

Invitation to “Communities, People and Work Creation Conference” held at Prime Minister’s Office

Approval of super downsized mobile CTG (Petit CTG) as medical device

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### Introduction

On November 21, 2018, Ms. Ogata, CEO of Melody International Ltd. and I were invited to “Communities, People and Work Creation Conference” held at Prime Minister’s Office. We were given an opportunity to present ultra-small-sized mobile CTG called Petit CTG, its approval as medical device, and its global development at the conference. It was very honorable that we could directly speak with Prime Minister Abe about our development plan not only in Japan but also in ASEAN nations, African nations, South and Central American nations, and other parts of the world. We also took commemorative photos (Fig. 1).



(Fig.1) Commemorative photo with Prime Minister Abe at “Communities, People and Work Creation Conference” held at Prime Minister’s Office



(Fig.2) Commemorative photo with Mr. Suga, the Chief Cabinet Secretary and Ms. Ogata, CEO of Melody International Ltd.

This paper reports the purpose and direction of “Communities, People and Work Creation Conference”, which is one of the most important national policies that the national government is promoting. It also discusses how telemedicine, perinatal control, medical IT innovation especially on medical device development, and its global expansion draw particular attention.

1. What is “Communities, People and Work Creation Conference”?

“Communities, People and Work Creation Conference” is held by “Communities, People and Work Creation Conference Headquarter”. The headquarter was organized under the second Abe administration on Sep. 3, 2014, with aims to generate sustainable and autonomous society utilizing each region’s unique features. It addresses significant issues of rapid population decline and extreme aging society that Japan is currently facing and to tackle those problems with the entire government members united as one team. It is a legal organization directly established under the cabinet.

The conference was held 17 times between September 2014 and December 2018, and the results were presented as “Communities, People and Work Creation Conference comprehensive strategy” every year.

<https://www.kantei.go.jp/jp/singi/sousei/info/pdf/h30-06-15-kihonhousin2018hontai.pdf>

Its fundamental missions are as follow;

- (1) Overcoming population decline and revitalizing shrinking regional economy
- (2) Establishment of favorable circulation among communities, people and jobs
  - Creation of jobs
  - Creation of people
  - Creation of communities

In short, its main tasks are to halt population decline, correct population concentration in metropolitan area, secure work-life balance in regional areas, and to sustain energetic Japanese society for the future. In order for that to happen, the central government, regional municipalities, educational institutions such as university, and private companies should work together as one team to vitalize regional areas, nurture energetic companies and human resources, and secure worksites where young people can work with hope and provide places for them to safely give birth and raise children.

For the above purposes, basic policies for revitalization of regional areas were settled as follows.

- (1) Fulfillment and reinforcement of regional area for each stage of life
- (2) Implementation of “Realization policy of exciting life in regional area”
  - Fundamental reinforcement measures to promote transferring young people to regional areas
  - Finding new manpower through active participation of females and elderly
  - Utilization of foreign labor force in regional areas
  - Effective and strategic advertisement to draw people’s attention

The followings are listed as particularly important policies.

- Reinforcing competitiveness of regional industry (cross-industrial measures)
- Creation of environment to promote start-ups by females
- Promotion of start-up companies’ entry into public sector projects
- Bringing in foreign and exterior demands into regional areas for revitalization of regional economy
- Supporting top companies/top global companies in niche industry by public offices’ cooperation
- Formulating regional comprehensive strategy policy for each municipality

Kagawa Prefecture already established “Kagawa Prefecture Industry Growth Strategy” in 2013, one year prior to national “Communities, People and Work Creation Comprehensive Strategy”. Later, “Kagawa Prefecture Industry Growth Strategy” was

revised to be “Kagawa Generation Comprehensive Strategy” as Kagawa Prefecture version of regional comprehensive strategy.

[https://www.pref.kagawa.lg.jp/content/etc/web/upfiles/wsb3bt151030115001\\_f03.pdf](https://www.pref.kagawa.lg.jp/content/etc/web/upfiles/wsb3bt151030115001_f03.pdf)

The followings are the list of specific measures of “Kagawa Prefecture Industry Growth Strategy” and “Kagawa Generation Comprehensive Strategy.”

