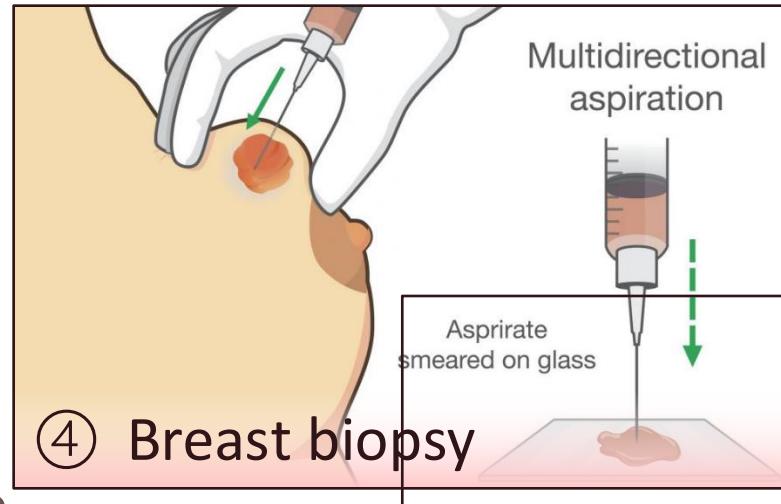
Global breast cancer initiative implementation framework:  
assessing, strengthening and scaling up of services for  
the early detection and management of breast cancer:  
executive summary – 2023 P8



## Breast Cancer Screening

Breast-cancer screening (an alternate early detection programmatic strategy in which women in a target age group without recognized signs or symptoms of breast cancer are invited to undergo testing yearly or every other year) may be an aspirational goal once health-system prerequisites have been established.

WHO advocates annual check-ups  
(minimum target)



The four tests are performed in medical institutions

①②③ are all imaging techniques that require the development of nodular tissue or cancerous changes to be captured by the imaging equipment.

## *The shortcomings of medical institution testing scenarios*

- ① Passive screening
- ② High time and cost of testing
- ③ Unequal distribution of medical resources

## *The difficulties of individual female self-testing*

- ① High work pressure
- ② Lack of self-awareness
- ③ Inconvenient access to medical services

~~Early  
Detection~~



National Institutes of Health  
*Turning Discovery Into Health*

# Early Detection

According to the National Institutes of Health (NIH) report,  
**50%** of breast cancer cases **double in size** within **25** days.



Hospital examinations can only detect 5.2% of patients, and 82.1% of patients are diagnosed only after seeking medical attention due to obvious abnormal symptoms, but by this time, most are already in the middle or late stages, greatly reducing the survival rate.

Regular hospital check-ups can detect breast cancer patients

5.2%

Those who actively seek medical attention due to obvious discomfort are the ones who are diagnosed with breast cancer

82.1%

*This makes the traditional annual physical examination insufficient, inevitably leading to a "window period."*

