



Instructions For Use

iTalk4

Issue Date: February 26, 2024

Revision: 1.0

Model: 1000028

UDID: 00186648000531

 <p>AbleNet, Inc. 2625 Patton Road Roseville, MN 55113 United States of America www.ablenetinc.com</p>	 <p>EUCEREP Roald Dahllaan 33, 5629MC Eindhoven The Netherlands eucerep@eucerep.com</p>	<p>UK Responsible Person</p> <p>EUCEREP LTD 7 Tibbets Close, Meeting Lane Alcester, Warwickshire B49 5QU England, United Kingdom</p>
---	--	--

 <p>MedEnvoy Switzerland Gotthardstrasse 28 6302 Zug Switzerland Telephone: +41 41 562 01 42</p>

INTENDED PURPOSE

iTalk4 is an easy-to-use communication aid with voice output and intended for people who cannot or cannot yet use more complex static or dynamic systems.

CLINICAL BENEFITS OF THE DEVICE

Beginning device to assist a patient with verbal communication. The benefit is to maximize the efficiency and effectiveness of communication for individuals who are unable to communicate via verbal speech.

PERFORMANCE CHARACTERISTICS AND INFORMATION FOR HEALTH CARE PROFESSIONAL

Activation Type: Pressure

Activation Surface Size: Small (less than 2.5-in or 6.35-cm)

Recording Time: 6-min

Number of Message Locations: 4

Weight: 23.2-oz

Weight-Metric: 658-g

Batteries: Qty 4 - AA Alkaline (not included)

HCPCS Code: E2500

Product Warranty: 2-year Limited Warranty

Mounting: Threaded inserts

Qty: 2

Thread: 6-32

Center Distance: 2.04-in (5.17-cm)

Material: Housing - ABS Plastic

Suggested Operating Environment:

Ambient Temperature Range: 32°F - 95°F (0°C - 35°C)

Humidity: 10% - 95% (no condensation on device)

Suggested Transportation and Storage:

Ambient Temperature Range: -25°F - 158°F (-31°C - 70°C)

Humidity: 10% - 95% (no condensation on the device)

RISKS, WARNINGS, AND CONTRA-INDICATIONS

iTalk4 is neither waterproof nor completely water resistant. Do not immerse iTalk4 in water or any other liquid. Make sure that no liquids are spilled on iTalk4.

iTalk4 is not recommended to be used as access to a call system.

DEVICE OVERVIEW

1	Switch Tops (x4)
2	Microphone



3	On/Off switch and Volume Control
4	Recording Levels



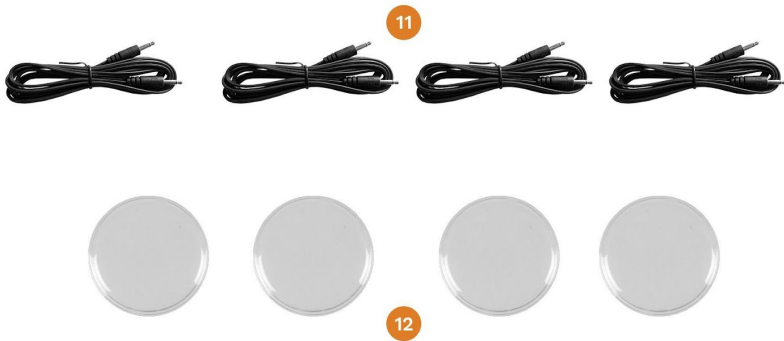
5	Speaker
6	Battery Cover
7	Record Button
8	Recording Indicator Light
9	Switch Input/Output Jacks



10	Threaded Inserts For Mounting
----	-------------------------------



11	1/8-in/3.5-mm mono cables (x4)
12	Clear Switch Caps (x4)



USE INSTRUCTIONS

First Time Use

1. Remove the battery cover.
2. Insert 4 “AA” batteries.
3. Replace battery cover.
4. Turn iTalk4 on using the On/Off switch and Volume Control dial.
5. Select the desired level using the Recording Levels switch.
6. Press and hold the record button until the record light activates.
7. Press and hold a switch top, and begin speaking into the microphone when you hear a beep.
8. Release the switch top when finished recording the message.
9. Repeat this process for the remaining switch tops.
10. When done recording, press and release the record button to turn the recording indicator light off and exit record mode.
11. You can now use iTalk4.

