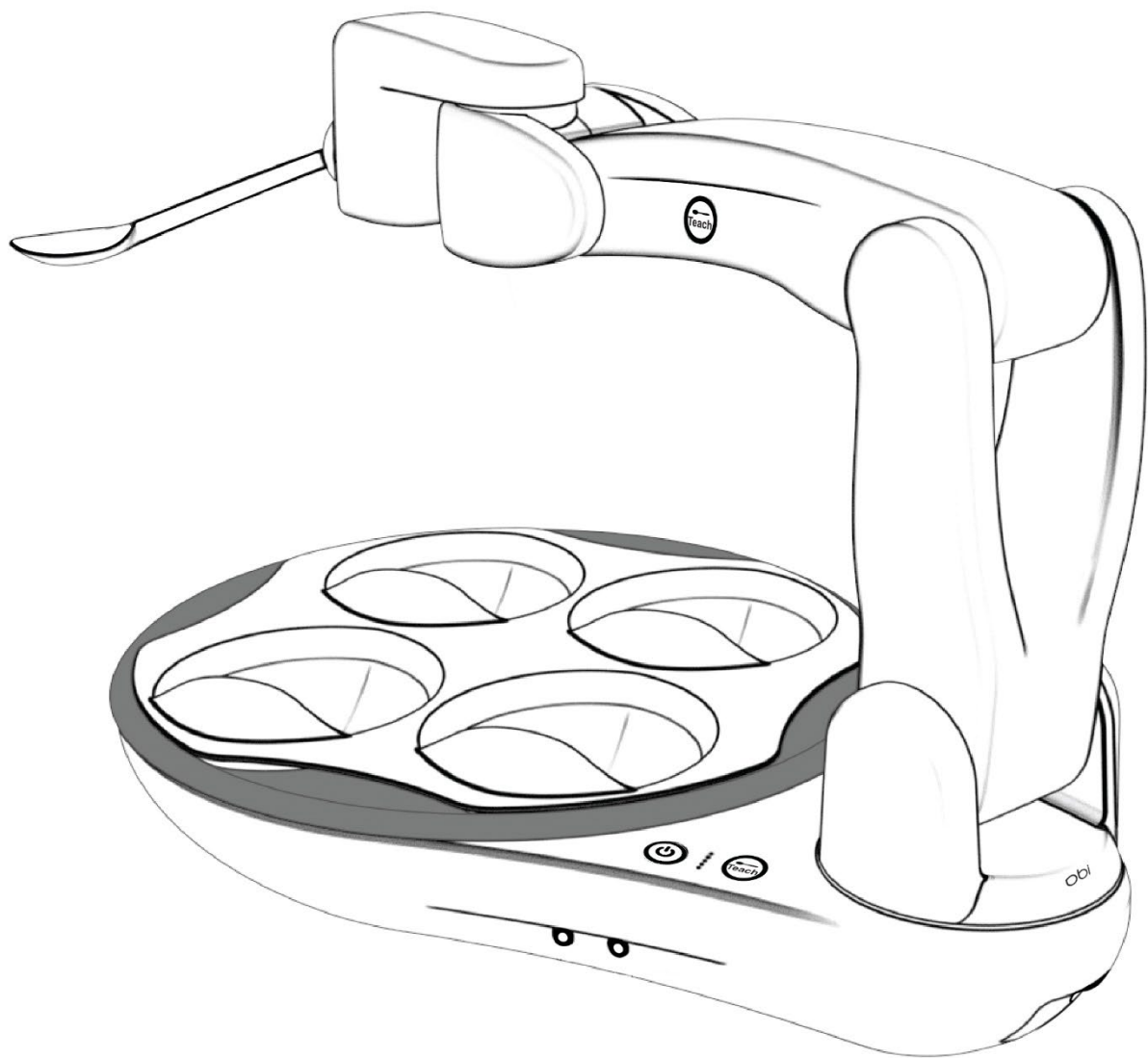


obi[®]



INSTRUCTIONS FOR USE

UDI-DI (GTIN by GS1): 0869174000106
IFD-600-003, INSTRUCTIONS FOR USE, R4.0.1 (ECO#167-2)

ABOUT DESIN LLC

DESIN LLC was founded in response to a personal family health tragedy in which DESIN LLC's founder witnessed his grandfather lose the ability to eat independently due to a degenerative neuromuscular disease. He painfully watched as his grandfather became depressed and especially apprehensive about his daily meals. After observing the same issue in nursing homes, and even with young patients, and unsatisfied with limited technology available on marketplace, DESIN has made it its mission since 2010 to lead the creation of a first of its kind medical device, Obi, the robot dining companion.

It is our sincere mission to provide an unparalleled experience and benefits to everyone in need of access to lasting independence.

DISCLAIMER

The content of this instructions for use is for informational use only, is subject to change without notice, and should not be construed as a commitment by DESIN LLC. Changes are made periodically to the information herein; these changes will be incorporated into new revisions of this publication. DESIN LLC may make improvements and/or changes to the products and/or software programs described in this publication at any time.

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This product uses software/firmware to which the company holds the rights.

Address comments to: info@meetobi.com

TRADEMARKS

® Obi is a registered trademark of DESIN LLC.

NOTES

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INTRODUCTION

Obi is indicated for people 5 years and older living with congenital or acquired neurological and/or physical impairment of the upper extremities/limbs affecting the ability to independently perform and participate in mealtime activities for daily living.

Obi is a reusable robotic utensil intended to compensate for the function of a human arm during mealtime activities to restore a person's functional eating status. Obi thereby alleviates/ameliorates the disability caused by medical diseases/conditions that completely or severely impair the upper extremities/limbs. Obi provides a cross cultural, broad user demographic with the ability to make decisions on what and when to eat through a user interface which is easy to learn and use.

The user interface accommodates mobility on most areas of the body through connections which are compatible with many different types of off-the-shelf Accessibility Switches. Further, the arm can adjust within a large volume of space thus accommodating individual ergonomic needs pertaining to the chosen food delivery position. Through Obi's Teach Mode, the food delivery point is taught easily, and the device will perpetually store this position, thus eliminating the need for re-currant setup and minimizing caregiver involvement.

By fulfilling its' intended use, Obi has the potential to improve quality of life and to alleviate/ameliorate or prevent medical issues known to be associated with lack of self-feeding, including but not limited to gastroesophageal reflux disease (GERD), aspiration, aspiration pneumonia, malnutrition, dehydration, psychological and/or social health impairment.

About the Instructions for Use:

This document contains information regarding intended use and how to ensure a safe and successful interaction with Obi. This instruction for use contains the essential safety warnings, instructions for interaction with the product, including its disposal, and contact information if needed.

Please read this information carefully: more knowledge obtained will increase safety and enjoyment of your Obi dining experience.

Always remember to keep this instructions for use in a convenient location for reference at any time.

This document is also available in electronic version at www.meetobi.com.

Obi is registered and listed with the *United States Food and Drug Administration (FDA)* and the *European Union (EU)*.

This instructions for use complies with *IEC60601-1: Medical Electrical Equipment – Requirements for Basic Safety and Essential Performance* (including applicable collateral standards).

IMPORTANT SAFEGUARDS

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

When using electrical products, especially when children are present, basic safety precautions should always be followed, including the following:

READ ALL INSTRUCTIONS BEFORE USING



DANGER:

To reduce the risk of electrocution, burns and injury:

- DO NOT use this device in a manner inconsistent with its' intended use and operating instructions.
- DO NOT use Obi as a method of administering medication.
- Never use Obi while sleeping or drowsy.
- DO NOT use Obi while bathing.
- DO NOT place or store Obi where it can fall or be pulled into a tub or sink.
- DO NOT place in or drop Obi into water, other liquid or snow. Obi is water resistant only (IP21)
- DO NOT reach for Obi if it has fallen into water. Unplug immediately.
- Check the Charging Cable for damage before each use.