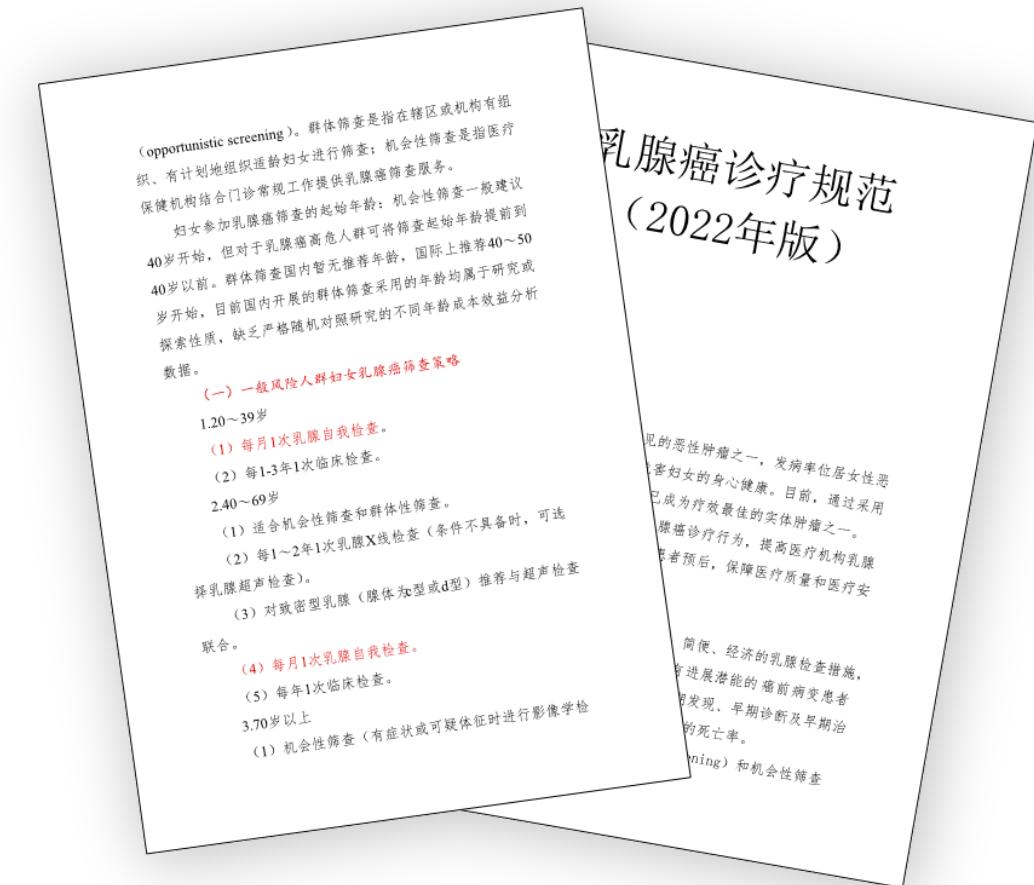
# Breast self-examination

Can help detect and combat breast cancer early  
Home breast self-examination is a simple  
and convenient method for breast cancer  
screening.

The National Health Commission of China  
advocates that women over 20 years of  
age with general risk should 「 perform  
breast self-examination once a month\* 」  
in order to detect and treat breast cancer  
early and reduce mortality.

\* National Health Commission. (2022). "Breast Cancer Diagnosis and Treatment Guidelines (2022 Edition)".

China: National Health Commission of the People's Republic of China.



《 Breast Cancer Diagnosis and Treatment Guidelines (2022 Edition) 》

「 Product Info 」

Bio-Rhythm Group -

New Breast Self-Examination Solution

The key to preventing and treating breast cancer lies in one word: 「early」

By adopting new technologies and tools, we can monitor our breast health at home at any time and show genuine care to ourselves and the women around us.

「Early detection」  
At home



「Early diagnosis」  
「Early treatment」  
At the hospital

Women need a scientific and home-based self-breast health monitoring tool to fill the gap between two physical examinations and to enhance the effectiveness of breast self-examination

## Data collection



## Algorithm analysis



Cloud-based database  
and data analysis system

- The user wears the device continuously for 8 hours.
- The device continuously collects data and transmits it to the mobile app via Bluetooth. The app displays real-time rhythm charts

## Report analysis



- The user's phone sends data to the cloud-based database via WiFi
- After preliminary processing, the data will undergo various analyses and comparisons, and a detection report will be generated
- The report is sent to the user's client and displayed in the app, providing risk level prompts
- Early breast feature data analysis and reporting results

## Continuous follow-up



- Professional customer service, continuously following up on customer usage and experience

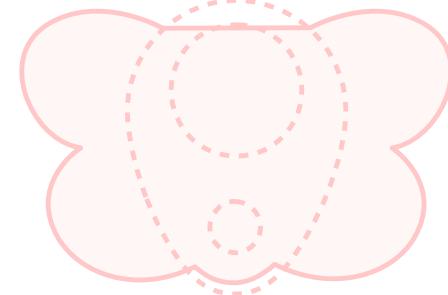


- Health consultant, answering customer questions online

**Filled the market gap for home (outside of the hospital) breast self-examination and supplemented imaging tests**



Breast Guardian  
乳房溫度持續監測儀



Use tape to correctly attach the devices labeled "L" and "R" to the breasts as shown in the picture, ensuring that the sensors' metal probes are directly adhered to the skin



Insert the testing devices labeled with "L" and "R" into the corresponding compartments on the left and right sides of the bra, ensuring that the sensors' metal probes are exposed and directly adhere to the skin of the breasts to ensure good contact. Once the bra is worn, the monitoring can begin.



