KOKEN

Neonatal Resuscitation Simulator– Advance

LM-111GM

Instruction Manual

Thank you for purchasing the Neonatal Resuscitation Simulator–Advance.
Please read this instruction manual carefully to ensure correct use of the product, and store it in a safe place for easy access.

Instruction manuals for the Neonatal Resuscitation Simulator-Advance in English, German, French, Spanish and Dutch available for download.

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Handling and Safety Precautions

These precautions should be strictly observed in order to ensure safe, long-term use of the product.

The following precautions should be observed particularly strictly:

1. This product is made from a special silicone with a feel similar to that of a living body. Please handle it carefully, as you would a living body, as much as possible. The application of excessive force may damage the product.

2. If you sense any abnormalities in action during use, immediately cease training and have the product inspected and repaired by our company.

3. Under any circumstances, avoid using this product outdoors on rainy days, in damp conditions, or when the product is wet, as this may cause damage.

4. Avoid exposing this product to direct sunlight as much as possible when using it outdoors.

5. Use AA size alkaline batteries for the main body of the model.
   Do not mix old and new batteries or batteries of different types.
   Doing so may cause fire, injury or fouling of the surrounding area due to rupture and leakage of battery fluid.
   Turn off the power of the main body of the model before inserting or replacing batteries.

6. Remove the batteries when storing this product. Otherwise, fluid may leak from the batteries.

7. This model is designed for use in the general environment. Please do not use it in a heavy industry environment.

8. This product is approved for sale in restricted countries only.
   For further details please refer to our website.
   https://www.kokenmpc.co.jp/english/products/educational_medical_models/cpr/lm-111gm.html

Caring for the model after use

1. After use, turn off the power switch of the main body of the model and then remove batteries.

2. Any oil-based ink, pencil, chalk, paint, etc., used will soak into the model and become impossible to remove. Do not use any of these under any circumstances.

3. If the skin of the model becomes dirty, wipe it off with a soft cloth such as gauze soaked in mild detergent diluted with water.

4. To remove tough stains, wipe them off with a soft cloth such as gauze soaked in ethanol for disinfection.

5. Avoid using solvents such as paint thinner or benzene under any circumstances.

6. Store the model in the correct position to avoid deformation.

7. Store the model in a place where it will not be exposed to direct sunlight or ultraviolet light.

The following precautions should be observed when using this product for exercises:

1. This product cannot be used for bathing exercises. Do not immerse the product in water, hot water, etc., as this will impair normal use.

2. If this model is used in airway management training using a tracheal tube or laryngeal mask, first spray a lubricant (silicone spray) into the oral cavity of the model and onto the tip of the tracheal tube or laryngeal mask.

3. Lubricant (silicone spray) is not included. Prepare the lubricant in accordance with the following precautions.

   ・Use a silicone oil-based lubricant (silicone spray).

   Use of a spray containing oil other than grease or silicone oil can damage the model. Ensure that you use silicone spray.

   ・Use an aerosol lubricant (silicone spray).

   ・Use the prepared lubricant (silicone spray) after spraying a small amount onto a part of the model that does not interfere with its functioning and checking that no problems occur.

4. Do not attempt mouth-to-mouth artificial respiration, as the inside of the airway cannot be disinfected due to the structure of the model.

5. Air leakage can occur during positive-pressure ventilation using a bag valve mask.
   Air leakage can be reduced by using an air cushion mask.

6. Umbilical vein catheterization can be practiced, but do not administer any actual drug solution or water, because this model has no drainage function.

7. Pulling strongly on the umbilical cord or tube for umbilical cord pulsation can damage the model.

8. The ventilator alarm may continue to sound when using this model with a ventilator attached to the flow rate inflatable bag due to the structure of this product.

9. This product's application is specific to the Android operating system. Use a tablet PC loaded with Android.

10. The recommended operating environment for the application is Android: 5.0 or later; memory: 2 GB or more; resolution: 1280 × 720 pixels or higher. The application may not correctly operate when using a tablet PC with lower specifications.

11. If you expect to use the model continuously for several hours, we recommend replacing the batteries with new batteries before use. Otherwise the model's batteries might run out during use.