WARNING:

To reduce the risk of electrocution, burns, fire, or injury to persons / device:



Charge Cable (AC Adapter):

- Never operate Obi if: it has damaged cords or plugs; if it is not working properly; if it has been damaged or dropped into water. Return the product to a service center for examination and repair. Please see the "Contact Information" section.
- Keep the cords away from heated surfaces.
- DO NOT use the Charging Cable in steamy, damp, or dusty areas.
- DO NOT modify the Charging Cable in any way.
- DO NOT cover the Charging Cable with clothing, blankets, or other materials.
- DO NOT touch the Charging Cable with wet hands.

- DO NOT plug this device into a voltage system that is different from the voltage system specified on Obi or the Obi Charging Cable.
- DO NOT place the Charging Cable within any bodily orifice.
- DO NOT use or leave the Charging Cable in direct sunlight.
- DO NOT touch the Charging Cable for a long period of time.
- Only use the provided Charging Cable to charge Obi:

Power Partners, PEAMD-72SF-13-1-BT1

- If the Obi Charge Cable does not fit the wall outlet in your region, please contact the distributor for a different power supply or a recommended power adapter. Only use a power adapter recommended by the distributor or DESIN LLC.
- Unplug the Charging Cable during lightning storms or when unused for long periods of time.

**Children:**

- Close supervision is highly recommended when initially observing or evaluating a child's ability to operate Obi safely and successfully. Young children, because of their small fingers, are at greater risk of being pinched by the Arm.
- To avoid danger of suffocation, keep plastic bags away from babies and children.
- DO NOT use bags in cribs, beds, carriages, or playpens. The bags are not toys.
- CHOKING HAZARD – small parts. Not for children under 3 years. Use with adult supervision only.

**Electromagnetic Energy:**

- Be aware that adding accessories or components, close to Obi's base, may make it more susceptible to electromagnetic interference (EMI) (There is no easy way to evaluate their effect on the overall immunity of the power wheelchair and/or your Obi).
- Be aware of nearby transmitters, such as radio or TV stations, and try to avoid coming close to them.
- In the presence of EMI, the following degradations may occur, and are free from unacceptable safety risk to the patient or user:
 - Motion disrupted by arm falling with all visual indicators flashing, then powering off.

- Movement from above one bowl to above another (choose sequence), without a user command.
- Scoping movement into a bowl, followed by movement to the point of delivery (food delivery sequence), without a user command.
- Report all incidents of unintended shut down to the manufacturer or a local distributor, and note whether there is a source of EMI nearby.

**Environment of Use:**

- DO NOT use where aerosol (spray) products are being used or in an oxygen enriched environment such as a hyperbaric oxygen chamber.
- DO NOT operate or store Obi outdoors or in extreme environments. Obi is for indoor use only.
- DO NOT place Obi on a wet surface.
- DO NOT place, store or operate Obi on an inclined surface.
- DO NOT place containers of liquid or any other item within 12 inches of the device to prevent interference with the arm during motion.

**Food Preparation:**

- Unplug Obi before filling with foods or liquids.
- Only fill the Plate's bowls with food and beverages.
- DO NOT place any component of Obi in an oven.

**Microwave Heating:**

- DO NOT microwave any other portion of Obi other than the Plate.
- When heating food, DO NOT use a power setting greater than 600Watts.
- DO NOT microwave past 70°C (158 °F) – migration has not been evaluated above this limit.
- If any food in contact with the Plate reaches a temperature of 150°C (300°F) or greater, damage to the Plate is possible (blistering, discoloration, etc).
- Microwave at your own risk of damage to the Plate.
- Do not cook food in the Plate; reheat only.

**Miscellaneous:**

- DO NOT carry Obi by the Arm.
- DO NOT place any part of Obi, other than the Plate, Placemat, and Spoons, in the dishwasher.
- DO NOT use solvents on Obi (example: turpentine, mineral spirits, gasoline, petroleum distillates, etc.). See Operating Instructions for proper cleaning.
- DO NOT cross or tangle wires connected to Obi to prevent trip hazards.
- Wash the Obi Spoon, Plate, and Placemat before their first use and after each subsequent use.
- To maximize Obi's lifespan, avoid using continuously keeping the robot in motion for periods longer than one hour at a time.
- The product label with the serial number is located on the bottom (sitting surface) of Obi. See "Technical Specifications" for more information.

**Modifications:**

- Any modification or disassembly of the device may void the product's warranty.
- DO NOT modify Obi in any way as this may damage the device or lead to severe injury.
- Only use attachments recommended by the manufacturer.
- Modifications made by the user not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
- DO NOT intentionally deform or misshape the Spoons. The product will no longer work.
- Never drop or insert any object into any opening.
- DO NOT push, pull, or force the Arm to move while Obi is powered on.
- DO NOT remove any labeling from Obi.
- DO NOT place anything on the Arm. This may damage the Arm.
- DO NOT crack or damage the housing of Obi. If the housing of Obi is cracked or damaged, DO NOT operate the device and contact the manufacturer immediately.
- Improper assembly of the Plate and Placemat on Obi may cause damage to the device and spillage of food.

- DO NOT drop Obi – this could degrade the product’s performance. Handle with care and only as directed.
- Save the original packaging box! Obi is a delicate precision instrument, DESIN LLC will not be responsible for the failure of custom packaging to adequately protect Obi from damage.



Service:

- DO NOT attempt to disassemble Obi, this will void the warranty.
- Only service the device with an authorized service representative.
- Return the product in the original packaging box.

SAVE THESE INSTRUCTIONS

REGARDING THE LITHIUM-ION BATTERY



For Customers in the U.S.A. and Europe:

THIS PRODUCT CONTAINS A 49Wh LITHIUM ION BATTERY.

DISPOSE OF LITHIUM-ION BATTERIES PROPERLY.

DO NOT attempt to disassemble Obi and remove or replace the battery pack.

Contact a local recycler, waste treatment facility, the distributor or DESIN LLC for further information on proper disposal. Please see the “Contact Information” section.



WARNING:

- The battery pack used in this device may present a fire or chemical burn hazard if mishandled.
- DO NOT dispose of batteries in a fire or trash incinerator.
- Use of a different battery may present a risk of fire or explosion.
- DO NOT disassemble, puncture, modify, drop, throw, or provide unnecessary stress to batteries.
- The battery pack used in this device can be recycled and a local waste treatment center may accept it.
- Dispose of batteries according to local laws and regulations in your region.
- Some regions prohibit the disposal of lithium-ion batteries in household and business trash.
- If you are not able to identify the applicable rules or waste treatment centers in your area, please contact a distributor or DESIN LLC.
- Special shipping requirements for lithium-ion batteries may apply.



CAUTION:

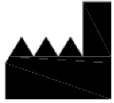
- Charge the battery at least once a year for infrequent use.
- Ensure the battery has at least a 40% nominal charge (2 solid LEDs) prior to storing for prolonged periods. This will help prevent a dead battery and increase battery life.

SYMBOLS

The following is a list of symbols that appear on the product, its packaging or labeling:



ISO 15223-1, No. 5.4.4: Caution. Consult the instructions for use for important cautionary information such as warnings and precautions. Also used to highlight the fact that there are specific warnings or precautions associated with the medical device, which are not otherwise found on the label.



