

Ventilator Business Strategy

Nihon Kohden Corporation

(Ticker Code: 6849)

March 9, 2023

Fighting Disease with Electronics



Treasure Every Breath.

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Long-term Vision, Three-year Business Plan, Outline of Treatment Equipment Business

Long-term Vision and Three-year Business Plan

We contribute to the world by fighting disease and improving health with advanced technology, and create a fulfilling life for our employees.



Illuminating Medicine for Humanity

Create a better future for people and healthcare by solving global medical issues

Targets for
FY2029

Operating
Margin

15%

Overseas
Sales Ratio

45%

Management
Philosophy

Long-term
Vision

Three-year
Business Plan

Core Values

Apr. 2027 - Mar. 2030 **BEACON 2030** Phase III: Realize BEACON 2030

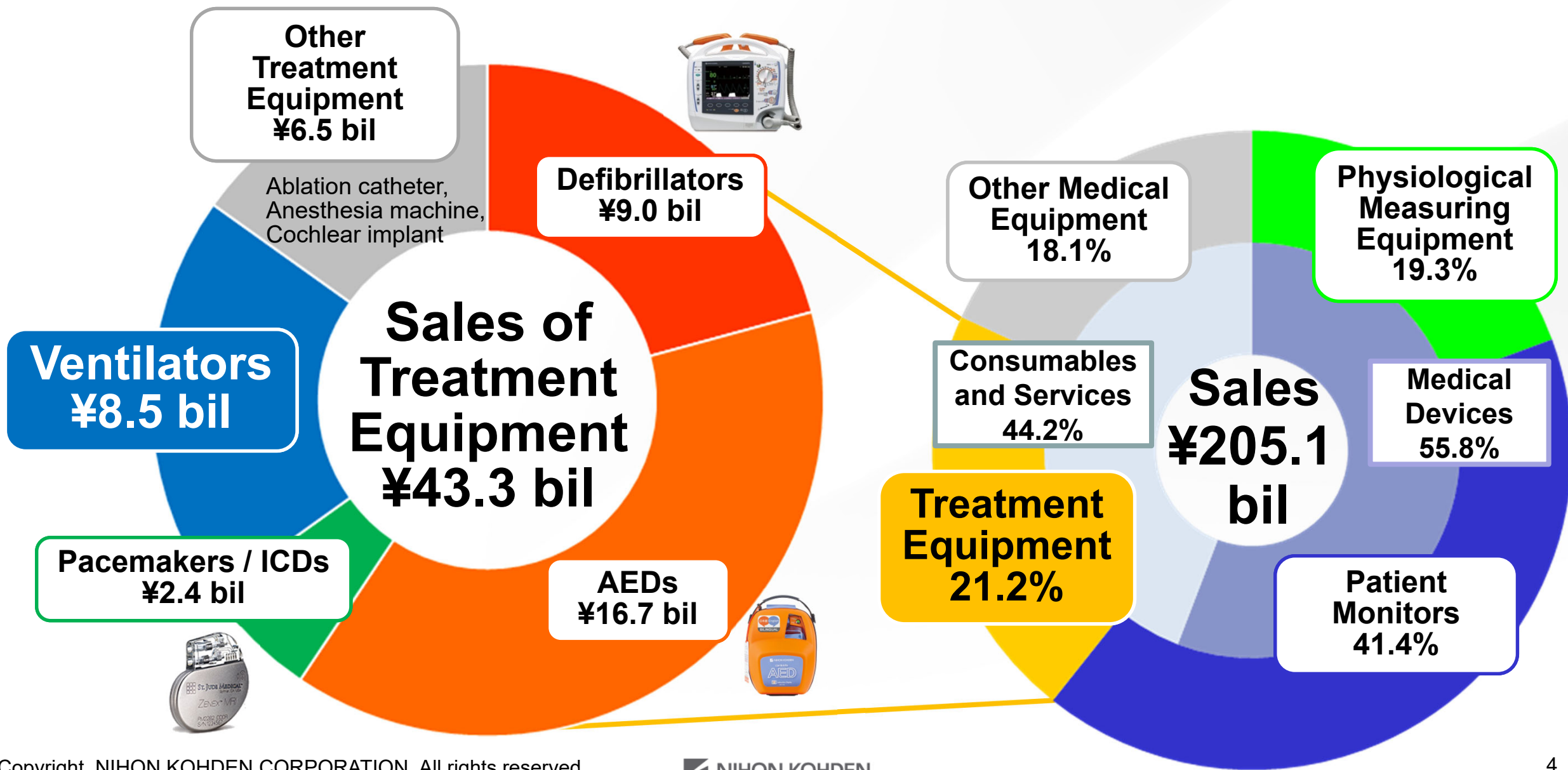
Apr. 2024 - Mar. 2027 **BEACON 2030** Phase II: Invest for growth

Apr. 2021 - Mar. 2024 **BEACON 2030** Phase I: Strengthen foundation

Core values are shared by Nihon Kohden staff worldwide, helping to connect them and contributing to the promotion of our Management Philosophy, Long-term Vision, and Three-year Business Plan.

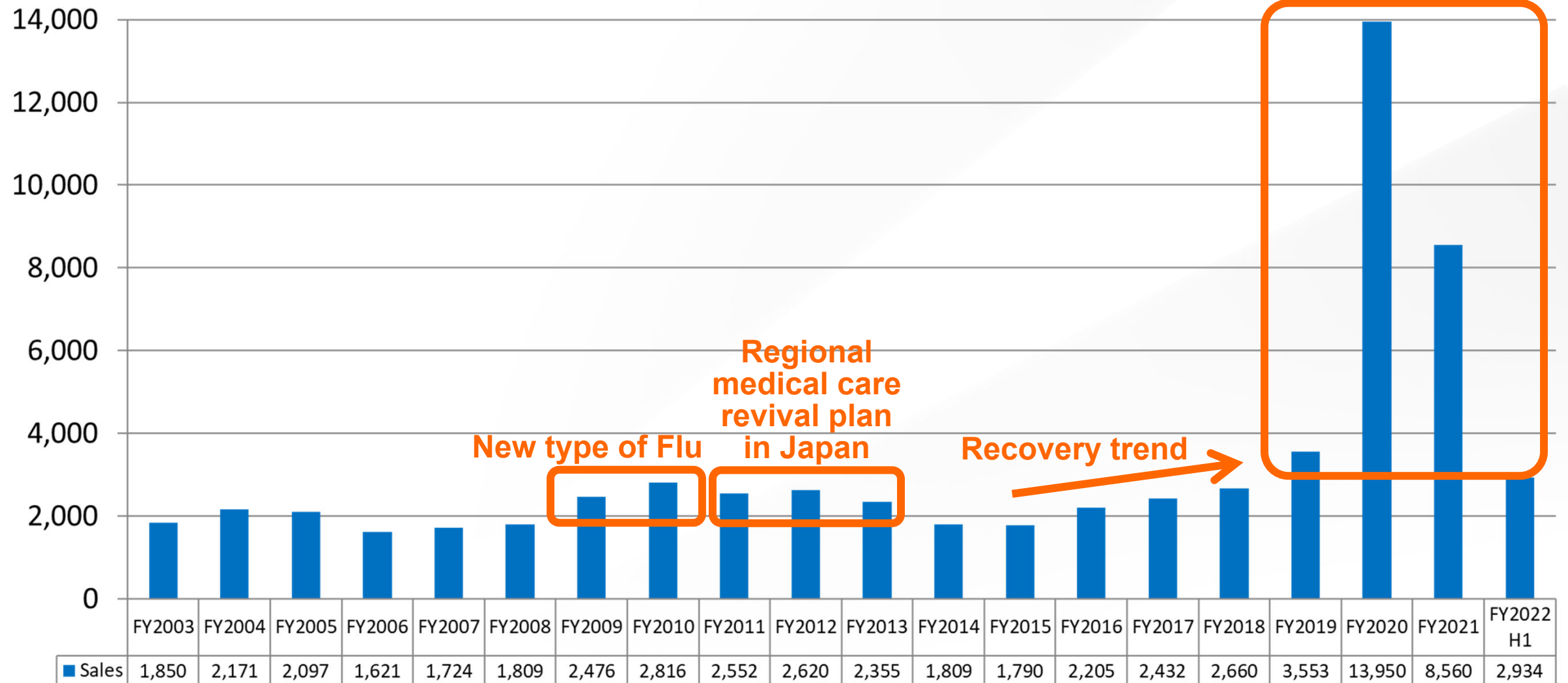
Integrity / Humbleness / Diversity / Initiative / Customer Centric / Goal Oriented / Creativity

Sales Composition of Treatment Equipment in FY2021



Sales of Ventilators

(Millions of yen)



Nihon Kohden's Future Vision of Treatment Equipment and Efforts During the COVID-19 Pandemic

Fumio Hirose, Director, Senior Operating Officer,
General Manager of Business Strategy Division