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1. The contents of this instruction manual are subject to change without notice.
2. This instruction manual may not be reproduced in part or in its entirety without permission.
3. Please contact the manufacturer in the event that any errors or omissions are found in the contents of this instruction manual.
4. This product should be used only as described in this instruction manual. In particular, the product should not be used in any way that contravenes the precautions noted in the instruction manual.

Table of Contents

1. Outline and Features

Outline

This model is for neonatal cardiopulmonary resuscitation training. The model can reproduce heart, respiration, and voice sounds, and can be wirelessly operated by a tablet PC. It is also possible to practice other techniques, such as artificial respiration and chest compression, making it useful for various training sessions such as neonatal resuscitation courses.

Features

1. In addition to the functions of the previous "Neonatal Resuscitation Model," heart and respiratory sounds can be auscultated on the chest, and a crying voice can be heard from the mouth. Heart, respiration, and voice sounds can be easily controlled on a tablet PC.

2. The tablet PC can display the heart rate and SpO_2 as a simulated monitor.

3. This product is made of a silicone rubber that has a realistic texture and feel.

4. Elevation of the chest can be observed through positive-pressure ventilation utilizing a bag valve mask, etc.

5. The airway can be managed by utilizing the tracheal tube or laryngeal mask.

6. With deep-seated intubation of the tracheal tube, elevation of the right lung can be checked during tracheal intubation. (One-sided lung intubation)

7. A tube can be inserted for oral and nasal suction.

8. Chest compression can be practiced. The xiphoid process of the sternum can also be checked.

9. Umbilical vein catheterization can be practiced.

10. Pulsation at the base of the umbilical cord can be measured to determine the heart rate.

2. Components and Configuration

Components	Quantity
Neonatal Resuscitation Simulator –Advance main body	1
Storage bag	1
Instruction manual (this document)	1

*The kit does not include batteries. Please prepare four AA-size alkaline batteries.

3. Handling

3-1 Installing the application

Install the application from Google Play.
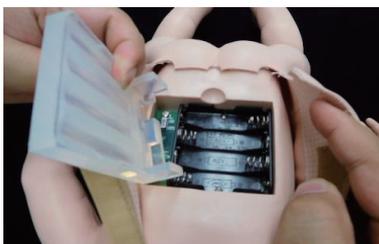Search "LM111GM" on Google Play, and install it by selecting the page with the following icon.
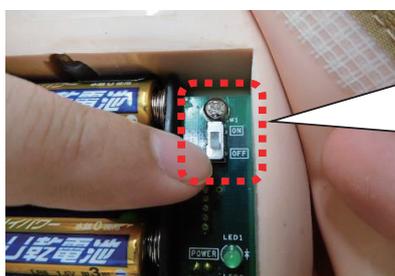
 Application icon

*Please be sure to read the terms of use before installing the application.

3-2 How to pair the model with the tablet PC

1. Switch on the tablet PC and turn Bluetooth OFF from the configuration screen. For how to configure Bluetooth, see your tablet PC's instruction manual.
2. Open the back of the main body of the model and remove the protective cover. Place batteries in the battery box, paying attention to the direction of the positive(+) and negative(-) poles. *Use AA-size alkaline batteries (× 4).

3. Turn on the power of the model's main body by sliding the switch to the ON position. When it is activated correctly, the green LED lamp lights up and an electronic sound is emitted. After that, put the protective cover back on.

4. Turn Bluetooth ON from the tablet PC's Bluetooth configuration panel.
   After that, connect it to the "KOKEN Neonatal Advance" device displayed on the tablet PC.
   * An electronic sound is emitted when it connects.
* During pairing, do not turn on the power of other models than that to be paired.

If two or more models are turned on, the tablet PC cannot distinguish one model from another.