Customized bras



Medical tape

# 產品資質

## PRODUCTS QUALIFICATION

Class II medical device registered with the NMPA

Obtained testing report from Shanghai Medical Device Testing Institute

Complies with EU electronic product safety certification (CE)



专利类型	申请号	名称
发明	201410644411.4	一种连续体温检测同期对比算法
外观	US29549586	Tumor_Cell_Thermometer(肿瘤细胞温度计)
发明	201510260991.1	一种体温曲线的去燥方法及去燥系统
发明	201510260995.X	一种体温预警3D模型及其使用方法
发明	201510290980.8	一种乳腺癌预警系统
发明	201510542383.X	一种温度传感装置及温度传感内衣
发明	201510757081.4	基于人体体温建模的健康评估方法及专家系统
发明	201510979345.0	体表癌变区域的温度四维透视图的生成方法
发明	201510960794.0	基于体表温度场的癌变区域的精准测量及识别装置
发明	201610059511.X	基于肿瘤细胞异常的温湿度场模型的比对评估方法及装置
实用新型	201620280385.6	皮肤贴附式癌细胞异常温度探针
发明	201510289591.3	一种体温数据采集方法
发明	201510289553.8	一种体温检测及处理系统
发明	201510374003.6	一种体温监测筛查方法及系统
发明	201510466386.X	一种温度测量方法及装置

*The technical challenges of the "heat dissipation model" research on body surface temperature*

- 1、年龄因素：年龄越大体温变化会接近下限值
- 2、性别因素：成年女性的黄体酮有升高时对体温有影像。
- 3、昼夜因素：昼夜的节律性波动，与代谢、血液循环、肾上腺素分泌的周期性变化有关。
- 4、情绪因素：激动、紧张等可使交感神经兴奋，机体代谢率增高。
- 5、运动因素：运动时由于骨骼肌紧张产热超过散热量，导致体温一时性升高。
- 6、环境因素：环境温度的高低直接影响体表温度。
- 7、其他因素：睡眠、饮食影响等均可使体温变化。
- 8、药物治疗：影响体温的调定点（生活方式）
- 9、疾病因素：癌性发热、感染、发热待查患者
- 0、系统影响：活体热传导、组织内循环、免疫系统、代谢系统、内分泌系统 .....