Using Levels

The iTalk4 provides three recording levels for increased flexibility.

1. Use the toggle switch on top of the iTalk4 to select the appropriate recording level.
2. Press and hold the record button until the recording indicator light lights up, then record the messages to each switch top.
3. Use the toggle switch to choose a different level.
4. Press and hold the record button until the recording indicator light lights up, then record the messages to each switch top.
5. Use the toggle switch again to choose the final level.
6. Press and hold the record button until the recording indicator light lights up, then record the messages to each switch top.
7. Release the switch top when finished recording the message.

Using External Switches

The iTalk4 can be controlled with an external switch.

1. Make sure iTalk4 is off.
2. Attach the switch of your choice with a 1/8-inch/3.5mm plug into the switch input jack that corresponds with the message location you would like activated.
3. While activating the external switch, turn iTalk4 on.

Controlling Toys or Appliances

The iTalk4 Toy/Appliance jack allows you to activate switch-adapted toys or appliances with this device.

Plug any switch-adapted toy or appliance into the corresponding Toy/Appliance jack you would like to use to control the toy or appliance.

Some electrical appliances will require a PowerLink to be activated.

PREPARATORY TREATMENT

Cleaning and disinfecting your AbleNet assistive technology devices between uses is essential to the health and safety of the user. To help fight against the spread of germs, here are some helpful steps to cleaning and disinfecting your AbleNet device.

Always be sure to wear the appropriate personal protective equipment such as protective gloves and safety glasses.

Cleaning Your Device

Before disinfecting your device, remove any dirt or debris that may be on the device.

1. Turn the device off and remove the batteries.
 1. Remove any large chunks, visible heavy dirt, or debris that is attached to the device.
2. Wipe down the device with cleaning wipes.
3. Use a cotton swab soaked with cleaner to get into any tight areas that were not accessible with the cleaning wipes.
4. Let the device completely dry.

Disinfect Your Device

Now that the device is clean, it is time to disinfect it. Changing protective gloves may be required before disinfecting the device to ensure no dirt or debris is transferred back to the device.

1. Make sure the device is still turned off and that the batteries are removed.
2. Use a clean towel or wipes with Virucidal, Bactericidal, Pseudomonacidal, Tuberculocidal, or Fungicidal to disinfect the surfaces of the device. It is important to note that these chemicals only disinfect when they are wet and should be left wet on the device for at least 4-minutes.
3. Use a cotton swab soaked with Virucidal, Bactericidal, Pseudomonacidal, Tuberculocidal, or Fungicidal to disinfect the tight areas that were not accessible with the towel or wipes. Make sure the chemical stays wet on the device for at least 4-minutes.
4. Let the device air-dry entirely before using it.

TROUBLESHOOTING

Does not play message(s)

If the iTalk4 does not play a message, check the following:

1. Verify you have fresh alkaline batteries. We do not recommend any other battery chemistry.
2. Verify that batteries are installed correctly. You can place the AA batteries in the wrong orientation.
3. Verify that iTalk4 is turned on and the volume level is turned up.

iTalk4 has low volume

When activated, iTalk4 is too quiet.

1. Make sure iTalk4 is turned up all the way.
2. Rerecord message. The louder the sound being recorded, the louder the sound will playback.

PREVENTATIVE AND REGULAR MAINTENANCE

Clean the iTalk4 if necessary. No scheduled maintenance is required.

REUSABLE

iTalk4 should be sent back to the manufacturer for cleaning, testing and refurbishment before reuse with another patient.

DEVICES USED TOGETHER WITH

iTalk4 can be used to control other devices that are switch adapted.

iTalk4 messages can be also used with any ability switch that has a male 1/4 in (3.2mm) mono phone plug. Examples - AbleNet Jellybean Switch, AbleNet Spec switch, AbleNet Big Red switch

PROPER DISPOSAL

iTalk4 contains electronic components and should not be disposed of in your normal home or business waste collection. iTalk4 should be disposed of with a licensed electronics recycler.

WHEN TO CONTACT A HEALTHCARE PROFESSIONAL

If you have difficulty accessing the switches or need assistance with product placement.

Change in your condition.

NOTICE OF SERIOUS INCIDENT

Notice - If any serious incident has occurred while using this device, seek medical attention and then - please report to AbleNet, Inc and your competent authority of the member state in which you are in.