Fighting Disease with Electronics



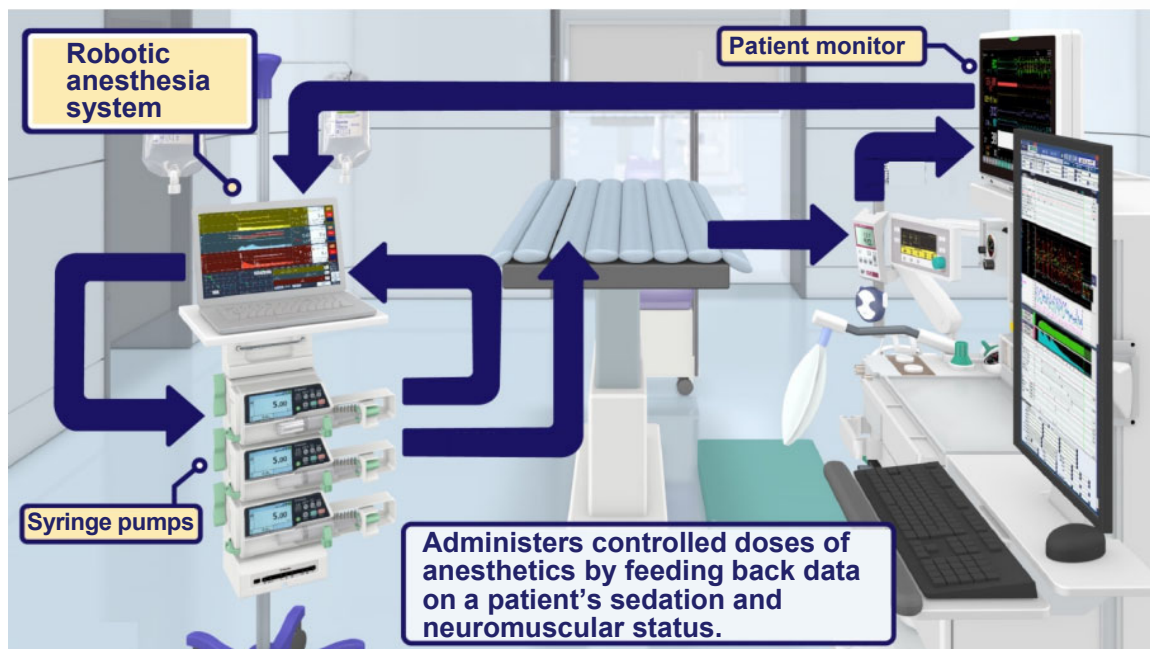
Treasure Every Breath.

Nihon Kohden's Future Vision of Treatment Equipment

Nihon Kohden's Future Vision of Treatment Equipment

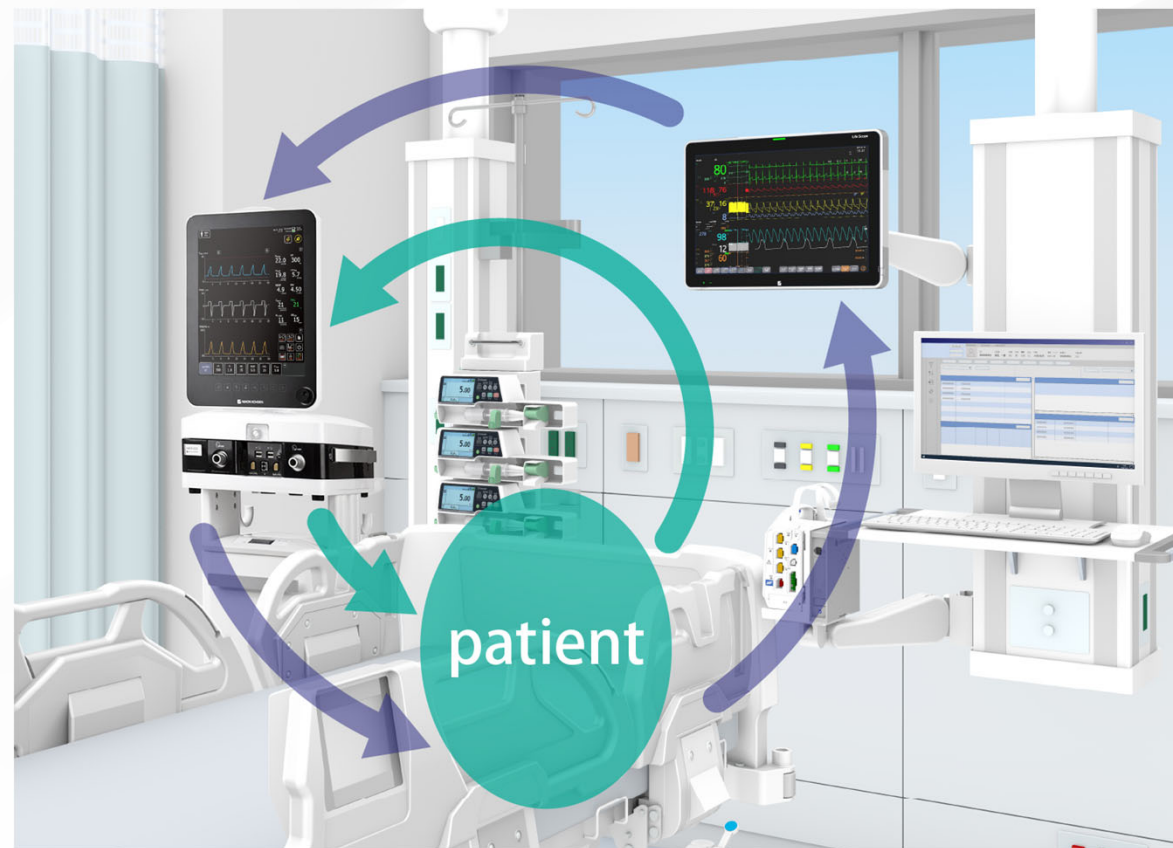
Robotic anesthesia system*

Administers controlled doses of anesthetics based on the patient's conditions and vital signs

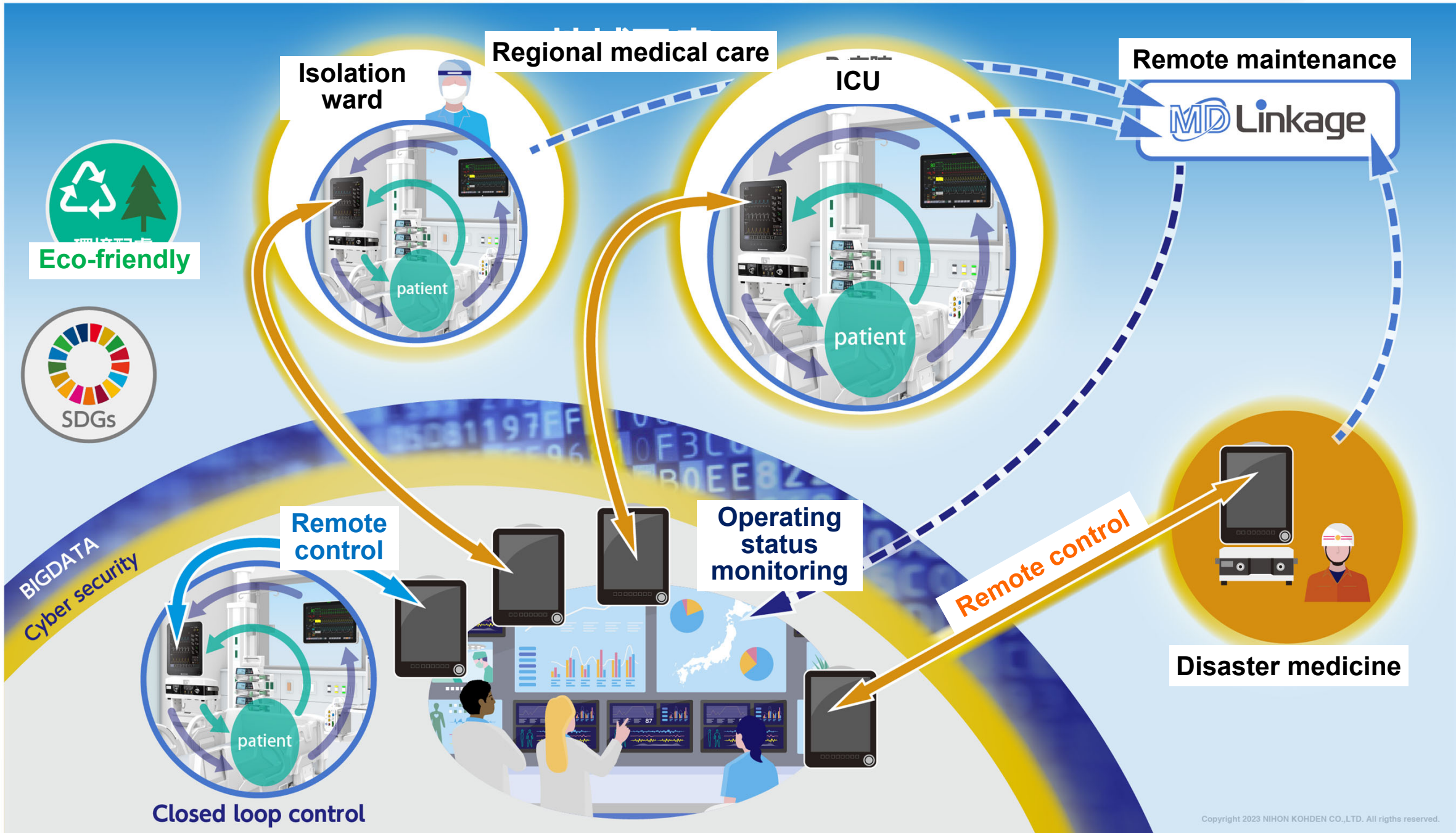


Ventilator system

Administers controlled ventilation based on the patients' conditions and vital signs, and enables remote control



* Planned to launch syringe pump control software for assisting with total intravenous anesthesia.