- 1) Growth/accumulation of growing industry
  - Promotion of manufacturing project “Studying the past to learn new things”
  - Promotion of “Kagawa rare sugar white valley” project
  - Promotion of olive industry reinforcement project
  - Promotion of K-MIX related industry development project
  - Promotion of attractive agricultural and fishery products into sixth industry
- 2) Support companies with unique features and reinforce their competitiveness
  - Accelerating promotion of start-ups and secondary business
  - Reinforcement of R&D/fundamental technology
  - Support companies for overseas development
  - Development and securing human resources to support industry development
  - Reinforcement of enterprise location and industry foundation

National government’s “Communities, People, Work Creation Comprehensive Strategy” stated the following three.

- Finding new manpower through active participation of females and elderly
- Promotion of start-up companies’ entry into public sector projects
- Bringing in foreign and exterior demands into regional areas for revitalization of regional economy

“Kagawa Prefecture Industry Growth Strategy” and “Kagawa Generation Comprehensive Strategy” stated the followings.

- Promotion of K-MIX related industry development project
- Support companies for overseas development

The above items of national policies match with our long-term work of the followings.

- Development of ultra-small-sized mobile CTG (Petit CTG)
- Approval as university originated start-up company
- Approval as a medical device
- Our oversea projects in Thailand, Laos, Myanmar, South Africa supported by Ministry of Internal Affairs and Communication (MIC), Ministry of Economy,

Trade and Industry (METI), and Japan International Cooperation Agency (JICA.)

Therefore, it is considered that we were given an opportunity to present our work in “Communities, People and Work Creation Conference”.



(Fig.3) “Kagawa Prefecture Industry Growth Strategy”

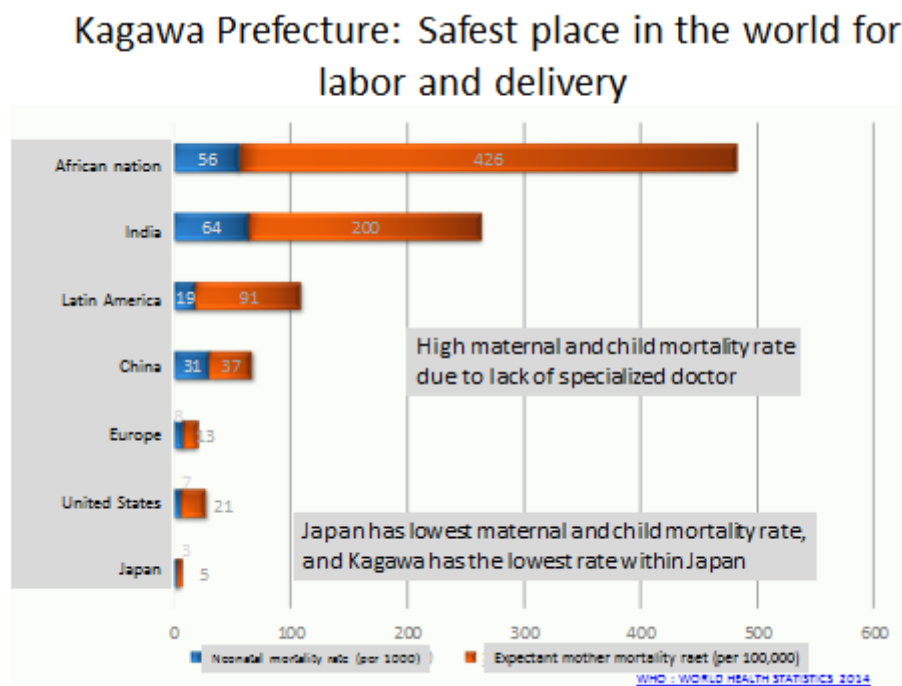
To promote K-MIX related industry growth project, the followings are clearly described.

2. Spreading the wonderful Japanese prenatal (fetus/neonate) management to developing nations

As I already reported in the past article (December 2014 and January 2017), we have been working on development of fetal monitor known as cardiotocomonitor for over 40 years. Our fetal heart rate detecting method is incorporated in the most fetal monitor currently used in the world. Fetal monitor is used for most pregnancy and delivery management in developed nations, and prenatal mortality rate declined significantly. Especially, Japan has the lowest prenatal mortality rate in the world. (Reference 1 and 2)

On the other hand, prenatal mortality rates in ASEAN nations, African and South American nations are several ten times higher than that of Japan. Therefore, prenatal medical situation in those nations needed immediate attention. (Fig.4)

Prenatal medical issues in those developing nations are due to insufficient number of foundation and core hospital to implement prenatal care. In addition to that, obstetrician/gynecologist and midwife are significantly insufficient, making it difficult to systematically and continuously manage pregnancy, delivery and newborn infants.