第六屆（2023）  
中國醫療器械  
創新創業大賽



## The usage process of the 24-hour breast Holter monitoring product



Scan the QR code to log in to the mini program

Bind/connect the device

Wear the device properly to start the 24-hour monitoring task

After the monitoring is completed, open the mini program to upload the data

View the report for peace of mind after monthly check-ups

## Biological rhythms of cellular metabolism

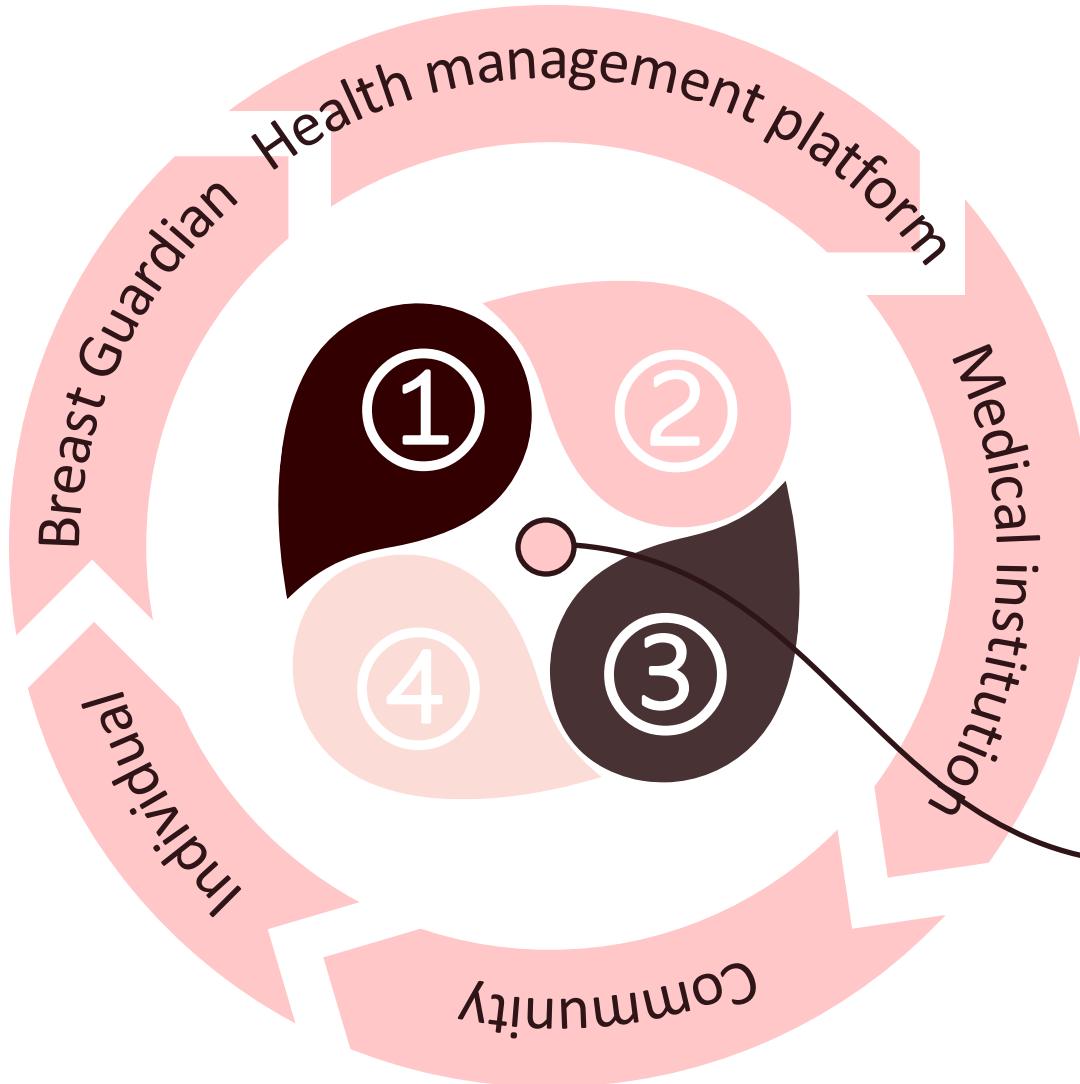
1. Multiple factors: **temperature + humidity**
2. High-precision intelligent sensors for continuous, dynamic monitoring: **rhythm characteristics**
3. AI big data model analysis can **quantitatively express** according to MRI grading

*Precisely mapping the biological rhythm chart to overcome the shortcomings of traditional metabolic heat observation*



# 「Integrated Medical Services」

How to integrate with hospitals, traditional Chinese medicine programs, and home visit services to form a closed-loop service



- I. Hospitals: earn treatment equipment fees and partial management fees by providing diagnosis and treatment services
- II. Health management platform: earn management fees and report fees by providing various health management services
- III. Community: sinking of medical resources / private doctors
- IV. Patients: enjoy convenient, high-quality health management services, and reduce medical costs
- V. Breast Guardian: achieve a win-win situation for all parties, promote the development and innovation of the medical industry