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Environment Surrounding Ventilators

Medical issues to be solved in ventilator business

**Work-style reform
for medical
professionals**

**Issues identified
by emerging
infectious diseases**

**Digital &
Data health
innovation**

Work-style
reform

Contribute to solving and balancing two
important issues **by using technology**

Ensuring quality
of medical care

**Utilize know-how in developing
robotic anesthesia system***

* Japan's first system to automatically control three elements of general anesthesia: sedation / analgesia / muscle relaxant
Plan to launch syringe pump control software for assisting with total intravenous anesthesia

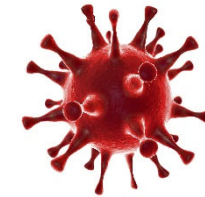
**Develop
Nihon Kohden's
own unique
ventilators**

Issues identified by emerging infectious diseases

2002~ SARS: Severe acute respiratory syndrome



2009~ New type of influenza (A/H1N1)



2012~ MERS: Middle East respiratory syndrome

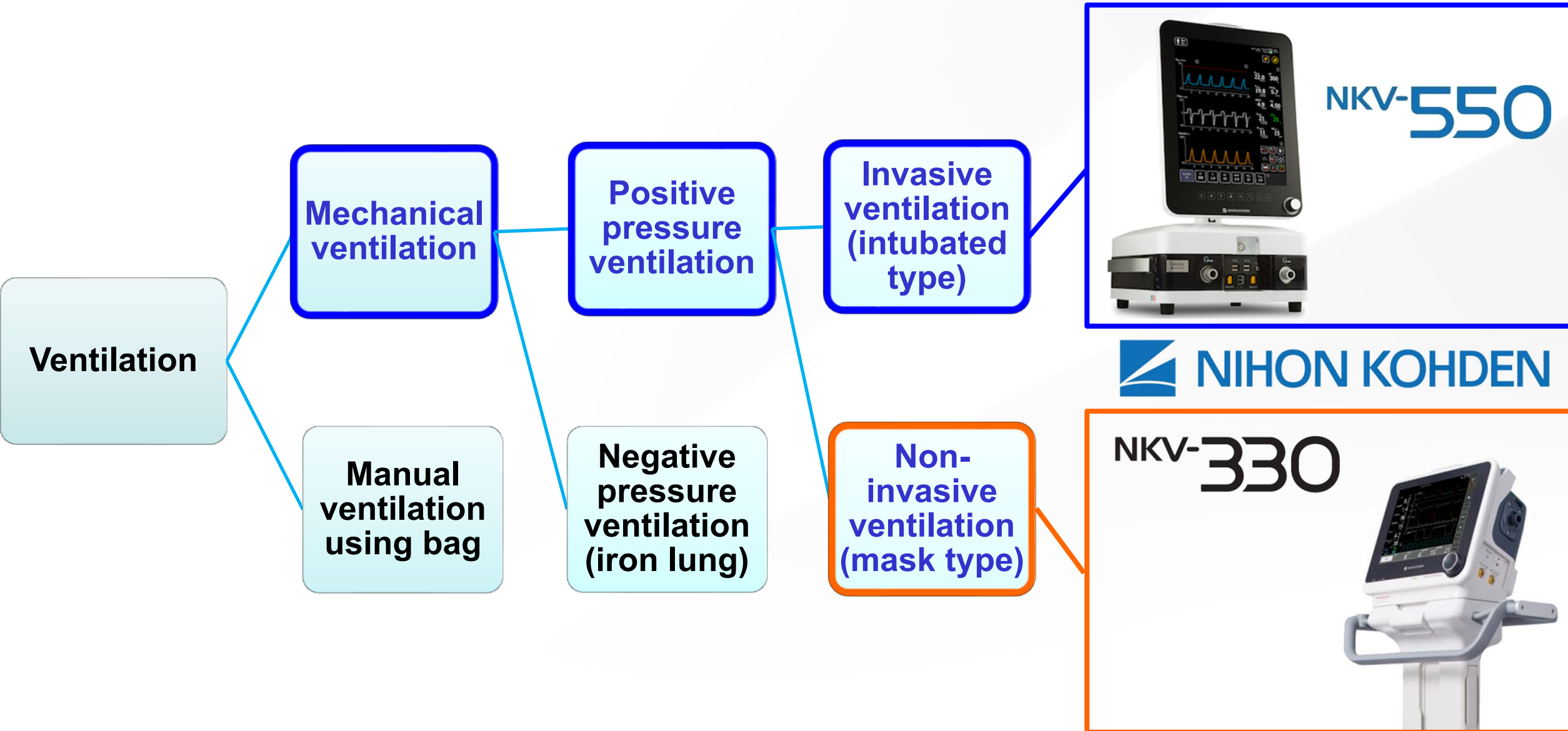


Difficult to obtain ventilators in Japan

Nihon Kohden developed and launched two types of in-house ventilators

2019~ COVID-19

Types of ventilators



Started to develop two types of in-house ventilators in 2010s

Treasure Every Breath[®]

Ventilator & Anesthesia Device Business Operations

NKV-330

- R&D and marketing of ventilators
- Established in Tokorozawa City in April 2013



Nihon Kohden OrangeMed, Inc.

NKV-550

- R&D, production, sales promotion of NKV-550
- Established in California in April 2015

Received ISO 13485:2016 certification
for quality management system



Size of Global Ventilator Market

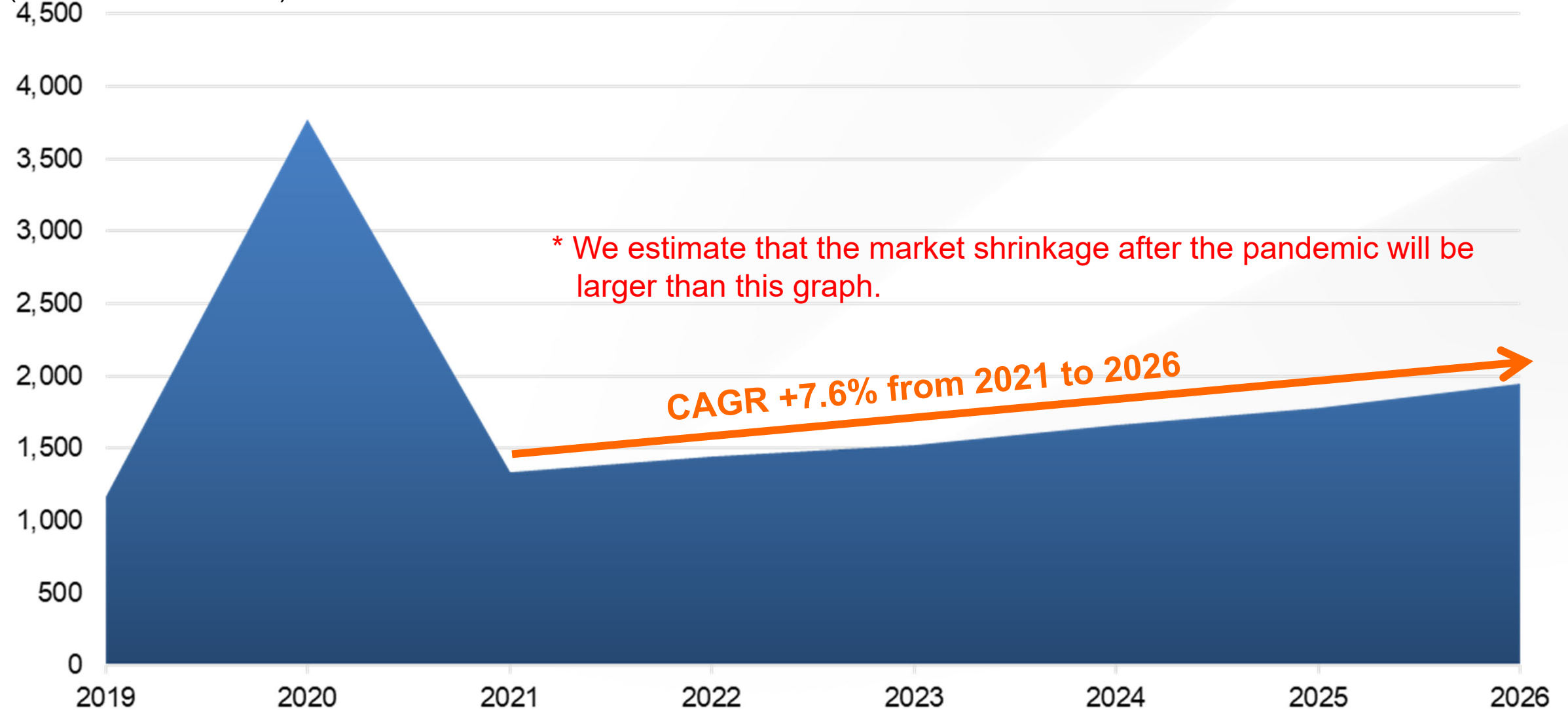
Global market size of ventilators

(millions of U.S. dollar)

	2015	2016	2017	2018	2019	2020	2021	2022	CAGR
Japan	148	158	167	175	182	188	194	199	4.3%
Americas	763	812	861	909	953	995	1,032	1,066	4.9%
Europe	341	362	383	402	420	435	449	462	4.4%
Asia & Other	518	565	615	667	719	771	821	868	7.6%
Total	1,771	1,897	2,025	2,153	2,274	2,390	2,496	2,594	5.6%