(Fig.4) Kagawa Prefecture, the safest place for pregnant women in the world  
Prenatal mortality rate in Japan is the lowest in the world. Kagawa has the lowest rate in Japan.

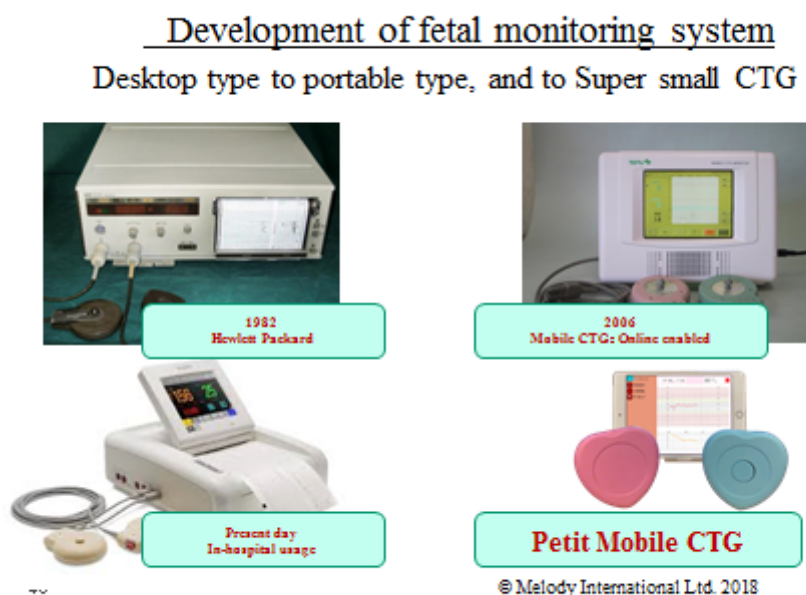
Prime Minister Abe visited all the ASEAN nations and strengthened supports for them. Support for medical field is especially emphasized, and various projects such as hospital construction and medical device implementation by official development aid (ODA) and JICA fund were implemented.

Kagawa Prefecture and Kagawa University also worked on prenatal projects using mobile CTG in Thailand, Laos, Myanmar, Indonesia, and South Africa with supports from Asia-Pacific Telecommunity (APT) of MIC and JICA. It has been very successful, yielding many positive results. (Reference 3-6)

As seen above, our overseas prenatal projects were highly evaluated, but demands for further light-weighted and downsized mobile CTG were very high.

### 3. The history of ultra-small sized mobile CTG development

As mentioned previously, fetal monitor was developed in 1970s. However, equipment was quite large and heavy back then, weighing over 10 kg. Therefore, it was unavoidable for it to become a stationary type installed in hospitals. It was also extremely expensive. (Fig. 5)



(Fig. 5) History of fetal monitor development

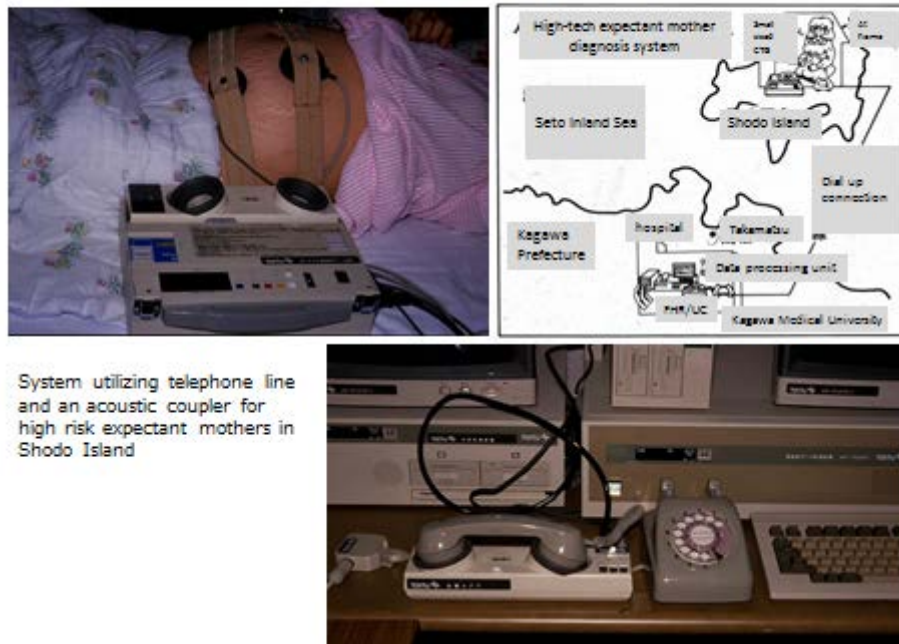
Large-sized installed type CTG to mobile CTG, and to super downsized Petit CTG