5. Start the dedicated application and set the language. You can select from the following eight options: Japanese, English, Chinese, German, French, Spanish, Russian and Korean.
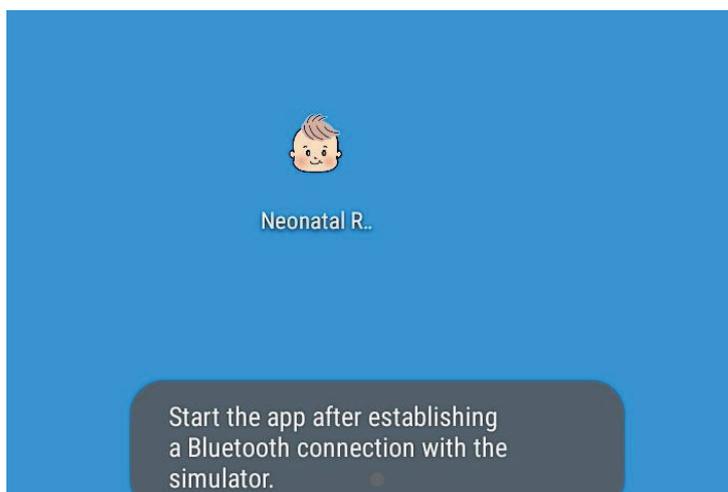

Dedicated application icon

6. Fasten the Velcro tape on the back of the model. Preparation is now complete.
   * If it does not operate correctly:
   If you start the application without connecting the model and tablet PC via Bluetooth, the following message will appear on the tablet PC, and the application will not start.
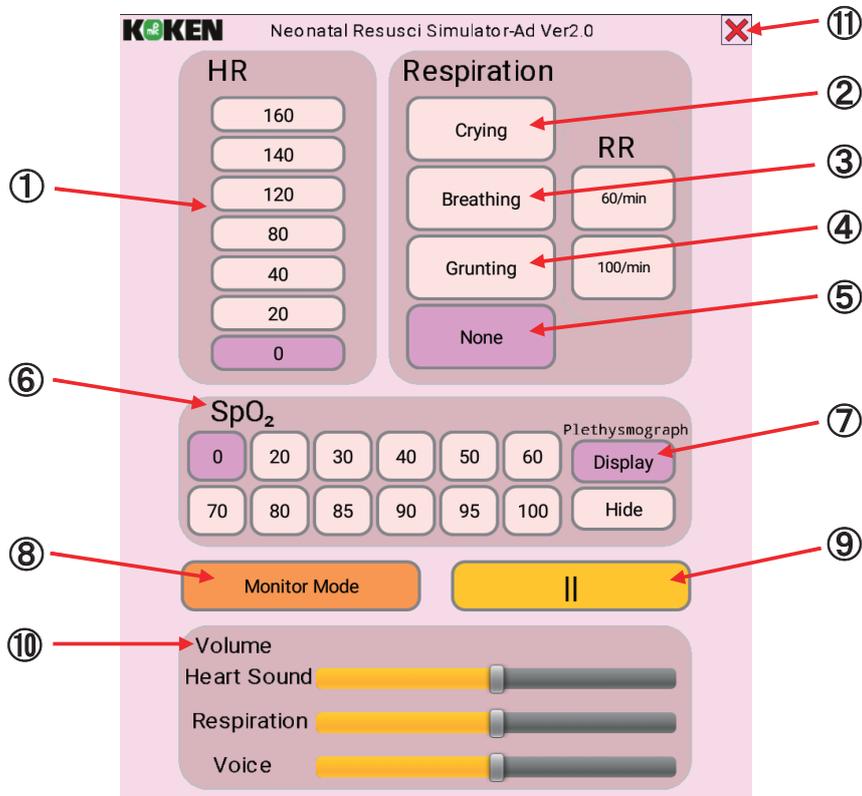

If pairing cannot be completed successfully, try the pairing process again according to the following steps:

1. Turn off the power of the main body of the model.
2. Close the dedicated application, and completely stop the application from Tasks on the tablet PC.
   *For how to operate Tasks, see your tablet PC's instruction manual.
3. Turn Bluetooth OFF via Configuration on the tablet PC.
4. Repeat the steps from 3-2 Procedure on page 6 to pair the model with the tablet PC.

3-3 Explanation of screen displays

Controller Mode

HR
① Model makes heart sounds at the selected numerical rate.

Respiration
② Crying: Model makes both crying and respiration. Select from a Respiratory Rate (RR) of 60/min or 100/min.
③ Breathing: Model makes breathing without voice.
④ Grunting: Model makes moaning as well as breathing. Select from a Respiratory Rate (RR) of 60/min or 100/min.
⑤ None: Model does not produce any lung sounds or crying sounds.

SpO$_2$
⑥ Selected SpO$_2$ value is displayed in Monitor Mode.
⑦ Can select Display or Hide of plethysmograph.
   No change in plethysmograph if SpO$_2$ is 0% or 20%.