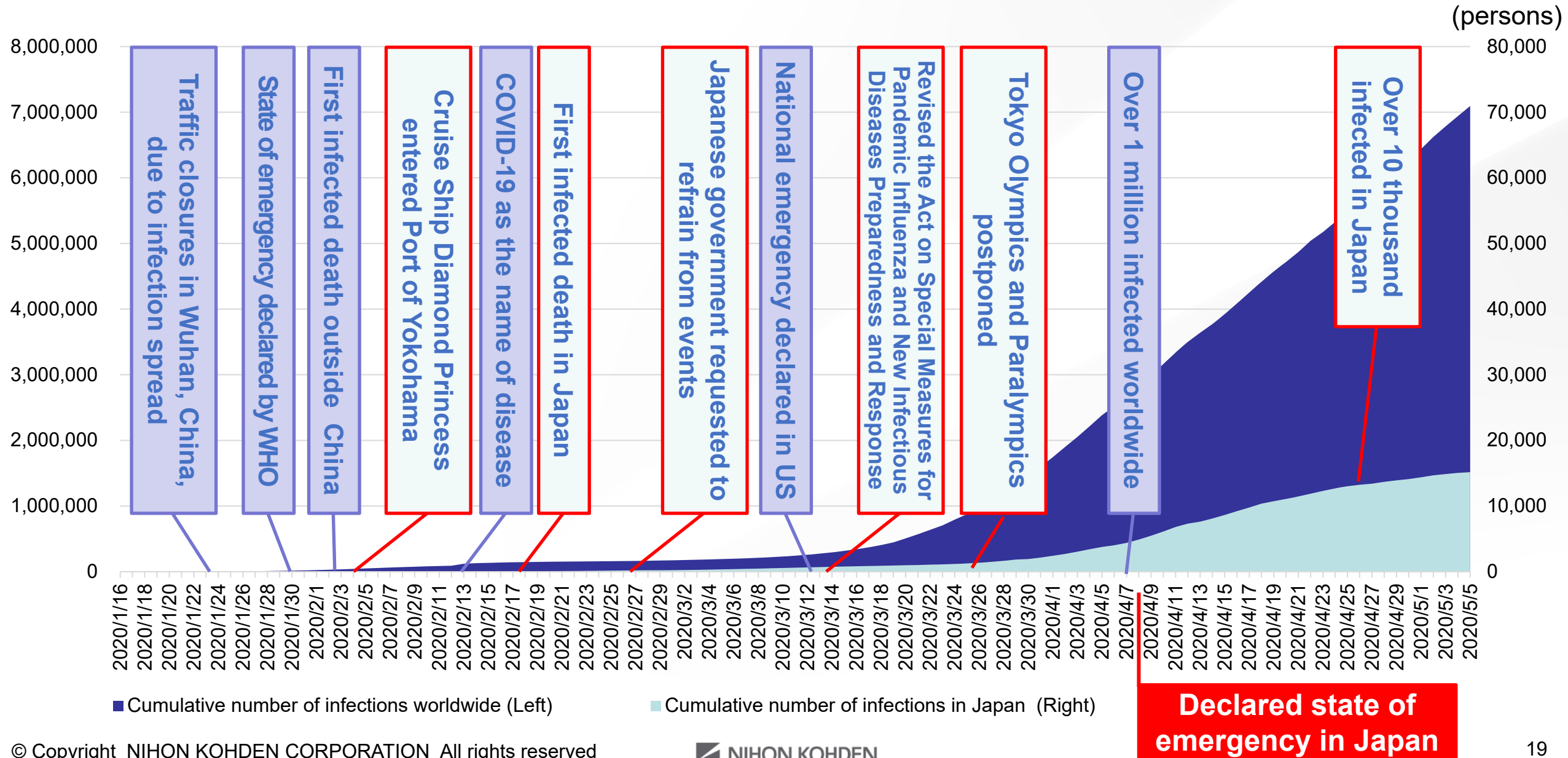
Global market size of ventilators before/after pandemic

(millions of U.S. dollar)





Nihon Kohden's Efforts During the COVID-19 Pandemic

COVID-19: Number of new infections and major events



COVID-19: Shortage of ventilators in each country

March 2020

-  Italy: Shortage of ventilators for severely ill patients
-  NY: Reported shortage of 16k to 30k ventilators
⇒ Estimated shortage of 40k ventilators in Japan based on population

April 2020

 **Request for full cooperation from the Japanese government**

- All-Japan efforts to manufacture ventilators to address the national crisis
- Set up domestic production and supply of ventilators designed in the U.S.



NKV-330



NKV-550

Increased production of ventilators and patient monitors

March 2020 OrangeMed

- Expanded production line in response to order requests that greatly exceeded production volume
- Obtained support from Japanese employees under training in the U.S. and sales reps with production experience as well as hiring additional production personnel



March 2020 Tomioka Production Center

- Order requests for patient monitors from around the world greatly exceeded production volume
- Negotiated with parts suppliers and secured production support from other companies

Supported by the Japanese Government and Automobile & Electronics Manufacturers

April to July 2020

Collaboration

Medical device
manufacturers



Manufacturers
from other industries

[Support for production]
[Outsourced production]
[Arrangement of parts]

Toyota Motor, DENSO, Tokai Rika
Honda Motor
Electronics & Sensor manufacturers



Explanation of ventilator operation



Meeting about production methods

Received Japanese approval for NKV-550

April 2020

Received Japanese approval in the shortest period of time since Nihon Kohden's founding, thanks to the prioritized and speedy processing of the necessary regulatory review procedures by the MHLW and PMDA

NKV-550



Main parts of ventilators

Difficulty in procurement of parts due to concentration of production in certain regions and increased demands



NKV-330

[Semiconductors] Worldwide
[LCD] Japan
[Pneumatic parts*] Mainly the U.S./ Europe

* Parts operated by air under pressure.