Nearly fifty years passed since then, and fetal monitor was gradually improved. Main unit was downsized, and connection between main unit and two probes, ultrasound transducer and uterine contraction monitor, became wireless. Pregnant women can now move around in hospital with transducer attached on their body.

By connecting the equipment to central monitor, it is now possible to monitor multiple pregnant women simultaneously. Recently, fetal heart rate pattern can be sent to physicians through internet. However, the equipment is still installed and used only in the hospital.

Therefore, mobile fetal monitors which can be used at home drew attention. We have been working on mobile CTG development for over twenty years since 1990s. In 1990s, we used system with telephone line and acoustic coupler for high risk pregnant women in Shodo Island. (Fig 6) Later, we used ISDN and modem for PC network. Following that, we developed downsized portable system (weight: 2.0 kg) in response to popularization of internet, cellphone and smartphone. With this device,

pregnant women and physicians can monitor fetal heart rate in or outside of hospitals.  
(Fig.7) (Reference 7-11)



(Fig.6) Fetal monitor at home at the initial stage of development  
It was prohibited to transmit digital signal on telephone line then, and acoustic coupler was used to transmit fetal heart rate.

## Development Mobile CTG



(Fig.7) Mobile fetal monitor at home (mobile CTG) development  
Cellular network has spread nationwide, enabling development of mobile CTG.



As for transmission of fetal heart rate, data standardization is important. Therefore, The Japan Association of Obstetricians and Gynecologists specified the data format for fetal heart rate information file (1999). (Reference 12)

<http://www.jaog.or.jp/sep2012/JAPANESE/jigyo/JOUHOU/H10/shinpaku.htm>

#### 4. The developmental concept of super downsized CTG (Petit CTG)

As for development of super downsized CTG (Petit CTG), we designed it based on totally new concepts without adherence to conventional technology.

- 1) It is to be portable and operates on Cloud, and fetal heart rate can be transmitted from anywhere both domestically and internationally.
- 2) Fetal heart rate is to be recorded on a server of data center.
- 3) Complete paperless is to be realized. No recording paper is used.
- 4) Electrical circuit of fetal heart monitor is to be downsized and mounted in the case of ultrasound transducer and contraction transducer.
- 5) Commercial tablets are to be used for display of fetal heart rate and uterine contraction, and internet connection.
- 6) Tablet's Bluetooth connection is to be used between ultrasound transducer and contraction transducer.
- 7) Li-ion battery is to be used as a power source, enabling cable-free usage. (This allows it to be used in developing countries where power supply is unstable.)

Of these goals, the most challenging technological obstacle was downsizing and integrating the electronic circuit (circuit for emitting and receiving ultrasound wave, and circuit for detecting fetal heart rate, hence analog circuit and digital circuit), and putting them into small transducer casing.

#### 5. Establishing "Melody International Ltd.," Kagawa University originated Start-up Company

It tends to be difficult for existing enterprises to develop medical equipment based on a totally new concept due to high risks they need to take. Therefore, we established a start-up company called "Melody International Ltd." whose president is Ms. Yuko Ogata, in partnership with Kagawa University (July, 2015). From Kagawa University, visiting professor Yasuto Takeuchi and I became advisers of the company. By the way, professor Takeuchi and I are the founders of the basic principle of fetal heart monitor (1974), which is now universal standard.

