



Instructions For Use

BIGmack

Issue Date: February 26, 2024
Revision: 1.0

Model: 1000041
UDID: 00850011150061

 <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

BIGmack 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

Messages/Levels: 1 message up to 2-minutes long / 1 level

Recording Time: 2-min

Switch Input: 1

Toy/Appliance Output/ECU: 1

Activation Surface: 5-in/12.7-cm

Activation Force: 3 to 5-oz/85 to 142-g

Weight with Battery: 15.5-oz/439-g

Battery Type: 9-volt, It is highly recommended to use a standard alkaline 9V battery with this device. Alternative batteries may be comprised of materials that do not distribute power in a suitable manner, and when installed, some users may experience inconsistencies.

Mounting Connection: Universal Mounting Plate for Assistive Technology

HCPC Code: E2500

Material: Housing - ABS Plastic

Mounting: Threaded inserts

Qty: 3

Thread: 10-32

Center Distance: 5.02-in (12.76-cm)

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

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

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

DEVICE OVERVIEW



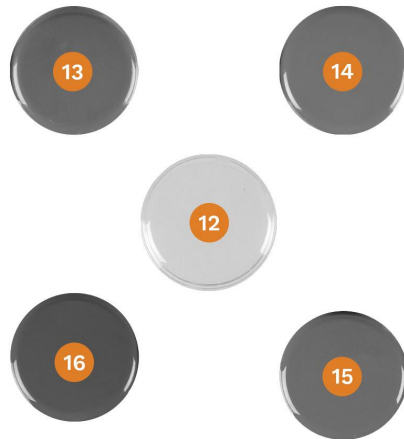
1	Switch Top
2	Speaker
3	Microphone



4	Battery Compartment
5	D-ring
6	Threaded Inserts For Mounting



7	1/8-in/3.5-mm toy/appliance input jack
9	1/8-in/3.5-mm switch input jack
9	On/Off and volume control
10	Record button
11	Recording Indicator light



12	Clear Cap
13	Yellow Switch Top
14	Blue Switch Top
15	Green Switch Top

USE INSTRUCTIONS

First Time Use

1. Turn BIGmack over, and open the Battery Compartment using the D-ring.
2. Insert a 9-volt battery, and close the battery compartment.
3. Turn on BIGmack.
4. Press and hold the record button until the recording indicator light turns on.
5. Press and hold the colored switch top. Begin speaking into the microphone after you hear the beep.
6. When done recording the message, release the colored switch top.
7. When done recording press the record button to exit record mode.
8. Adjust the volume as needed.

Using Overlays

A clear snap switch cap has been included with the BIGmack. Place a picture or symbol on the switch top, and secure by snapping your Switch Cap over it.

Using Alternate Switch Caps

1. Begin by removing the Clear Cap.
2. Firmly rotate the colored Switch Top counter-clockwise to remove it
3. Attach a new Switch Top by rotating the cap clockwise until it stops.
4. Replace the Clear Cap.

Using Ext. switch

The BIGmack can be controlled with an external switch.

Attach the switch of your choice with a 1/8-inch/3.5mm plug into the Switch Input jack on the back of BIGmack.

Controlling Toys or Appliances

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

1. Plug any switch-adapted toy or appliance into the Toy/Appliance jack.

While recording a message, press the Record Button one time to assign a toy or appliance to that message. When that message is played, an attached toy or appliance will activate for the length of the recorded message.

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 BIGmack 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 BIGmack is turned on and the volume level is turned up.

BIGmack has low volume

When activated, BIGmack is too quiet.

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

Will not operate toy or appliance that is plugged into it

Be sure BIGmack is turned on. Toy or appliance will activate for the length of time the message plays.

Will not work to operate a toy without playing a message.

PREVENTATIVE AND REGULAR MAINTENANCE

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

REUSABLE

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

DEVICES USED TOGETHER WITH

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

BIGmack message can also be accessed 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

BIGmack has electronic components and should not be disposed of in your normal home or business waste collection. BIGmack should be disposed of with a licensed electronics recycler that accepts lithium-ion batteries.

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.