ISO 15223-1, No. 5.1.1: Manufacturer.



ISO 15223-1, No. 5.1.2: Authorized representative in the European Community.



ISO 15223-1, No. 5.1.3: Date of Manufacture



ISO 15223-1, No. 05.3.1: Fragile, handle with care.



ISO 15223-1, No. 5.3.4: Keep dry.



ISO 15223-1, 5.4.3: Consult instructions for use.



ISO 15223-1, No. 5.7.7: This device is a Medical Device (MD).



IEC 60417-5031: Direct current.



IEC 60417-5333: Type-BF Applied Part (device)



ISO 7000, No. 0623: This way up.



ISO 7010-M002: Refer to instruction manual – mandatory action.



The letters "CE" abbreviate the French phrase *Conformité Européenne*, meaning, *European Conformity*. It signifies that the device complies with applicable directives and regulations of the European Union (see Declaration of Conformity).



For users in the European Union: Compliance with the current *Waste Electrical & Electronic Equipment Directive*.



This device complies with the current European *Restriction of Hazardous Substances Directive*.



This part is safe for food contact, with the exception of cooking food, and complies with the current European *Food Contact Directive*.



Microwave safe: In the presence of microwave radiation, the Plate alone will not heat to an unsafe handling temperature, warp, melt, or damage the microwave oven.



Dishwasher safe: Within a dishwasher top rack environment, the part alone will not heat to an unsafe handling temperature, warp, melt, or damage the dishwasher.



This part is safe to store in the refrigerator and freezer (Plate).



Please recycle this part at the end of its life (Plate, Placemat, & Spoons).



This part is BPA free (Plate, Placemat, & Spoons).

PACKAGE CONTENTS

This package includes the following contents:

- Obi
- Plate
- Placemat
- Spoons
- 2X Accessibility Switches
- Charging Cable / Power Supply
- Instructions for use
- Quick Start Guide
- Welcome Sheet



PLEASE SAVE OBI'S ORIGINAL PACKAGING MATERIALS IN CASE SHIPPING IS NECESSARY!

Obi is a precisely calibrated device and custom packaging solutions may not adequately protect Obi from functional damage.

INTENDED USE

Obi is a reusable robotic utensil intended to compensate for the function of a human arm during mealtime activities to restore a person's functional eating status. Obi thereby alleviates/ameliorates the disability caused by medical diseases/conditions that completely or severely impair the upper extremities/limbs.

In addition, by fulfilling its' intended use, Obi has the potential to improve quality of life and to alleviate/ameliorate or prevent medical issues known to be associated with impaired functional eating, including but not limited to gastroesophageal reflux disease (GERD), aspiration, aspiration pneumonia, malnutrition, dehydration, psychological and/or social health impairment.

**CAUTION:**

- It is the sole responsibility of the patient/user and/or their caregivers, to ensure a qualified clinician, appropriately knowledgeable of assistive feeding devices/Obi, assesses the patient's ability to operate Obi safely, including a determination of clinical benefits and medical necessity. Based upon benefit/risk ratio, the assessment should determine the amount of supervision required during use (if any), the patient's ability to chew and swallow without assistance and/or their risk of choking, and any appropriate dietary restrictions.
- Patients should be appropriately re-evaluated for benefit / risk when their disability type or severity significantly changes.
- Obi does not eliminate any prescribed/pre-existing dietary restrictions.

INDICATIONS FOR USE / INTENDED PURPOSE

Obi is indicated for people 5 years and older living with congenital or acquired neurological and/or physical impairment of the upper extremities/limbs affecting the ability to independently perform and participate in mealtime activities for daily living. Obi users may have the following medical diseases/conditions:

- A. Amputees
- B. Amyotrophic Lateral Sclerosis (ALS)
- C. Arthrogryposis Multiplex Congenital (AMC)
- D. Cerebral Palsy
- E. Congenital Limb Differences
- F. Developmental Disabilities
- G. Essential Tremor
- H. Multiple Sclerosis
- I. Muscular Dystrophy
- J. Parkinson's Disease
- K. Spinal Cord Injury
- L. Other conditions impairing motor control of the upper extremities.

In addition, Obi's users/patients must have the ability to operate a simple machine (e.g., a powered wheelchair), make decisions about food selection and consumption, and must be able to chew and swallow without assistance and/or risk of choking (see Contraindications).

CONTRAINDICATIONS

Any user with one or more following attributes should NOT eat with Obi:

- A. **Chewing Problems:** In mild or moderate cases, Obi can be used if the food is prepared to an appropriate consistency.
- B. **Cognitive Impairment:** Inability to understand correct use of the device.
- C. **Dysphagia:** Significant choking and swallowing impairment (unless Obi is indicated by an experienced physician or therapist and considered safe).
- D. **Head & Tongue Control Problems:** Insufficient tongue or head control appropriate to receive and swallow food offered by Obi.
- E. **Insufficient Movement:** Unable to operate any Accessibility Switch: Pressure Switch, Toggle Switch, Pillow Switch, Sip and Puff, etc.
- F. **Open Mouth Sores:** Any significant cuts, ulcerations, or oral bleeding.
- G. **Open Skin Sores:** Any open wound on an area of the body used to activate Accessibility Switch(es) or to contact Obi.
- H. **Reclined Positions:** Patients that cannot maintain a sufficiently upright position.

INTENDED USE ENVIRONMENT

Obi is intended to be used in a variety of environments and locations including (but not limited to):

1. Residential and Commercial Facilities:

- a. Assisted living centers
- b. Homes
- c. Hospices
- d. Hospitals
- e. Nursing homes
- f. Rehabilitation centers
- g. Restaurants
- h. Schools / Universities

2. Locations:

- a. Cafeterias
- b. Dining Rooms
- c. Kitchens
- d. Living room

3. Mounting: Use the device on a surface meeting all the following characteristics:

- a. Stationary, flat and dry.
- b. Cleaned or disinfected sufficiently for an eating environment and the user's needs.

4. Mobility: In case the user is in a mechanical or powered wheelchair at the time of use, ensure the wheelchair is positioned in the following manner:

- a. Fixed in appropriate location for use.
- b. Oriented in a sufficiently upright position promoting safe and effective swallowing behavior.

5. Hygienic:

- a. Clean and disinfect the Plate, Placemat and Spoons in accordance with the CLEANING & DISINFECTION section of this instructions for use.
- b. Follow basic hygiene practices, such as vigorous hand washing with soap and water, before and after handling food and food contact parts.