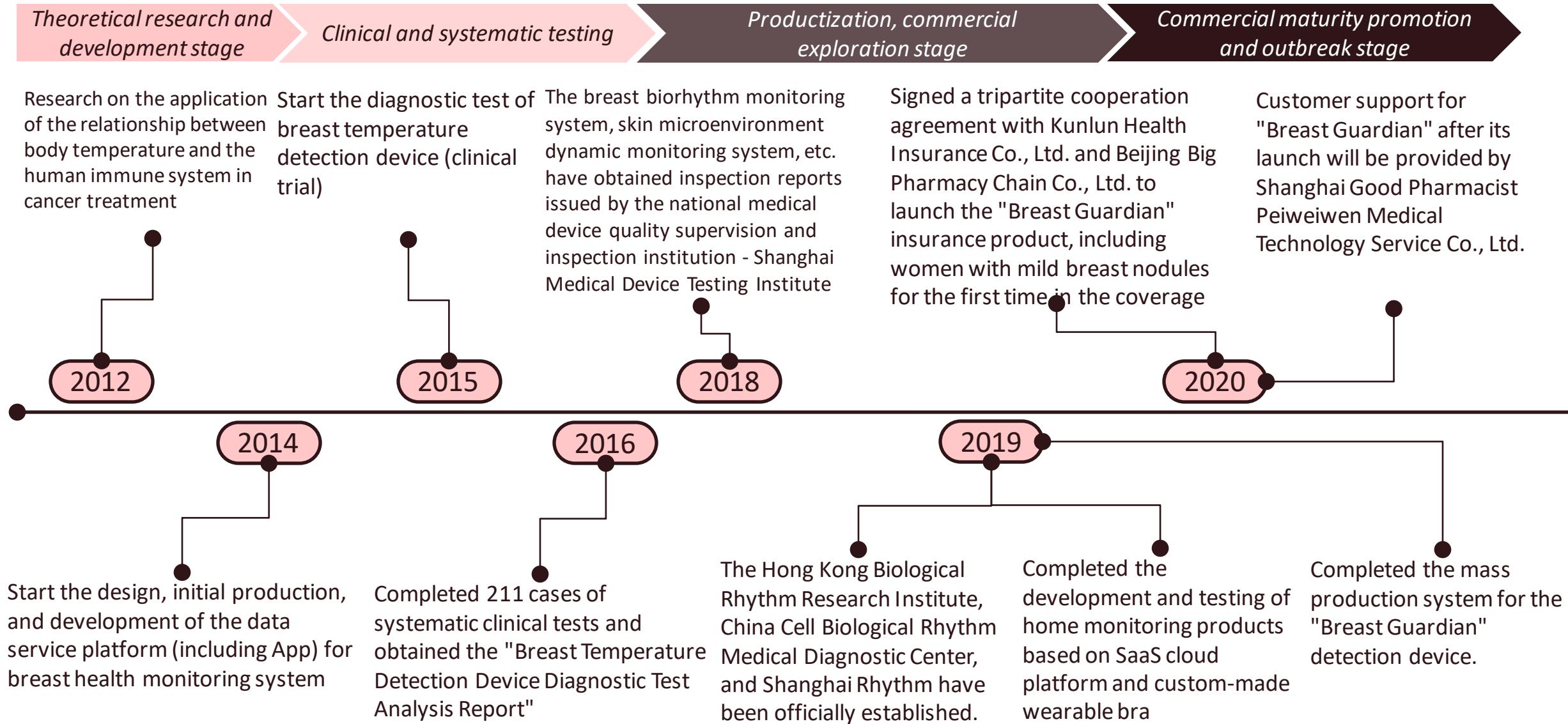
- ① Self-health testing products
- ② Hospital's green channel
- ③ Traditional Chinese medicine solutions
- ④ Medical home visit services

# 「About Corp」

## Background, Mission, Vision, and Core Values of Bio-Rhythm Group

HK Bio-Rhythm Research Institute Limited (China Cell Biological Rhythm Medical Diagnostic Center Limited) was established in 2019 and entered the Hong Kong Science Park in 2020. It is a leading home-based non-invasive cancer early screening biotechnology company. With the aim of "promoting early detection and reducing cancer mortality", we focus on the research and development of home-based disease early screening equipment and analysis systems.

Our vision is to become a practitioner and standard setter for non-invasive self-early screening, and our mission is to promote the transformation and upgrading of cancer home screening with a strong spirit of research and development. Our value is to cherish life and innovate with technology



*Commercial maturity promotion and outbreak stage*

*Business model replication, capital market listing, new product R&D*

Signed a memorandum of strategic cooperation with the Hong Kong University of Science and Technology

The strategic subsidiaries (Shenzhen BioRhythm, Hunan BioRhythm) have been established to collaborate on the registration of existing medical devices and medical software, as well as the development of new product

Obtained the registration certificate for Class II medical devices and software, as well as the medical device production license in the same year

2021

2021

Signed an agreement with Tiger Pharmaceuticals to initiate a new round of clinical trials for the breast biological detection device

Established the strategic mainland headquarters (Sanhao Rhythm Company), which is responsible for domestic capital financing, capital listing, and overall sales functions

2022

2023

2024 - 2027

A hopeful future can be expected



## Applicable scope

- The product is suitable for women between the ages of 20 and 70.
- The following conditions require the use of the product under the guidance of a doctor or customer service center:
  - ① Patients suspected of breast cancer and have undergone breast fluid cytology pathological examination.
  - ② Patients suspected of breast cancer and have undergone hollow needle biopsy (CNB).
  - ③ Patients who have received chemotherapy for breast diseases in the past.