Carts developed in the U.S./Japan



O₂ sensors produced in Europe

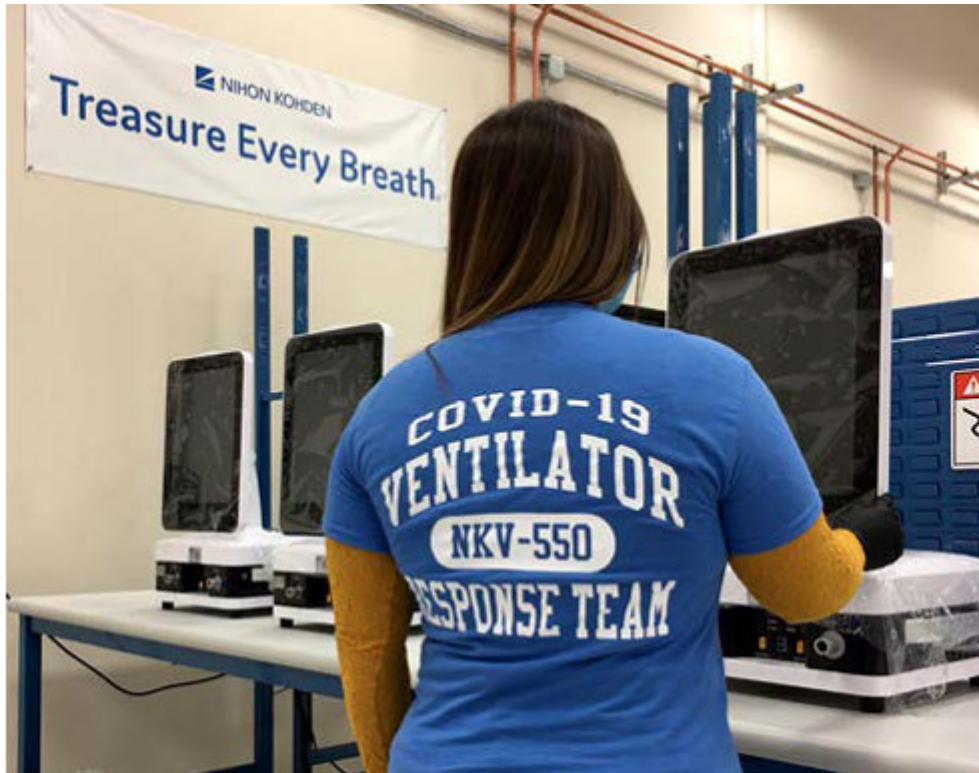


Ventilator circuits produced in China



Masks developed in Japan

Transfer of NKV-550 production from the U.S. to Japan



Nihon Kohden OrangeMed



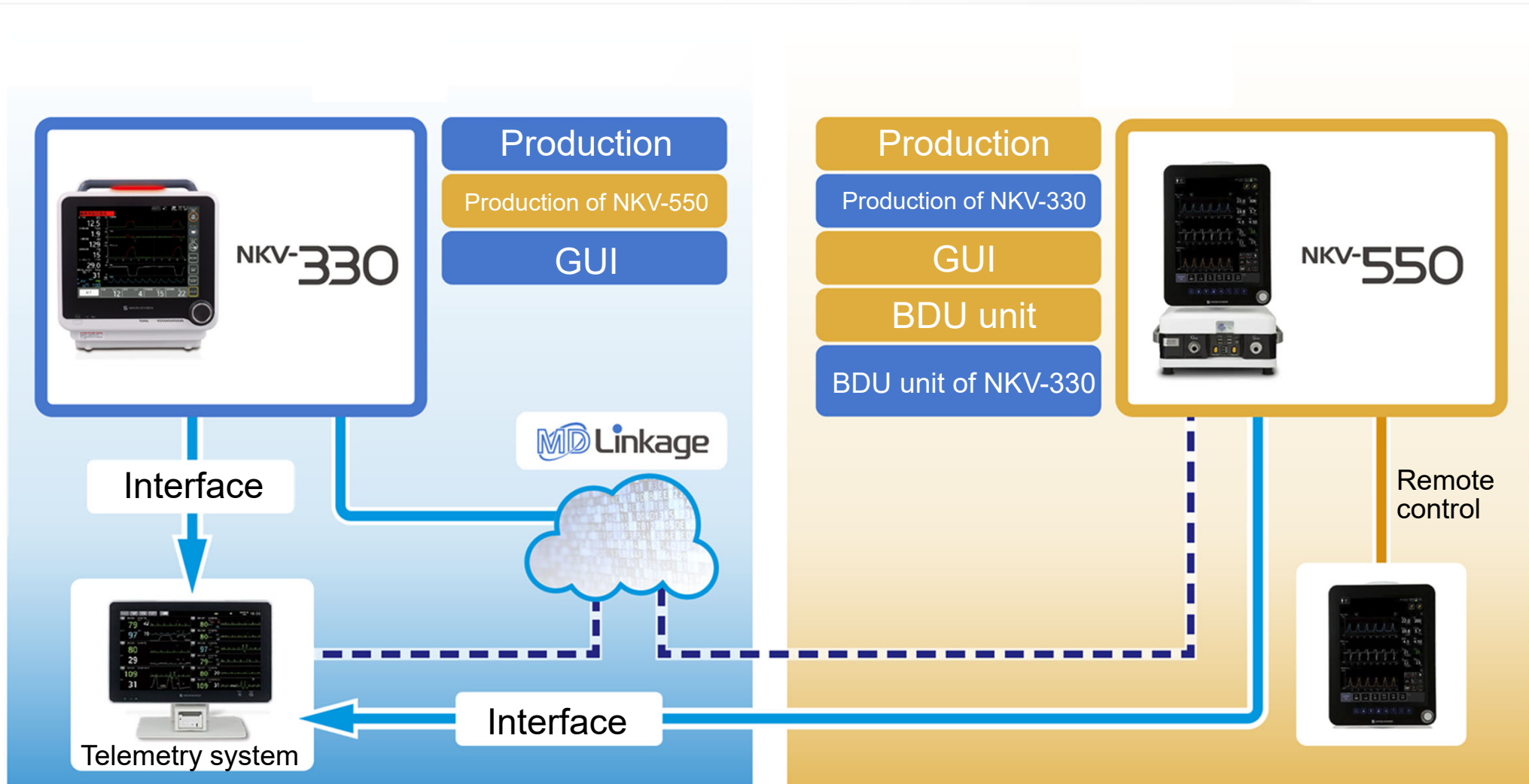
Tomioka Production Center

Prepared production line where even Japanese workers unfamiliar with the process can assemble NKV-550

Our future tasks

- Increase the number of parts which can be procured in Japan
- Secure sufficient inventories of parts for about one year of production in case of emergencies
- Realize new services which enable us to view the operating status and excess or shortage of ventilators in each region, utilizing medical DX such as our medical device remote monitoring system
- Develop ventilators which medical professionals can operate easily, safely, and securely

Current R&D and production structure for ventilators



* GUI: Graphic User Interface
BDU: Breath Delivery Unit

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R&D of Ventilators in Japan

Linkage with our telemetry system and medical device remote monitoring system

Isao Matsubara,
Senior Manager of Ventilator & Anesthesia Products Department,
Monitoring Technology Development Division,
Technology Development Operations

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Contribute to providing safe and secure medicine

Linkage with telemetry system

Alerts use the same alarm messages as ventilators



General ward

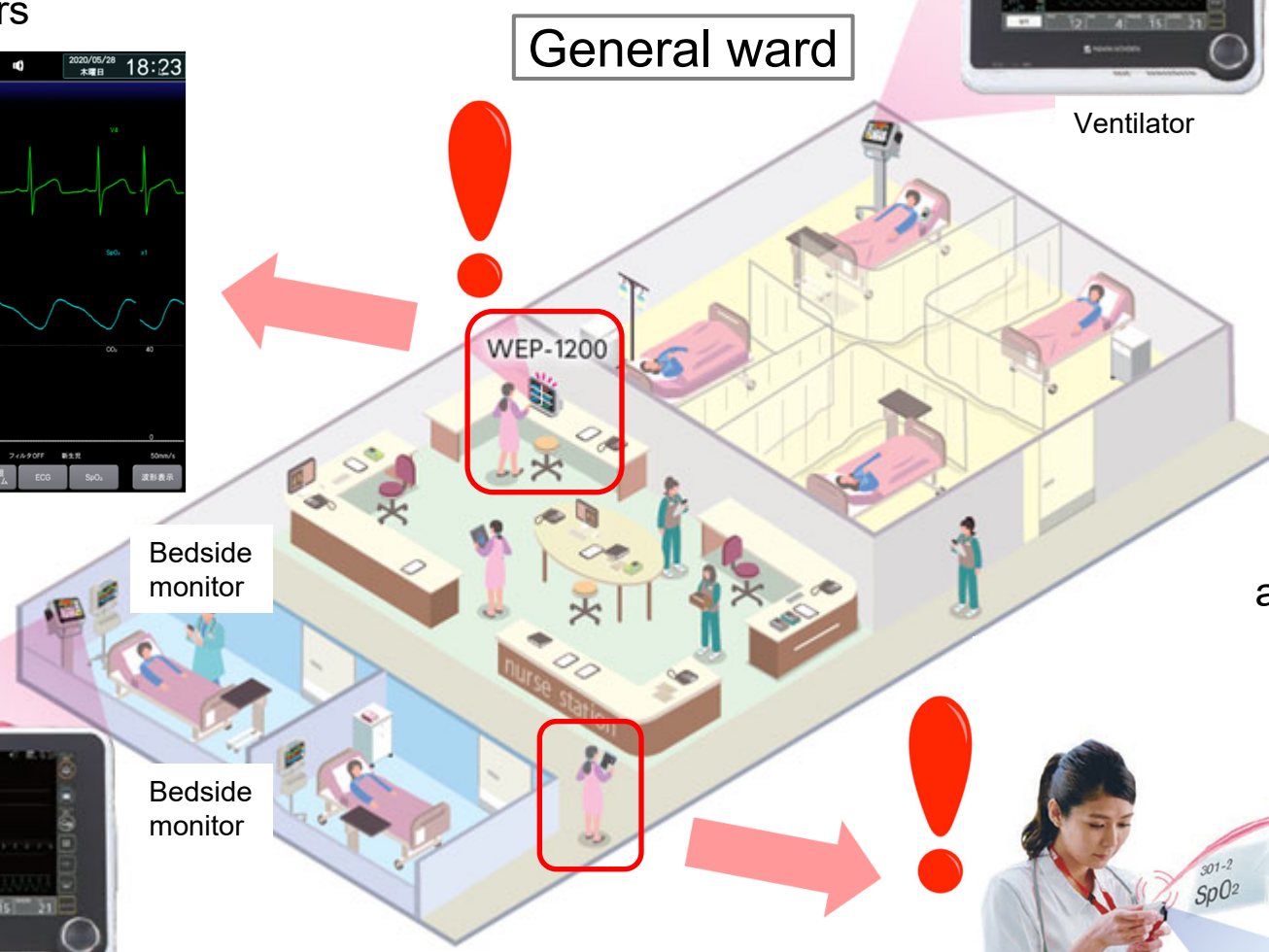


NKV-330

Ventilator

Linkage with nurse call system

Alerts with room number and alarm message appear on PHS



NKV-330

Ventilator

Bedside monitor

Bedside monitor

303-1
アブーア

302-2
カイロハスレ

302-1
V.TACH

301-2
SpO₂

301-1
V.FIB

Display example of ventilator alarm on telemetry system

Important alarms can be displayed with the same priority and message as NKV-330



NKV-330



Display of telemetry system

Contributing to improving operational efficiency of medical professionals

Why did you introduce NKV-330?