6. Frequency of Use:

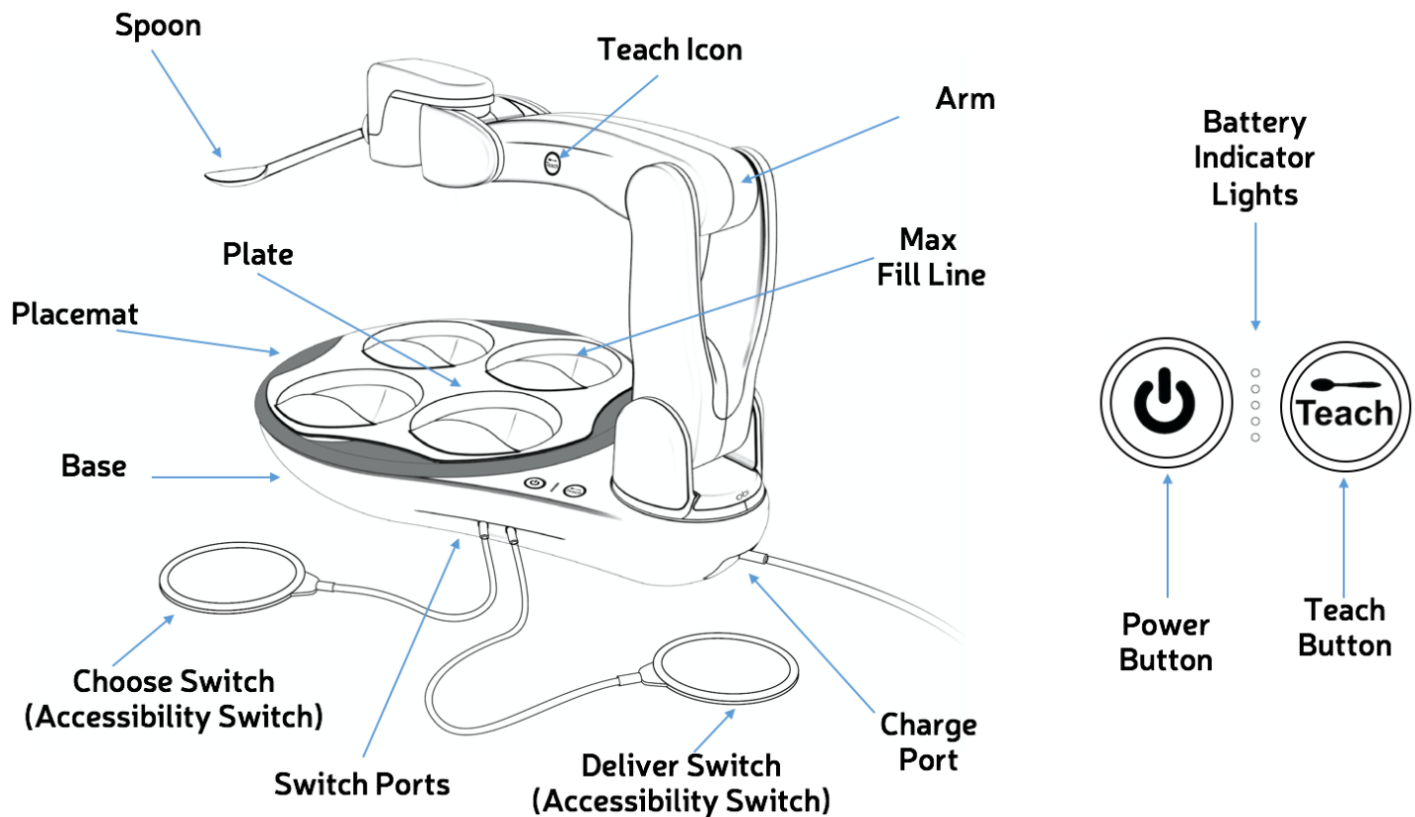
- a. Obi is intended for intermittent use; to be operated continuously for an hour interval or less.
- b. Between each meal, at least a one-hour power-off break is good practice. Sufficient power off breaks help maximize the life of Obi.

PRODUCT DESCRIPTION

Obi is a machine intended for individuals who cannot feed themselves. Obi's functionality mimics a human arm during eating. At least one off-the-shelf Accessibility Switch is required to eat with Obi. There are various types and styles of Accessibility Switches for purchase through DESIGN LLC and other vendors. Obi easily accommodates these, allowing the user to:

- Select what food to eat (Choose Switch).
- Command how to eat (Deliver Switch).

The following image illustrates Obi's main parts and features:



OPERATING INSTRUCTIONS

Prior to first time use, please charge the device for approximately half an hour.

Please refer to the **Quick Start Guide** for general operating instructions and added visuals. If needed, download an electronic copy of the **Quick Start Guide** at www.meetobi.com

FOOD PREPARATION

Obi's Plate is for serving, and warming food only. It is NOT for cooking food.

If prepared to an appropriate size, nearly any food works with Obi. Optimally, ¼" by ¼" (6mm X 6mm) or about the size of a pea works best. However, up to ¾" by ¾" (19mm X 19mm) or about the size of a raspberry should also work.

For an optimal experience, always fill the Bowls up to, but not exceeding, the Max Fill Line.

Note1: The Plate (with or without food) may be safely stored in the refrigerator or freezer.



CAUTION:

- DO NOT cook food in the Plate.
- Always vigorously wash hands with soap and water prior to preparing food or handling food contact parts.
- Filling beyond the Max Fill Line makes capturing and delivering food more difficult for Obi and may cause spillage upon capture and delivery.
- DO NOT place excessively hot food or liquids in the Plate which could potentially burn the user / patient.
- Use care if placing the Plate under a heat lamp. Do not leave under the lamp for extended periods as the part could soften and warp and will not be covered under warranty.

MICROWAVE

Use the microwave to warm or reheat food or liquid to a desirable eating temperature.

The Plate is the only Obi component deemed “microwave safe”. When the Plate alone is in presence of microwave radiation, it will not heat to an unsafe handling temperature, warp, melt or damage the microwave oven.

When heating food in the Plate, use a low power setting (≤ 600 Watts).

Microwave in short intervals (≤ 1 minute), stirring frequently in-between each interval to avoid hot spots.

Note1: To maximize Plate life, warm or cook food in other glass or ceramic cookware.



CAUTION:

- DO NOT cook food in the Plate.
- DO NOT microwave any other portion of Obi other than the Plate.
- When heating food, DO NOT use a power setting greater than 600Watts.
- DO NOT microwave past 70°C (158°F) – migration has not been evaluated above this limit.
- If any food in contact with the Plate reaches a temperature of 150°C (300°F) or greater, damage to the Plate is possible (blistering, discoloration, etc).
- Microwave at your own risk of damage to the Plate. Microwave damage will not be covered under warranty.

SET UP

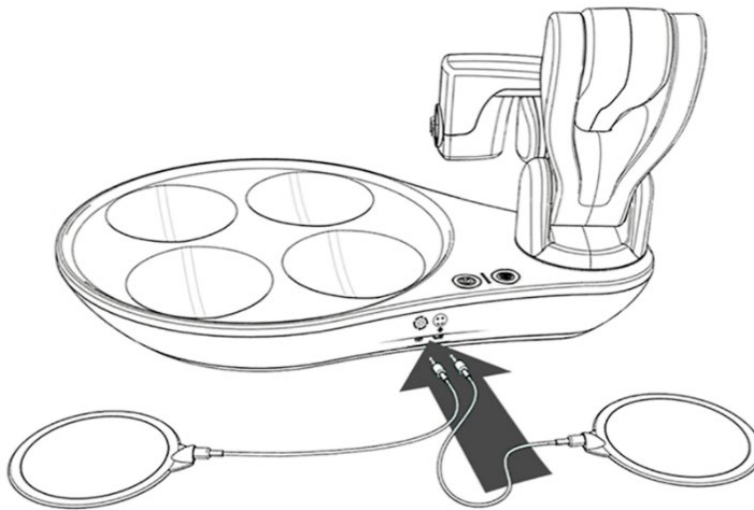
Place Obi on a stationary, flat and dry surface. Ensure there are no dinner glasses or other objects within approximately 25cm (12in) of any part of Obi's Base.

Next, ensure Obi is seated at a location and orientation accommodating a region in front of the user's mouth (See TEACH MODE section). This may take trial and error before achieving a desirable configuration.

Once positioned properly, gently move the Arm to the right of the bowl compartments as shown below.

Prior to inserting the accessibility switch barrel jack connectors into the receptacles on Obi, check to ensure they are clean and free of dust or debris. This practice will help prevent wear and maximize the life of the connection.