The basic policy of establishment of "Melody International Ltd." was in line

with “Kagawa Industrial Growth Strategy.” The goal was to conduct everything from designing to manufacturing in Kagawa prefecture, where the perinatal mortality rate is the lowest in Japan and the world, and appeal the device as “Made in Kagawa” brand in the world.

University-launched startup company  
“Melody International Ltd.”

## Team Member

NEXT Kagawa Radiowave Darkroom

Received quick Medical Device approval by utilizing in-facility world standard radiowave darkroom

(Fig.8) “Melody International Ltd.”, a venture company originated in Kagawa University

From Kagawa University, visiting professor Yasuto Takeuchi and I took office as advisers of the company.

Launching business enterprise required a large amount of fund for research and development. Fortunately, we were able to obtain following subsidies to cover such costs.

- “Subsidy for creating fields to accelerate growth” from Kagawa prefecture
- “ICT innovation creation challenge program (I-Challenge!)” from MIC
- “Tobidase-Japan! Subsidy for development in growing markets in the world” from METI

Thanks to the subsidies above, on May 2018, we obtained an approval for production and distribution for medical equipment “Petit CTG,” and were officially approved as Kagawa University-originated Startup Company (Fig.9)



(Fig.9) Approved as a start-up company originated in Kagawa University  
Commemorative picture with dean of Kagawa University

It is generally said that rural start up enterprises have difficulty obtaining such approval for medical devices, but Melody International Ltd. was able to obtain it only 2 years and 10 months after its establishment. We are grateful for the entire concerned individual's support in making this possible. It was also fortunate that the building complex which Melody International Ltd. moved into (NEXT Kagawa, Kagawa Industry Support Foundation) had its own radiowave darkroom, an essential facility in confirming medical device's safety.

#### 6. Configuration of Petit CTG and actual usage

The official name of Petit CTG is Mobile Cardiotocomonitor “iCTG”, and it comprises of an ultrasound transducer for detecting fetal heart rate, transducer for detecting uterine contraction, data displaying tablet, and controlling software. Controlling software is to be installed into the tablet (windows 10 device, iOS device). The transducers and the tablet transfer data via Bluetooth. The data transferred to the tablet is transmitted to the internet through WiFi at medical institution or home, or 4G (LTE) mobile network system.

Back in the 70s, cardiotocomonitor weighed more than 15kg (including carrying cart), but our Petit CTG system weighs only 300g (weight of 2 transducers). That is up to 1/40~1/50 downsizing.

As for actual use of the device, heart-shaped ultrasound transducer is placed on the abdomen of a pregnant woman. Stabilize it once you found an optimal location for detecting fetal heart sound. This makes it easier to extract fetal heart rate. The transducer itself only weighs like an average smartphone and it is complete cable-free, enabling expectant mothers to easily move around. (fig.10)



(Fig. 10) Further downsizing was enabled. Petit CTG

Ultrasound transducer is placed on the abdomen of a pregnant woman to search for a spot where fetal heart rate can be heard. Significantly easy detection of fetal heart rate change is enabled.

If you are connected to an internet, not only you can use it in medical facilities and at home, but also within vehicles, trains, and inside an ambulance for emergency transfer. Oversea tests have been done already in ASEAN countries like Thailand and Indonesia, and also in African nations like South Africa and Zambia. Basically, as long as you are connected to an internet, you can use this system from anywhere in the world.

7. Achieving complete paperless cloud system, suitable for an era of electronic medical record

An electronic medical record system is quickly adopted in today's medical field, making a shift towards paperless environment. Another recent trend is to accept cloud server instead of placing data server within a medical facility.

Traditionally, cardiotocomonitor required recording paper, and recent devices still have built in instrument for recording paper. It takes a lot of space to keep and store past recording papers, becoming a burden for medical facilities. It was also time and energy consuming to find necessary fetal heart rate from a bundle of paper record.

Since its initial designing, Petit CTG aimed to get rid of paper recording and use cloud server to save and store information semi-permanently. This would decrease a burden of medical facilities to maintain physical storage space for recording paper, and enables easy referencing of past fetal heart records. It can be said that Petit CTG is one step ahead of trend of the era.