- It enables us to use both high flow therapy and NPPV (non-invasive positive pressure) functions in one unit
- It enables us to send vital signs and alarm data obtained from ventilators to patient monitors

⇒ **Expected it to reduce the workload of medical professionals and the number of times they enter and exit infection control rooms**

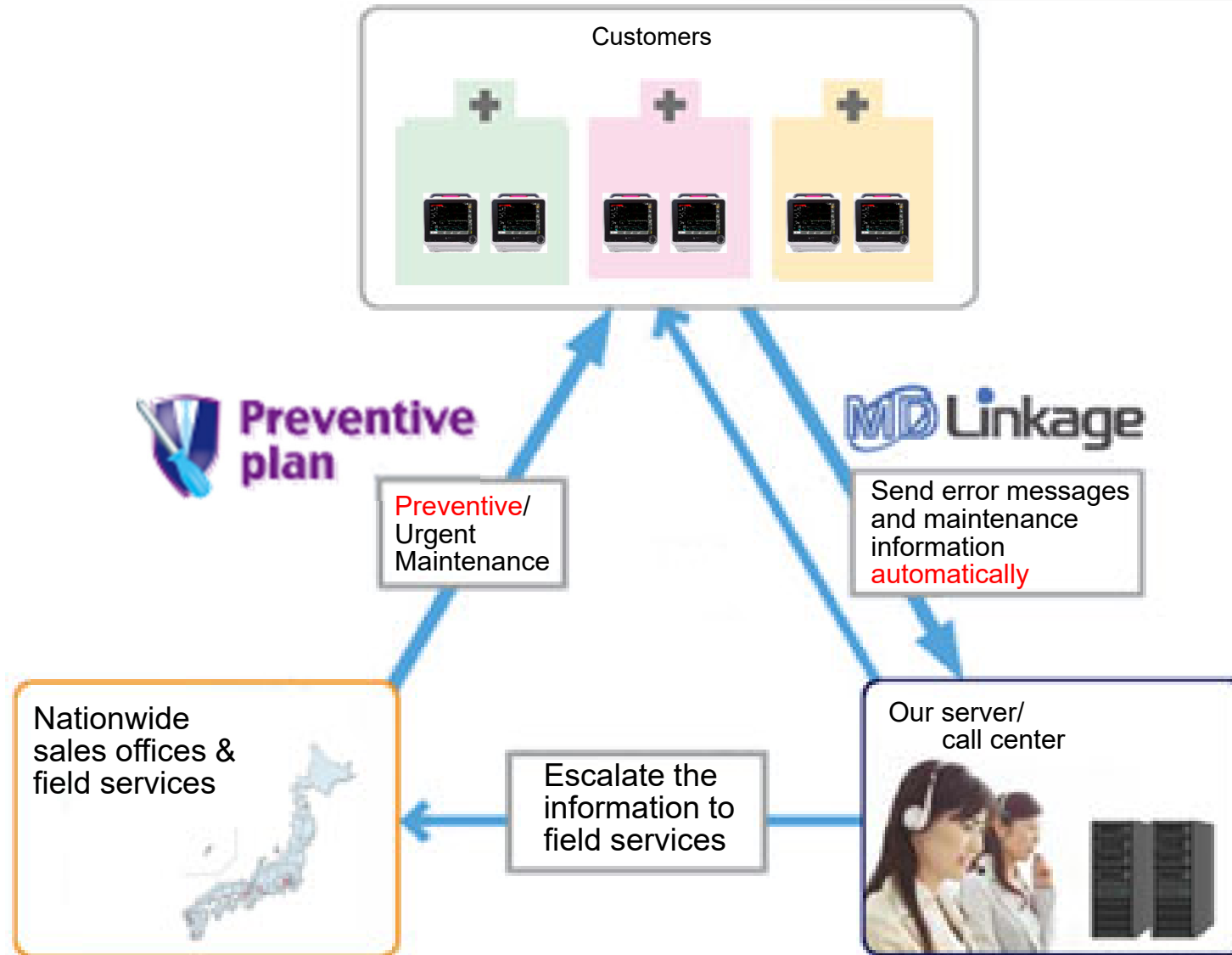


What are your impressions after installing NKV-330?

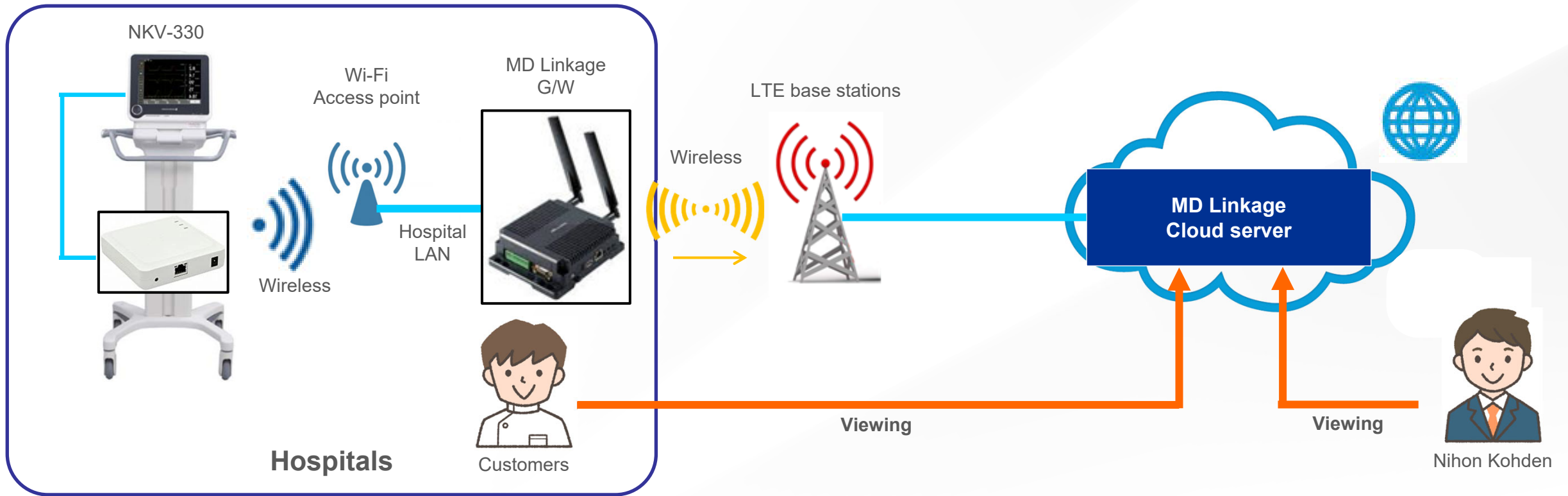
- It streamlined the workflow of medical professionals compared to previous operational methods that only used ventilators
- Reduced number of times medical professionals entered and exited infection control rooms and consumption of PPE (Personal Protective Equipment)



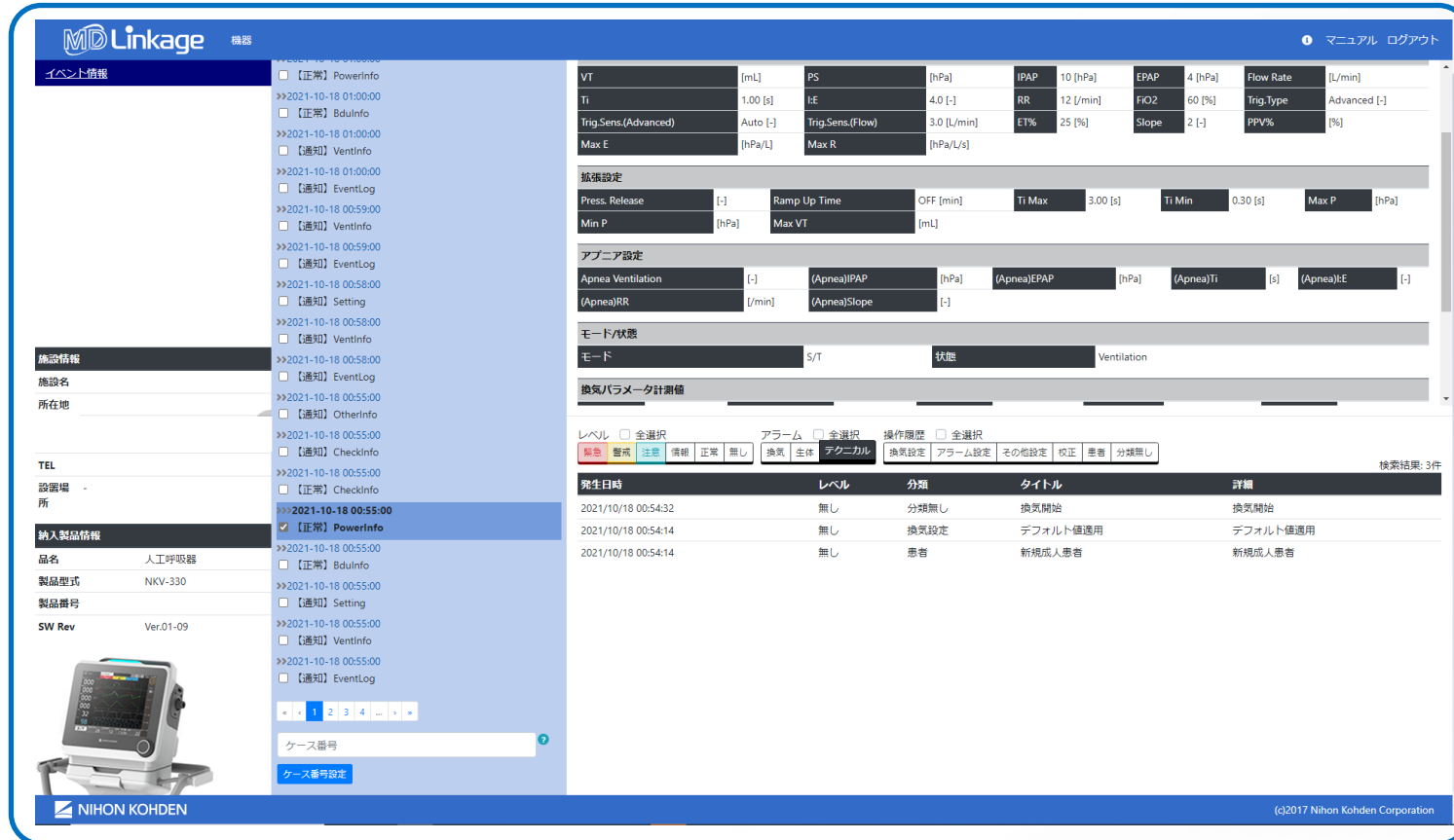
Medical device remote monitoring system



MD Linkage system linkage chart



Remote monitoring of operating status with



The screenshot displays the MD Linkage web interface for a ventilator. The interface is in Japanese and includes a sidebar with navigation options like '機体情報' (Device Information) and '納入製品情報' (Product Information). The main area shows various data tables and settings:

VT	[mL]	PS	[hPa]	IPAP	10 [hPa]	EPAP	4 [hPa]	Flow Rate	[L/min]
Ti	1.00 [s]	FE	4.0 [-]	RR	12 [L/min]	FIO2	60 [%]	Trig.Type	Advanced [-]
Trig.Sens.(Advanced)	Auto [-]	Trig.Sens.(Flow)	3.0 [L/min]	ET%	25 [%]	Slope	2 [-]	PPV%	[%]
Max E	[hPa/L]	Max R	[hPa/L/s]						

Additional sections include '拡張設定' (Expansion Settings) with parameters like Press. Release, Ramp Up Time, Ti Max, Ti Min, and Max P; 'アプnea設定' (Apnea Settings) with parameters like (Apnea)PAP, (Apnea)EPAP, (Apnea)Ti, (Apnea)RR, and (Apnea)Slope; and 'モード/状態' (Mode/Status) showing Mode as S/T and Status as Ventilation.