Monitor Mode
⑧ Switch screen to Monitor Mode.

Pause
⑨ Pause heart sound, respiration, voice, and all operations.
   During pause, an arrow for "PLAY" ▶ is displayed. Press the arrow to resume.

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Volume

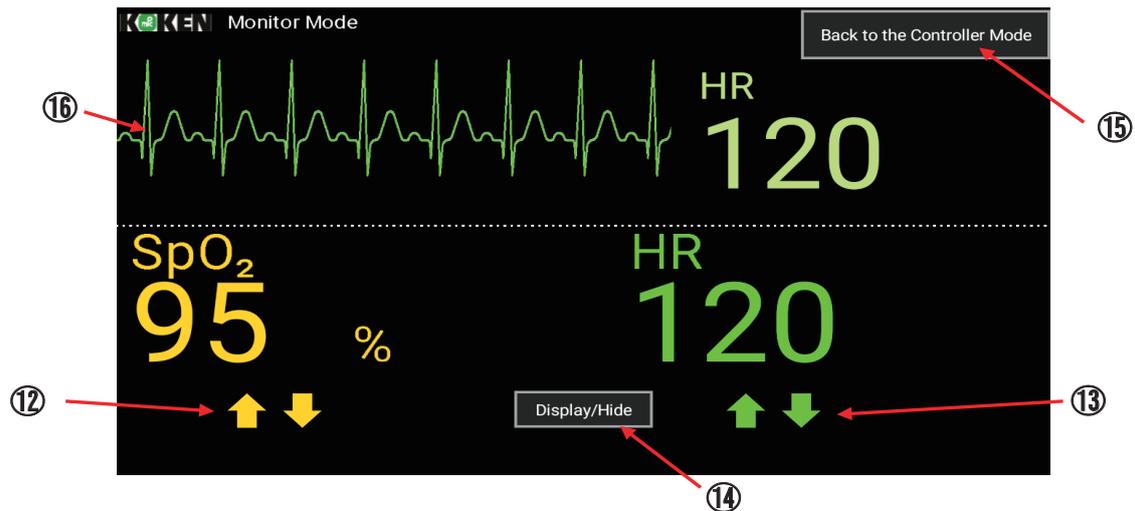⑩ Adjusts volume for heart sound, respiration, and voice.

　*Use the volume adjustment button on the tablet PC to adjust the volume of all sounds.

End Button

⑪ Closes application.

　*This operation does not stop operations running in Tasks.

Monitor Mode

⑫ 🔼🔽 These buttons can be used to change the SpO_2 value.

　* No change in plethysmograph if SpO_2 is 0% or 20%.

⑬ 🔼🔽 These buttons can be used to change the HR. *HR of the main body of the model is also changed.

⑭ The plethysmograph display can be switched Display and Hide.

⑮ The screen can be switched to Controller Mode.

⑯ The ECG changes according to HR. *ECG waveforms do not move.
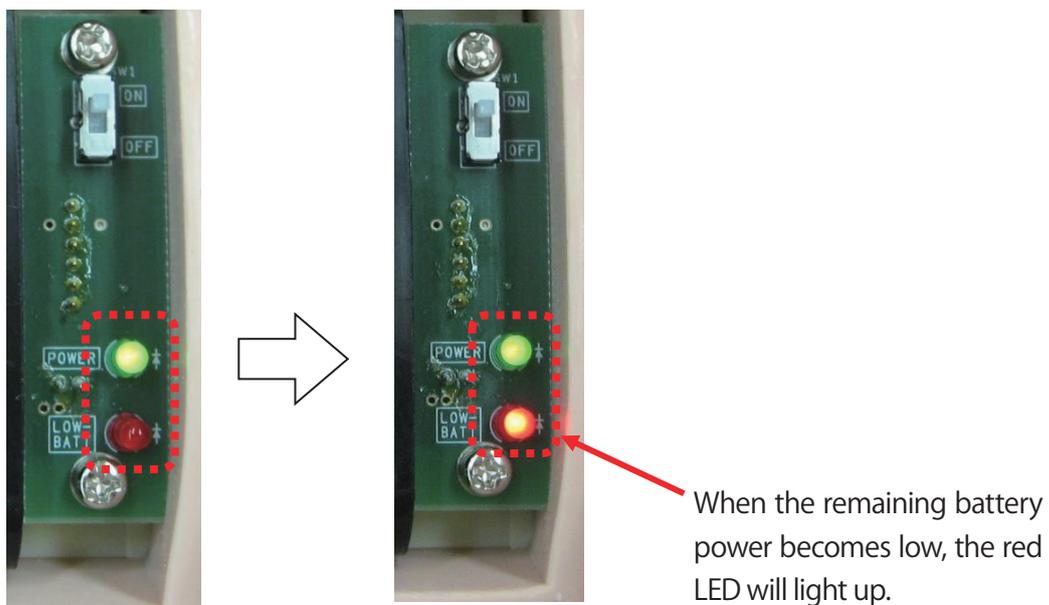
3-4 Tidying up after use