Next, Insert the desired accessibility switches into the Deliver Port and/or Choose Port of Obi until a click is felt and heard. Obi also operates with a single Accessibility Switch installed. See ONE SWITCH MODE section.



CAUTION:

- DO NOT place containers of liquid or any other item within 25cm (12in) of the device to prevent obstructions with the Arm when it's in motion.
- DO NOT place Obi on a wet surface.
- DO NOT place Obi on an inclined surface.

Next, insert the Placemat then Plate, ensuring the keyed slots align.

Note1: Obi's Switch Ports are 3.5mm barrel jack (headphone jack) connectors. Any wired, un-powered accessibility switch, less than 153cm (5ft) in length is recommended for use.

Note2: Velcro tape may be helpful to secure adaptive switches in place i.e., headrest, floor, tabletop, armrests etc.

Note3: Wheelchair specific table and tray attachments may be available to use with Obi. Please contact your wheelchair manufacturer to see if such an accessory is available.

POWER ON

Ensure the battery is sufficiently charged prior to use.

Ensure the Arm is positioned similarly to the previous image in the "Setup" section; to the right of the four bowls, then gently touch the Power Button. The button will illuminate a continuous white and Obi will wake to greet you. Obi's Arm will then position itself above the first bowl.

Note1: If the Teach Button flashes after pressing the Power Button, the Arm must be moved. Please ensure the Arm is in a similar area and orientation to the previous image in the "Set Up" section.

Note 2: If the device indicates an Alternating Flash of Power and Teach Button, the device is too cold or too warm. Please allow the device to sit at room temperature for up to a half hour before powering on again.



CAUTION:

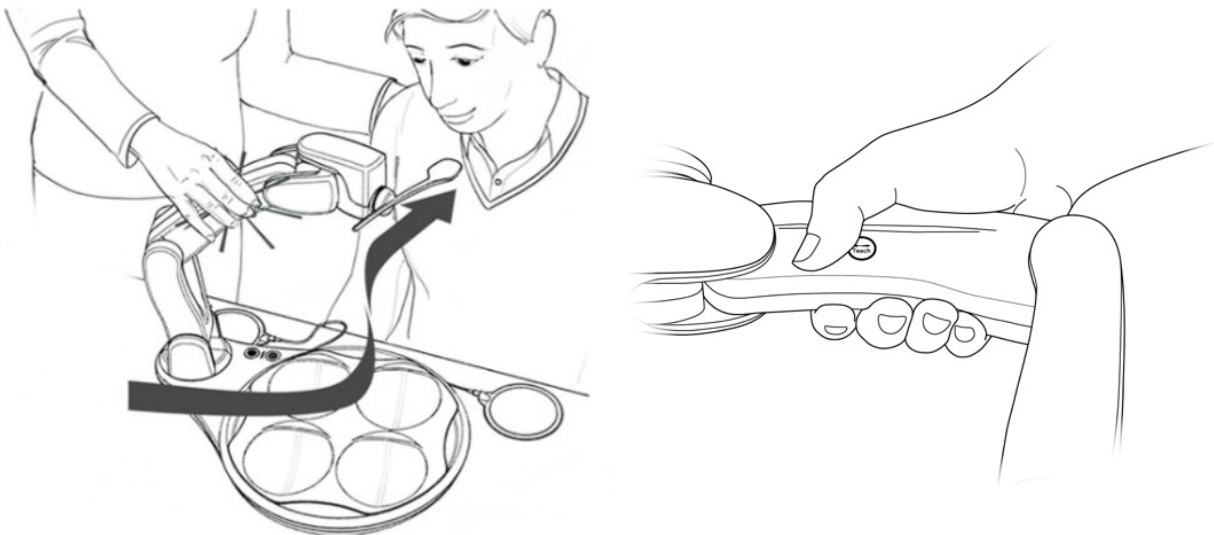
- When the Placemat and Plate align incorrectly, they are NOT fixed, and Obi will NOT function properly.

TEACH MODE

Teach Mode enables a caregiver to quickly tailor a custom food delivery location in front of the user's mouth. Before entering Teach Mode, ensure the patient is sitting upright, and that the table and chair are sufficiently fixed, such that they will not roll away during a meal.

To enter Teach Mode, gently touch the Teach Button on the Base. When the button activates, it illuminates a continuous white.

Grasp the Arm, with a finger touching the Teach Icon. Ideally, the thumb should cover the Teach Icon and the fingers should wrap around the Arm, as shown below. While continuing to make contact with the Teach Icon, lift the Arm as shown in the images below.



When the Teach Icon is covered, the Arm will be free for the caregiver to move. The last two sections of the Arm will remain engaged and will keep the Spoon level when moving within the teach space. If resistance to movement is present, the thumb is probably not completely covering the Teach Icon.

Teach the spoon to deliver food in front of the user's mouth. Only after achieving a desired location, release the Arm. Obi will immediately hold position. If another change in position is necessary, simply grasp the Arm, with your thumb or finger covering the Teach Icon, and move as previously instructed. Repeat as many times as needed until a satisfactory position is achieved.

Once satisfied with the food delivery location, press the illuminated Teach Button on Obi's Base to store the position to Obi's memory. Obi will remember the taught position until re-taught (irrespective of how many times powered on and off). If the Teach Button is flashing, the current position is invalid (see notes below) and cannot be stored.

Note1: Not all physical positions are valid for teaching a point of delivery. An approximate recommended teach space (for the tip of the Spoon) is illustrated grey in the aerial view below.

If the Arm has been moved outside the illustrated teach space, the Teach Button on the Base will begin to flash, and Obi will shake / rotate his head side to side. This signal means: “please relocate the Arm”.



Note2: If left unsupported in an extended invalid position, the Arm will fall, and the Teach Button will continue to flash. When this occurs, promptly re-teach the Arm as previously instructed. If left unsupported for several seconds, Obi will power off. If this happens, simply move the Arm to the right of the Plate as shown in the “Set Up” section and power on Obi again.

Note3: A continuously illuminated Teach Button with the head shaking / rotating side to side means, “the Arm is being handled incorrectly”. A user is pulling or pushing the Arm without touching the Teach Icon.

Note4: During Teach Mode, the Arm should move easily. First, please ensure a finger is in contact with the Teach Icon.



WARNING:

- Choking Hazard: DO NOT Teach a delivery position such that the Spoon will penetrate the user’s mouth.
- Choking Hazard: DO NOT Teach a delivery position to accommodate a reclined position.



CAUTION:

- DO NOT force the Arm to move when teaching. If there are any issues, please see the “Contact Information” section of this instructions for use.
- DO NOT intentionally deform or misshape the Spoons as they will no longer scoop through the bowls correctly. Attempt to re-teach the arm instead.



DELIVERY COMMAND

To capture and transport food and liquid to the taught location, activate the Deliver Switch:

Note1: After activating an Accessibility Switch, Obi will carry out the complete choose or deliver sequence. While the Arm is in motion, interruptions (besides collision) cannot occur. That is, the Accessibility Switches and Teach Button will only operate when the Arm is stationary. However, the user may activate the Power Button at any time to Power Off the device.

CHOOSE COMMAND

To select a bowl, activate the Choose Switch:



RETURN COMMAND

After eating from the Spoon, either the Deliver Switch or the Choose Switch can be activated. Press the Deliver Switch to return the Arm to the same Bowl. Press the Choose Switch to return the Arm to a different Bowl.

FOOD REMOVAL & REPLACEMENT COMMAND

If the user initiates a Return Command immediately before or after the Spoon arrives at the food delivery location, the Arm will dispense the food back in the proper Bowl.