At the bottom, there is a table for '換気パラメータ計測値' (Ventilation Parameter Measurement Values) with columns for '発生日時' (Occurrence Date/Time), 'レベル' (Level), '分類' (Classification), 'タイトル' (Title), and '詳細' (Details).

発生日時	レベル	分類	タイトル	詳細
2021/10/18 00:54:32	無し	分類無し	換気開始	換気開始
2021/10/18 00:54:14	無し	換気設定	デフォルト値適用	デフォルト値適用
2021/10/18 00:54:14	無し	患者	新規成人患者	新規成人患者

Viewing each type of data in a web browser

- Operating status, such as operating or standing by
- Settings, measurement data, operating status



* Only Japanese

Enables operating status and error data of ventilators to be viewed remotely when used in infection control rooms or red zones

Remote monitoring of operating status with MD Linkage

Enables any data recorded more than one minute ago to be viewed as necessary

Settings

基本設定					
VT [mL]	PS [hPa]	IPAP 10 [hPa]	EPAP 4 [hPa]		
Ti 1.00 [s]	I:E 4.0 [-]	RR 12 [/min]	FIO2 97 [%]		
Trig.Sens.(Advanced) Auto [-]	Trig.Sens.(Flow) 3.0 [L/min]	ET% 25 [%]	Slope 2 [-]		
Max E [hPa/L]	Max R [hPa/L/s]				
拡張設定					
Press. Release [-]	Ramp Up Time OFF [min]	Ti Max 3.00 [s]	Ti Min 0.5 [s]		
Min P [hPa]	Max VT [mL]				

Alarm settings

換気							
PIP [hPa]	40.0	Apnea [s]	20	MV [L/min]	15.0	FIO2 [%]	OFF
	OFF				3.0		90
RR [/min]	40						
	6						
CO2							
EtCO2 [mmHg]		FiCO2 [mmHg]		RR(CO2) [/min]		Apnea(CO2) [s]	
SpO2							
SpO2 [%]				PR [/min]			

Measurement data

モード/状態							
モード	SPONT-PS			状態	Ventilation		
換気パラメータ計測値							
PIP	8.2 [hPa]	PEEP	3.9 [hPa]	Fi-peak	22.9 [L/min]	Fe-peak	-34.9 [L/min]
Flow	-	MV _i	1.9 [L/min]	MV _i spont	0.0 [L/min]	MV	2.0 [L/min]
MV spont	0.0 [L/min]	VT _i	123 [mL]	VT	126 [mL]	VT/kg	1.8 [mL/kg]
RR _{tot}	16 [/min]	RR _{spont}	0 [/min]	Ti	1.00 [s]	Te	2.74 [s]
Ti / T _{tot}	26 [%]	I:E	2.7	Leak total	39.8 [L/min]	Leak patient	16.9 [L/min]
Leak%	42 [%]	Pt.Trig.	0 [%]	O2 Gas Usage	0.0 [L/min]	FiCO2	21 [%]

Historical alarms

レベル <input type="checkbox"/> 全選択					アラーム <input type="checkbox"/> 全選択			操作履歴 <input type="checkbox"/> 全選択						
緊急	警戒	注意	情報	正常	無し	換気	生体	テクニカル	換気設定	アラーム設定	その他設定	校正	患者	分類無し
発生日時	レベル	分類	タイトル	詳										
2021/10/18 00:59:47 ~ 継続中	緊急	換気	PEEP上昇アラーム	PEE										
2021/10/18 00:59:28 ~ 継続中	警戒	換気	MV上昇アラーム	MV										
2021/10/18 00:59:26 ~ 継続中	警戒	換気	VT上昇アラーム	VT										
2021/10/18 00:59:19 ~ 継続中	緊急	換気	PEEP上昇アラーム	PEE										

Enhancing solution proposals through MD Linkage

Using remote access functions to enhance global after-sales services

1) Operating status

- ✓ Monitor operating status
- ✓ Planned service for viewing over- and under-utilization of ventilators



2) Prompt fault recovery

- ✓ Monitor error messages and failures
- ✓ Planned service intended to reduce downtime by enabling remote maintenance before aggravation of failures occurs



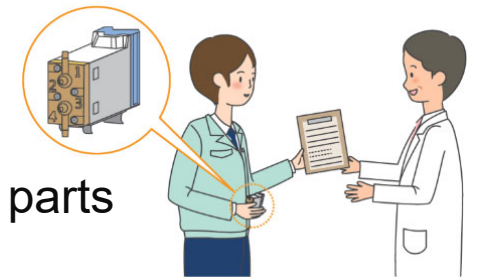
3) Preventive maintenance

- ✓ Monitor operating data
- ✓ Planned service intended to prevent shutdowns by providing maintenance before an abnormality or failure occurs

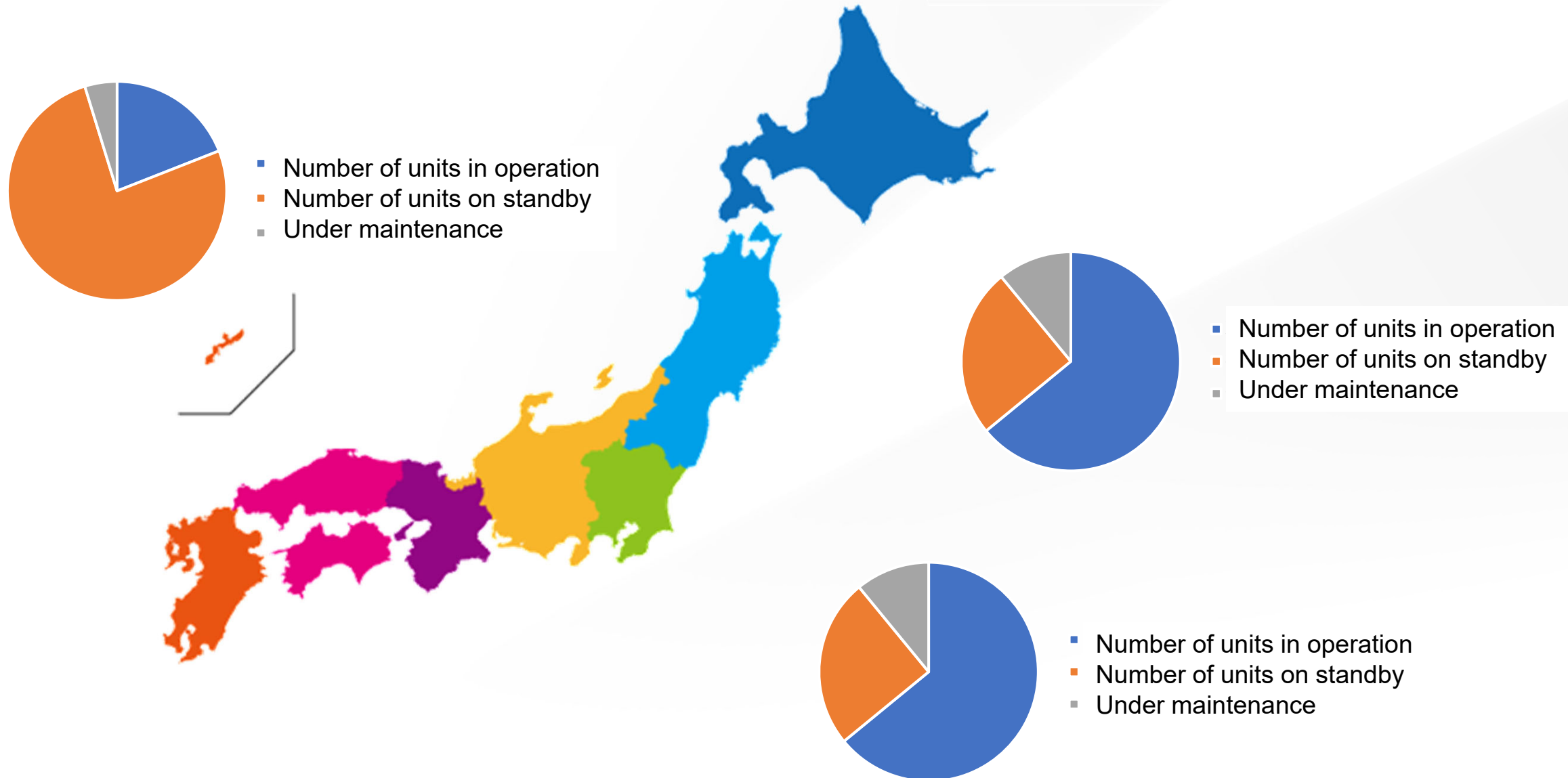


4) Regular maintenance

- ✓ Monitor maintenance notification data
- ✓ Promote replacement of periodic replacement parts
- ✓ Planned maintenance service intended to prevent failures



Plans to provide remote monitoring of operating status using MD Linkage



R&D of Ventilators in the U.S.