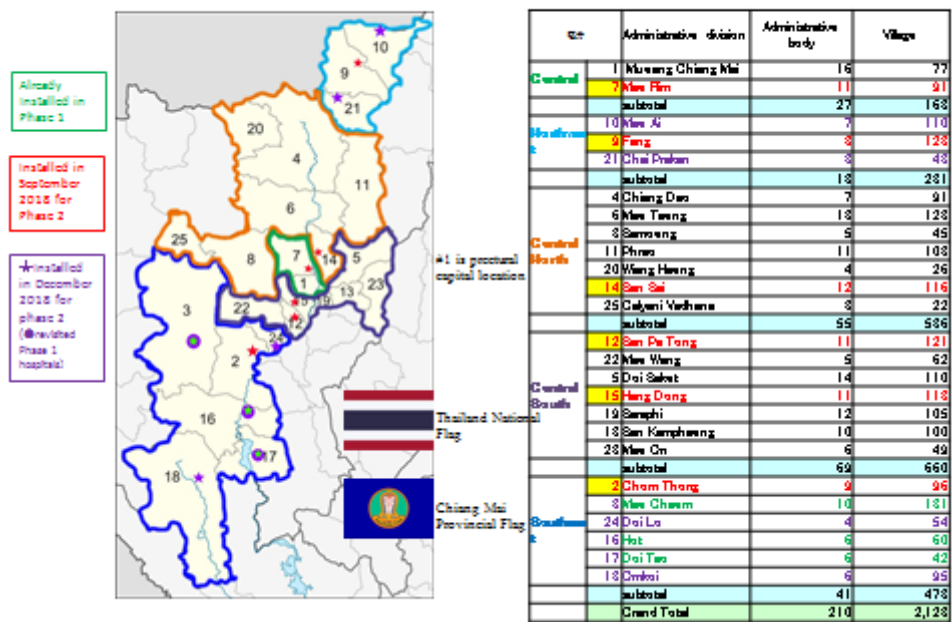
#### 8. The 2<sup>nd</sup> Phase “JICA Grassroot Technical Corporation Project” in Chiang Mai, Thailand and a research project in Myanmar

An overview of our oversea projects was mentioned in the previous article (January, 2017), and recently we newly working with Asia-Pacific Telecommunity (APT-CI, MIC) project in Kayin, Myanmar. The national government of Myanmar and Yangon First University of Medicine showed high interests in this project.

“A Collaboration Project for ICT Telemedicine for Perinatal Care and Diabetes in Thailand - JICA Grass roots Cooperation Project –“ in Chiang Mai, Thailand was particularly highly evaluated, and from this year, the second term (for 3 years) was approved. The scope is expanded from the region around Chiang Mai University (3 medical institutions) to the entire region of Chiang Mai Prefecture (25 medical institutions). It is a grand project to improve prenatal mortality rate.

Petit CTG is already introduced in 15 facilities and they are operating well. 10 remaining facilities (out of the total 25 facilities) will receive the device next year, and fruitful result is expected. (Fig.11)

### Phase 2 project's target is entire Chiang Mai Province



(Fig.11) The 2<sup>nd</sup> Phase “JICA Grassroot Technology Corporation Project” in Chiang Mai in Thailand

The scope is expanded from the region around Chiang Mai University (3 medical institutions) to the entire region of Chiang Mai Prefecture (25 medical institutions). Grand project to improve prenatal mortality rate has started.

### Conclusion

In the present article, purposes and concepts of “Communities, People and Work Creation Conference” which is promoted as the most important national policy was reported. An importance of innovation in telemedicine and medical device in related to the conference was also discussed. In such a social framework, we launched a university originated start-up company, and developed super downsized mobile CTG (Petit CTG) and gained approval as a medical device.

Outstanding features of Petit CTG are that it is Cloud-based, and usable in anywhere in the world if internet connection is available. It is technically possible to manage fetus in the whole world by Petit CTG in the future. In such case, the volume of CTG data will be significantly large, and it will be necessary to implement automatic diagnosis function by AI on a server. It will be an optimal model to collect medical big data.

Internet of Thing (IOT) is often mentioned recently. We would like to make Internet of Fetuses (IOF) into a reality in order to monitor fetuses in the entire world through internet network. (Fig.12) (Reference 13-16)



(Fig.12)

Internet of Thing (IOT) is often mentioned recently. We would like to make Internet of Fetuses (IOF) into a reality in order to monitor fetuses in the entire world through internet network.

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