REPOSITION SEQUENCE

After several scoops from the same bowl, Obi will automatically use the Spoon to reposition food back to the center of the bowl.

ONE SWITCH MODE

Obi can operate off of one Accessibility Switch. The installed Accessibility Switch will act like a Deliver Switch. That is, Obi will automate the choosing of bowls (moving one bowl position counterclockwise) every few delivery cycles.

SLEEP MODE

After two minutes of inactivity, the Arm will move to the Storage Position to save battery power. In this position, the Arm remains stationary, and the power button will stay illuminated. During this time, if the device senses any command, Obi will immediately wake up and continue normal operation. If the half hour elapses without any command, Obi will automatically power off.

COLLISION DETECTION

If an object interferes with the moving Arm, Obi will stop and slightly back away. During this situation, the Power Button will flash. After a collision occurs, please first remove the obstructing object. When ready, press either switch and Obi will continue the intended path.

Note1: If the Spoon collides with an object, it is likely to disconnect from the Arm and fall. This occurs to prevent injury.

POWER OFF

To turn off Obi, gently touch the Power Button continuously for one second. Obi will proceed to the Storage Position and turn off.

Note1: If the power off command initiates while the Arm is in motion, the Power Button will repeatedly double flash. Obi will proceed to the Storage Position and turn off once present movement is finished.

BATTERY CHARGE

Prior to first time use, please charge the device for approximately half an hour.

If attempting to charge a used device with a fully depleted and unresponsive battery, please see the TROUBLESHOOTING section.

When only one Battery Indicator Light is illuminated and flashing, Obi needs to charge. The single light will begin flashing quickly when Obi only has a few minutes of power left.

If Obi does run out of power during operation, the Arm will automatically move to the Storage Position and Obi will power off.

To Charge in the US:

Connect the Charging Cable to a 120V, 60hz socket and to the Obi Charge Port, located under the device Arm. See the “Product Description” section for a visual.

To Charge in the European Union:

Connect the Charging Cable to a 230V, 50hz socket and to the Obi Charge Port, located under the device Arm. See the “Product Description” section for a visual.

When the illuminated Battery Indicator Light flashes slowly, the battery is successfully charging. As the battery charges from empty to full, the five Battery Indicator Lights will proportionately illuminate a continuous white. For example, if three of the five Battery Indicator Lights are illuminated a continuous white, the battery is sixty percent charged.

Once all five Battery Indicator Lights are illuminated, and no flashing occurs, Obi has a full charge. Disconnect the Charging Cable from Obi and the wall socket.

NOTE 1: Obi does not need a full charge before disconnecting the Charging Cable; partial charging is acceptable.




CAUTION:

- Only use the Power Supply provided with Obi: *PEAMD72-SF-13-1-BTI*
- If the Obi Charge Cable does not fit the wall outlet in your region, please contact the distributor for a different power cord adapter. Only use an AC power adapter recommended by DESIN LLC.

CLEANING & DISINFECTION

Clean the Plate, Placemat and Spoons with dish soap and water or in a dishwasher (using a detergent) before the first use, and after each subsequent use. After each meal, clean or disinfect the device body and its' accessories immediately following completion of the meal. Always clean or disinfect in accordance with the following instructions:

Component	Clean (same patient, between uses)	Disinfect (between patients, or as needed)
Plate, Placemat, & Spoons	A. Frequency: after each meal B. Method(s): <ul style="list-style-type: none"> STEP 1: Rinse, and if necessary, scrub, components in the sink to remove bulk food particles. STEP 2: Place parts in the dishwasher using a detergent (set to "hot cycle"), top rack recommended. STEP 2 – alternate: Scrub all surfaces with dish soap & hot water, then rinse until all soap is removed. STEP 3: Prior to handling clean parts, vigorously wash hands with soap and water, then apply a new pair of clean nitrile gloves. STEP 4: Pat dry with a clean paper towel. STEP 5: Store in the same manner as other dishware (clean, dry place). STEP 6: Visually inspect all food contact parts prior to each use to ensure they are visibly clean and have not sustained any visual signs of degradation. 	
Base & Arm	A. Frequency: after each meal B. Method(s): <ul style="list-style-type: none"> STEP 1: Saturate a clean paper towel or cotton cloth with warm water. STEP 2: Wring out thoroughly. STEP 3: Wipe down the device to remove errant food particles. STEP 4: Obtain a household disinfecting wipe. STEP 5: Sufficiently wring out the wipe. STEP 6: Wipe down and let air dry. 	A. Frequency: after each meal B. Method(s): <ul style="list-style-type: none"> STEP 1: Saturate a clean paper towel or cotton cloth with warm water. STEP 2: Wring out thoroughly STEP 3: Wipe down the device to remove errant bulk food. STEP 4: Obtain a healthcare / hospital grade disinfecting wipe or solution (ex. <i>Clorox Healthcare</i>). STEP 5: Ensure the disinfecting solution is not expired and that it is compatible with PC/ABS plastic. STEP 6: Test in an inconspicuous area. STEP 7: Saturate a clean paper towel with a healthcare / hospital grade disinfecting solution. STEP 8: Follow instructions on disinfecting solution to ensure proper contact times.
 CAUTION: <ol style="list-style-type: none"> Ensuring sufficient cleaning and disinfection of the device is the sole responsibility of the customer. The product is not intended to be sterile or sterilized. <u>NO STERILIZATION PROCESS SHOULD BE APPLIED TO THE PRODUCT.</u> If operating Obi in a healthcare facility: <ol style="list-style-type: none"> Only handle food contact parts after vigorously washing hands with soap and water, and after applying a new set of nitrile gloves. It is best practice for each new user of Obi to obtain their own new set of a Plate and Spoons. Disinfect all components in-between uses by different patients. If cleaning within an industrial dishwasher, ensure the temperature of the dishwasher does not exceed 100°C. Exceeding this temperature could degrade the physical properties of the magnets mounted in the spoons. Industrial dishwashers may degrade components faster than dishwashers intended for home use. When attempting a new method of cleaning or disinfection, first attempt in an inconspicuous area. To maximize part life, wash the Plate, Placemat, and Spoon with dish soap by hand (recommended for home use only). DO NOT use food contact parts with visible signs of degradation. DO NOT spray the Base or Arm directly with any liquid. DO NOT place the electronic device in the dishwasher, or under a faucet of running water. DO NOT rub any components of the device with abrasive materials. DO NOT use solvents on Obi (example: turpentine, mineral spirits, gasoline, petroleum distillates, etc.). DO NOT use disinfecting wipes to clean food contact parts. DO NOT use food contact parts for which the level of cleanliness is unknown, such as: parts which have fallen on the floor, parts handled by people, or parts which have been left sitting out. 		

MAINTENANCE

Part(s)	Activity / Method	Conditions / Frequency
Plate, Placemat and Spoons	Replace components after A or B have occurred	A. The parts have undergone over four hundred (400) cycles in a dishwasher. B. The parts have visual signs of degradation, such as, but not limited to: warp, blisters, fissures, cracks or discoloration. C. To avoid parts with degradation, we recommend replacing the parts annually.
Battery	Charge past 40% (2 SOLID LEDS)	At least once every 6 months, or twice per year (2X/Yr) to avoid a dead or degraded battery.
Barrel Jack Connectors; Accessibility Switch Connections	<ul style="list-style-type: none"> STEP 1: Direct compressed, dry air into each barrel jack port to remove any bulk trapped debris. STEP 2: Insert then twist a Q-tip (some cotton may need to be stripped away to ensure it fits) into each port to remove finer debris and build up. STEP 3: Repeat Step 2 with additional Q-tips until there is no visible debris being removed. STEP 4: Use a soft cloth to gently wipe clean the barrel jack pins of the Accessibility Switches. 	At least once per year (1/Yr) recommended. If or when the Accessibility Switches become intermittently unresponsive; as needed.