Nihon Kohden OrangeMed, Inc.

CEO Hong-Lin Du, MD, MBA

Fighting Disease with Electronics



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Nihon Kohden OrangeMed, Inc.

Established in 2015

Received US FDA approval in 2018

Launched NKV-550 in 2019



Line-up of ventilators developed and manufactured by Nihon Kohden OrangeMed

NKV-550



- Multi-function and higher accuracy
- Lung Protection Apps
- Co-located Remote Control

NKV-440 **NEW!**



- Equipped with air compressor
- Lung Protection Apps
- Compact and easy to move

NKV-330



- Mask-type model
- Equipped with SpO₂/CO₂ monitoring function
- Compact and easy to move

New model: Ventilator NKV-440

Applied for US FDA approval in Aug. 2022
Received approval in Thailand in Oct. 2022
Limited Market Release in Thailand in Dec. 2022

**Mid-range model of ventilator
and more suitable for
emerging markets**

- Equipped with air compressor
- Lung Protection Apps
- Compact and easy to move



Graphic User Interface of NKV-440



The same basic operation as NKV-550



Easy for user training

Smaller, lighter, and longer time battery compared to NKV-550



Easy to move inside hospitals

Strengthening of ties with GPO/IDN in the U.S.

FY2022 4Q

- Signed contract with Premier Inc, one of the major GPOs* in the U.S.

FY2023 1Q

- Will start to sell our ventilators to Premier, Inc member hospitals (approx. 4,400 hospitals and health systems)

* GPO: Group Purchase Organization



NKV-330



NKV-550

Co-located Remote Control: The only ventilator with US FDA 510k clearance



US011213644B2

(12) **United States Patent**
Crawford, Jr. et al.

(10) **Patent No.:** **US 11,213,644 B2**
(45) **Date of Patent:** **Jan. 4, 2022**

(54) **MULTIPLE CONTROL INTERFACE FOR MEDICAL VENTILATOR**

(52) **U.S. CL.**
CPC *A61M 16/024* (2017.08); *A61G 10/005* (2013.01); *A61M 15/00* (2013.01); (Continued)

(71) Applicant: **Nihon Kohden OrangeMed, Inc.**, Santa Ana, CA (US)

(58) **Field of Classification Search**
CPC *A61M 16/00*; *A61M 16/021-024*; *A61G 10/00-04*; *G06F 21/00*; *G06F 21/30-31*; (Continued)

(72) Inventors: **Richard William Crawford, Jr.**, Yucaipa, CA (US); **Hong-Lin Du**, Irvine, CA (US); **Steven F. Landas**, Riverside, CA (US); **Phuoc Huu Vo**, Anaheim, CA (US)

(56) **References Cited**
U.S. PATENT DOCUMENTS

(73) Assignee: **Nihon Kohden OrangeMed, Inc.**, Santa Ana, CA (US)

6,369,838 B1 4/2002 Wallace et al.
7,188,621 B2 3/2007 DeVries et al.
(Continued)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 276 days.

Far Remote Control of Ventilators

June 2021

- A collaboration with the U.S. government
- Selected as a company to develop ventilator remote control technology in collaboration with USAMRDC and TATRC

News Release:

For More Information Contact: Ms. Lori DeBernardis

Director of Marketing & Public Affairs

Telemedicine & Advanced Technology Research Center (TATRC)

E-mail: usarmy.detrick.medcom-usamrmc.list.tatrc-PAO@mail.mil

TATRC Awards Projects to Accelerate Availability of Remote Controlled Ventilators and Infusion Pumps

“Virtual Hospital” Capabilities Extend Scale and Impact of Tele-Critical Care for COVID-19

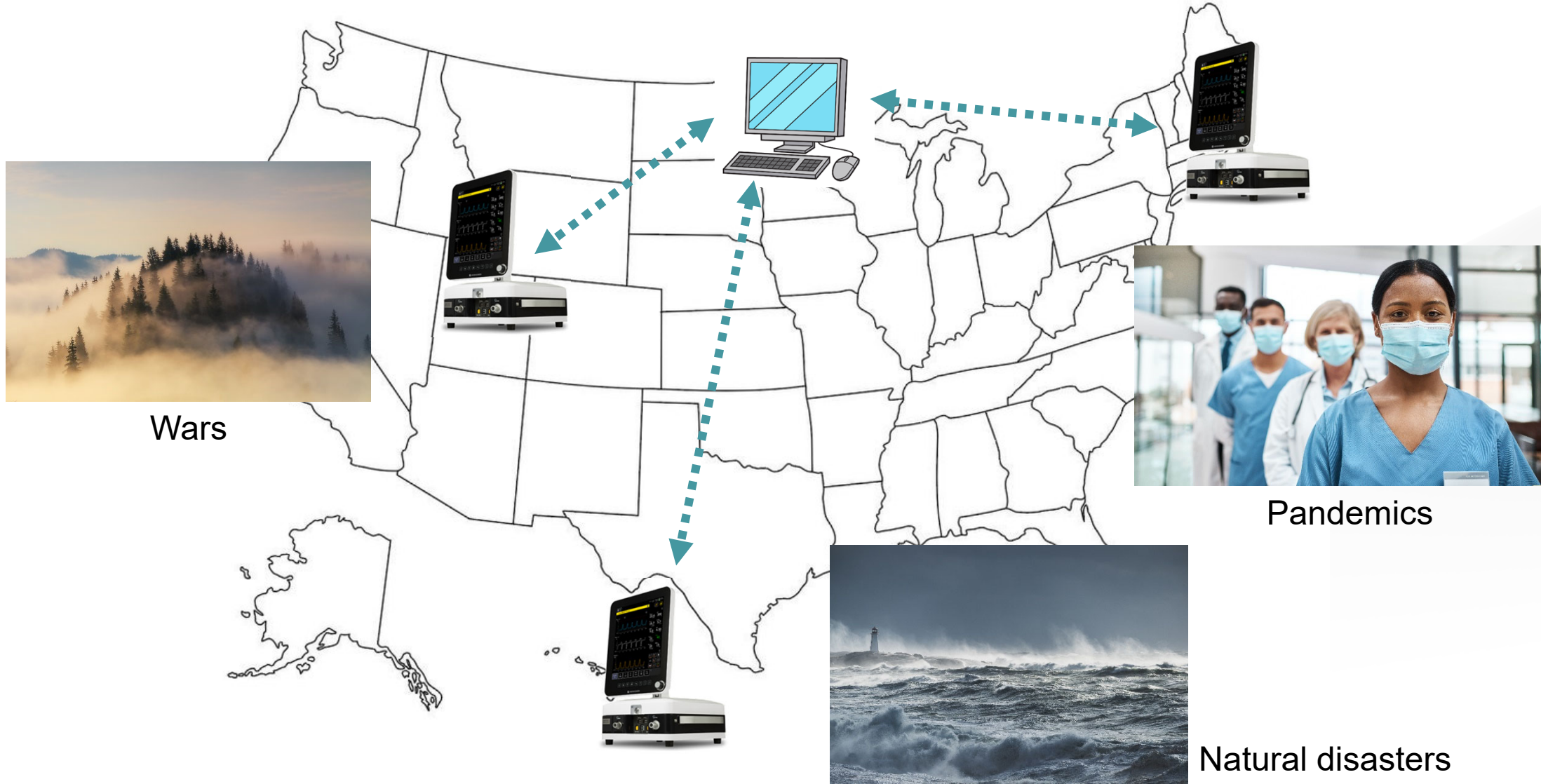
For Immediate Release – July 30, 2021

The U.S. Army Medical Research and Development Command’s (USAMRDC) Telemedicine and Advanced Technology Research Center (TATRC) has awarded a total of approximately \$2.8M in funding to three project teams to accelerate interoperability, remote control, and automation of mechanical ventilators and infusion pumps for integration into the National Emergency Tele-Critical Care Network (NETCCN) platforms in support of tele-critical care of COVID-19 patients. This effort will create and add “virtual hospital” capabilities to NETCCN and provide hospital-like functionality to the platform.

- Nihon Kohden OrangeMed Inc. to develop, test, and implement the NKV-550 ventilator remote control function in collaboration with NETCCN performers, cybersecurity experts, and medical device interoperability experts.

<https://www.tatrc.org/www/resources/docs/10-NETCCN-PR-TATRC-Awards-MDIA-Project.pdf>

Examples of purposes of using Far Remote Control of Ventilators



Wars

Pandemics

Natural disasters

Demonstration of the Ventilator Far Remote Control Technology

TATRC medical device remote control DIACC final demo Nov 18 2022

Demonstration Participants 1/2

UNCLASSIFIED

34

Harvard University

US Department of Defense Research Center

Nihon Kohden

Future directions of Nihon Kohden ventilator business

**Expand
Nihon Kohden's ventilator portfolio**

**Closed loop control
ventilation**

**Far remote control of
ventilators**

- **Reduce workload of medical professionals**
- **Important for pandemics, natural disasters, and wars**

Nihon Kohden OrangeMed, Inc.



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