1. Close applications. Also close this application running in Tasks.

2. Turn off the power switch of the main body of the model and remove the batteries. Storing the model with the batteries left in it may cause battery fluid to leak, etc.

3. Turn OFF Bluetooth via Configuration on the tablet PC.

   *About remaining battery power in the model's main body
   When the remaining battery power in the model's main body becomes low, the red LED lamp next to the power indicator light in the main body of the model lights up. When this happens, please replace the batteries. The model will stop operating about two hours after the red LED lamp lights up.

   The model's operating time depends on the batteries used and the use environment.

When the remaining battery power becomes low, the red LED will light up.

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3-5 Airway management using equipment

Ensure that you apply a lubricant (silicone spray) to the tip of the tube and within the oral cavity of the model when using the tracheal tube and laryngeal mask. Inserting the tube into the model without applying a silicone lubricant spray can cause damage. (The same applies when inserting a suction tube into the nasal cavity)
   * No lubricant (silicone spray) is included.
     Please prepare the lubricant (silicone spray) after reading the precautions regarding the lubricants (P.2).

Compatible tube sizes are shown in the table below.

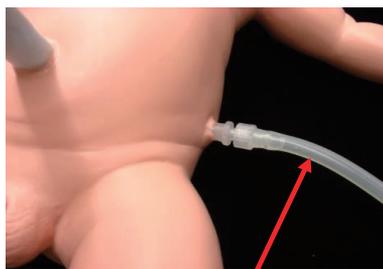| Tube name	Compatible size	Remarks
Tracheal tube	Internal diameter, 3.5 (mm)	Tracheal tubes with an internal diameter of 3.0 mm or less can be used, but a lot of air will leak from these.
Laryngeal mask	Size 1	Sizes 2 and above are not compatible.

3-6 Pulsation of the umbilical cord

Pulsation at the base of the umbilical cord can be measured by squeezing and opening the pump for umbilical cord pulsation protruding from the model.
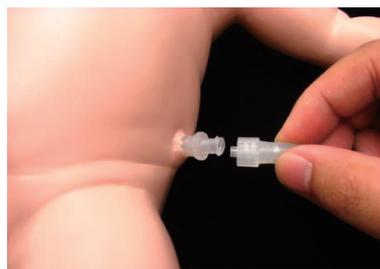Moreover, by releasing the connector on the left flank of the model, the tube for umbilical cord pulsation can be removed. Remove the tube when it is not needed.

Pump for umbilical cord pulsation

Tube for umbilical cord pulsation

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4. Specifications

Product name	Height	Weight
Neonatal Resuscitation Simulator–Advance: Main body	Approx. 50 cm	Approx. 2,500 g

5. Wireless Specifications

Bluetooth module：BM62SPKS1MC2 ／ Microchip ／ Bluetooth5.0 ／class2
Frequency range：2402MHz to 2480MHz
Size：29 × 15 × 2.5 mm
Operating voltage：3.2V to 4.2V
Operating temperature：-20℃ to +70℃
Hardware version / Batch No.：Rev1.0 / 1536
Firmware version：5506

Notice for Radio Equipment
Hereby, KOKEN CO., LTD. declares that the radio equipment type LM-111GM is in compliance with Directive 2014/53/EU.
The full text of the EU declaration of conformity is available at the following internet address:
https://www.kokenmpc.co.jp/english/support/index.html