CAUTION:

- DO NOT use food contact parts with visible signs of degradation.
- There is no "home serviceable" part inside the product. DO NOT open.
- If any fissure, crack or crevice traps food and removal is not achievable with the CLEANING AND DISINFECTION procedures of this instruction for use, please contact an authorized service representative.

STORAGE

Environmental Conditions for Storage:	-20° to 60°C, 15 to 93% humidity (short duration)
	12° to 30°C, 40 to 55% humidity (recommended)

Store the Plate, Placemat and Spoons in a location where there is a high confidence in an appropriate level of cleanliness for clean dishware.

Note1: Keep the Obi package, as it makes a great storage container.

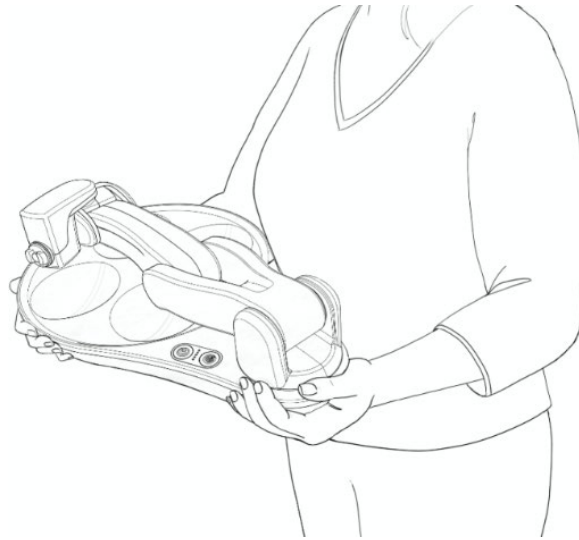


CAUTION:

- DO NOT store Obi near stovetops, fireplaces, and radiant heaters.
- DO NOT store Obi near a floor drain, or excessive source of humidity or moisture.

TRANSPORT & SHIPPING

For easy carrying or travel, place the Arm in the Transport Position as shown below (with or without the Spoon, Plate and Placemat).



Because of Obi's curved contours, carrying is convenient in a multitude of positions other than the one pictured above.

The Obi package includes a durable handle, making a convenient travel case.

When shipping Obi by ground, sea, or air please abide by the following:

Environmental Conditions for Transport:	-20° to 60°C, up to 93% humidity (short duration)
	12° to 30°C, 40 to 55% humidity (recommended)



CAUTION:

- Obi should ship in its original packaging box unless the box has sustained a great deal of damage.
- Obi is a precisely calibrated device and custom packaging solutions may not adequately protect Obi from functional damage.
- Please notify the shipper that Obi is a fragile, delicate instrument that necessitates handling with care.
- Obi encloses a 49Whr lithium-ion battery. Special shipping requirements for lithium-ion batteries may apply.
- Always include a desiccant bag (for at least 1.50 cubic feet) for protection against humidity and condensation.

END OF LIFE

Private households - Information on Disposal for Users of WEEE



This symbol on the product and / or accompanying documents means that used electrical and electronic equipment (WEEE) should not mix with general household waste. For proper treatment, recovery, and recycling, please take this product to designated collection points where it will be accepted free of charge.

Alternatively, in some countries, you may be able to return your products to your local retailer upon purchase of an equivalent new product.

Disposing of this product correctly will help save valuable resources and prevent any potential negative effects on human health and the environment, which could otherwise arise from inappropriate waste handling.

Please contact your local authority for further details of your nearest designated collection point.

Penalties may be applicable for incorrect disposal of this waste, in accordance with your national legislation.

For professional users in the European Union:

If you wish to discard electrical and electronic equipment (EEE), please contact your dealer or supplier for further information. Please see the "Contact Information" section.

For disposal in countries outside of the European Union:

This symbol is only valid in the European Union (EU). If you wish to discard this product, please contact your local authorities or dealer, and ask for the correct method of disposal. Please see the "Contact Information" section.

EU Waste Electrical and Electronic Equipment (WEEE) Directive:

In August of 2005, the European Union (EU) implemented the EU WEEE Directive 2002/96/EC and later the WEEE Recast Directive 2012/19/EU requiring Producers of electronic and electrical equipment (EEE) to manage and finance the collection, reuse, recycling and to appropriately treat WEEE that the Producer places on the EU market after August 13, 2005. The goal of this directive is to minimize the volume of electrical and electronic waste disposal and to encourage re-use and recycling at the end of life.

DESIN LLC has met its national obligations to the EU WEEE Directive by registering in those countries to which DESIN LLC is an importer. DESIN LLC has also elected to join WEEE Compliance Schemes in some countries to help manage customer returns at end-of-life.

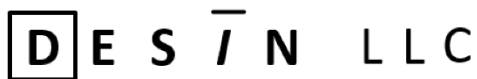
If you have purchased DESIN LLC -branded electrical or electronic products in the EU and are intending to discard these products at the end of their useful life, please DO NOT dispose of them with your other household or municipal waste. DESIN LLC has labeled its branded electronic products with the WEEE Symbol to alert our customers that products bearing this label should not be disposed of in a landfill or with municipal or household waste in the EU. Instead, please be aware that DESIN LLC is making a return and collection system available to you, free of transportation and recycling costs, for discarding these products.

CONTACT INFORMATION

If any serious safety incident has occurred in relation to Obi, report the incident to the manufacturer and the Food and Drug Administration (FDA). For users in Europe, report to the competent authority of the Member State in which the user and /or patient is established.

For Users in the United States:







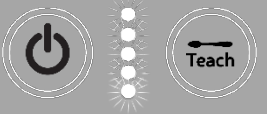
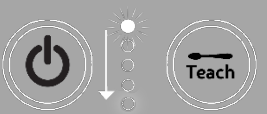



Designed, manufactured, and distributed by:



DESIN LLC (pronounced "Design")
7018 AC Skinner Parkway, Suite 270
Jacksonville, FL 32256
Tel: 1-844-HelpObi (435-7624)
E-mail: service@meetobi.com
Internet: www.meetobi.com

This list does not include the contact information for all distributors and suppliers of Obi.

APPENDIX I: LIGHTING PATTERNS


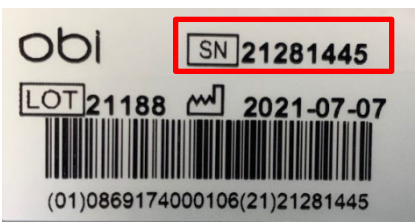
NORMAL OPERATION		
Lighting Pattern		Meaning
	Solid Power Button	Obi is powered on and running normally.
	Flashing (slow) Battery Point LED	Obi is actively charging the battery. Obi could be on or off.
	Flashing (fast) Bottom Battery Point LED	Obi has a critically low battery. The device will soon automatically return to the sleep position and power-off.
	Double Flashing Power Button	Obi is in the process of powering down.
	Solid Power and Teach Button	Obi is in Teach Mode; Delivery and Choose commands will not respond.
	Solid Power Button, Flashing Teach Button	The arm is out of position. If attempting to power on the device, please move the arm to a valid start up position, see the POWER ON section. If in Teach Mode, please move the arm to a different position using the Teach Icon.
FAULT/ERROR CONDITION		
If these errors occur frequently, please contact an authorized service representative.		
Lighting Pattern		Meaning
	Flashing, All Battery LEDs Simultaneously	Shutdown Error, Servo Voltage: An electrical anomaly may have been detected by the battery, Power Supply or Servo.
	Flashing, Downward Moving Battery LED	Shutdown Error, Servo Over-Load. Too much force may have been applied to the arm while at a stationary position (not moving).
	Flashing, Power Button	Collision: Normal movement has been stopped due to an overload sensed by one or more servos. An overload is likely due to interference with an environmental object.
	Flashing, Alternating Power and Teach Button	Shutdown Error, Extreme Temperature: Obi is outside the acceptable operational temperature window. Obi was probably recently removed from an extreme environment such as a car in winter/summer.
	Flashing, All LEDs Simultaneously	Shutdown Error, Servo Communication. A signal anomaly may have been detected on the communication line.

APPENDIX II: TROUBLESHOOTING

If the applicable issue is not listed below, or if the problem persists after troubleshooting, please contact an Obi authorized service representative with the serial number and date of purchase. Some common problems and their solutions are as follows:

SYMPTOM	REMEDY
Battery – Does Not Charge	<ul style="list-style-type: none"> a. Ensure the correct power supply is being used (PEAMD-72SF-13-1-BT1) b. Confirm that the power supply and charge cable are firmly connected together. c. If Obi has been unused for a long duration, the battery may have entered a protective standby mode. Please attempt the following to initiate a recovery charge: <ul style="list-style-type: none"> i. Insert the live charge cable into the Obi charge port. ii. Remove the charge cable from Obi then quickly re-connect it (within 3s). The bottom LED should start flashing. iii. Allow approximately 2 hours to charge. In this event, it is normal for Obi to take longer than normal to recharge.
Arm – Does Not Startup	<ul style="list-style-type: none"> a. Check to ensure the Arm is in a valid start up position (please see POWER ON section). If the Arm is in an invalid location, the Teach Button will flash, and movement will not start. b. Attempt a few slightly different arm locations to the right of the bowls.
Scooping / Food Delivery Issue	<p>To ensure an optimal experience, food size, quantity and consistency should be reasonably workable by a spoon (see FOOD PREPARATION section):</p> <ul style="list-style-type: none"> a. Size: Ensure food is prepared within the correct size: Optimally, $\frac{1}{4}$" by $\frac{1}{4}$" (6mm X 6mm), or about the size of a pea, works best. However, up to $\frac{3}{4}$" by $\frac{3}{4}$" (19mm X 19mm), or about the size of a raspberry, should also work. b. Quantity: Ensure food is not filled above the max fill line in each bowl. c. Consistency: Ensure food is appropriately un-sticky and can be easily separated by a spoon scoop.
Choose/Delivery Command - Unresponsive	<ul style="list-style-type: none"> a. Ensure both accessibility switches are fully and firmly inserted. b. Relocate the problem accessibility switch to the alternate switch port to determine whether the connector or the accessibility switch is the problem. c. Consult the MAINTENANCE section of this document and perform the listed activities for the barrel jack connectors.
Collisions	<p>As appropriate, ensure:</p> <ul style="list-style-type: none"> a. the spoon is not physically deformed from its proper shape. b. food bowls are free of any large/hard obstruction. c. there are no surrounding objects within Obi's space of movement. d. Obi comes to a complete stop at the delivery point before taking a bite. <p>If the problem persists – Obi is likely in need of calibration. Please contact an authorized service representative.</p>

APPENDIX III: TECHNICAL SPECIFICATIONS

Accessibility Switch Connector	3.5mm male, mono barrel jack (0.138") 
Adhesive - Arm	Epoxy (Medical Grade; ISO-10993)
Applied Part (entire device)	Type-BF
Base Mounting Surface Material	Thermoplastic elastomer (Latex & nat. rubber free)
Battery Life per Charge	2-5 hours
Battery Type	Lithium ion (49Wh / 3.2Ah)
Degree of Ingress Protection	IP21; safety protected against: <ul style="list-style-type: none"> • solid objects over 12.5mm • vertically falling drops of water or condensation
Dimensions (Transport Position)	30.5cm X 43.2cm X 15.2cm (12" X 17" X 6")
Dishwasher Safe Components	Plate, Placemat, Large Spoon and Small Spoon.
Enclosure Material	PC/ABS, UL94V-0 flame class rating
Food Bowl Volume Capacity	118mL (4 fl. Oz.) / Bowl (up to max fill line)
Food Safe Components	Plate, Placemat, Large Spoon and Small Spoon.
Food Safe Materials	Polypropylene (FDA & EU compliant ingredients)
UDI-DI (GTIN issued by GS1)	0869174000106
Lowest Food Delivery Height	5.0cm (2.0in) (below the mounting surface)
Maximum Food Delivery Height	38.1cm (15.3in) (above the mounting surface)
Maximum Motor Speed	20RPM
Medical Device Classification	Class I, active, non-sterile & non-measuring.
Microwave Safe Components	Plate
Environmental Operating Conditions	12° to 40°C, 15% to 93% humidity (short duration)
	12° to 30°C, 40% to 55% humidity (recommended)
	700 hPa to 1060 hPa atmospheric pressure
Peak Power	68Watts
Recyclable components	Plate (#5), Placemat (#5), Large Spoon (#5), Small Spoon (#5), Lithium Ion Battery (RRC2054). Other components may also qualify. Talk to your local waste treatment center.
Serial Number	<p>The number is located on the bottom surface of the Base, as shown:</p> 
Weight – Obi (no food)	3.49kg (7.7lbs)

APPENDIX IV: FCC COMPLIANCE STATEMENT

FOR UNITED STATES USERS:

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.



CAUTION:

- Modifications made by the user not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
- Operating Obi while the power supply is plugged in and actively charging may prevent compliance with 47CFR15 Class B for radiated emissions.

APPENDIX V: EU DECLARATION OF CONFORMITY



DECLARATION OF CONFORMITY

MANUFACTURER: DESIN LLC

SRN: US-MF-000008647

ADDRESS: 7018 AC Skinner Parkway, Suite 270
Jacksonville, FL 32256

TEL: 248-766-2085

FAX: 248-858-9076

E-mail: jdekar@desincorp.comWEBSITE: www.meetobi.com

MANUFACTURER'S AUTH. REP. Focal Meditech BV

SRN: NL-AR-000000549

ADDRESS: Droogdokkeneiland 19
5026SP Tilburg
Netherlands

TEL: Tel.: +31 (0)13-533 31 03

FAX: Fax: +31 (0)13-533 50 04

E-mail: info@focalmeditech.nlWEBSITE: www.focalmeditech.nl

WE, DESIN LLC, UNDER OUR SOLE RESPONSIBILITY, HEREBY DECLARE:

DEVICE (MODEL):

Obi (IFD-500-030)

DESCRIPTION

Independent Eating Device (Class I Medical Device, Active, Non-Sterile, Non-Measuring)
BASIC UDI-DI: 086917400010bi34

CONFORMS WITH THE FOLLOWING STANDARDS:

NUMBER	TITLE
ISO13485: 2016	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
IEC60601-1: 2012	Medical Electrical Equipment - General Requirements for Basic Safety and Essential Performance.
ISO 14971: 2019	Application of Risk Management to Medical Devices
IEC60601-1-2: 2020	Medical Electrical Equipment - Electromagnetic Disturbances - Requirements and Tests
IEC60601-1-6: 2020	Medical Electrical Equipment - Usability
IEC60601-1-11: 2015	Medical Electrical Equipment - Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment
IEC62304: 2015	Medical Device Software - Software Life Cycle Processes
NEN EN 15284: 2007	Materials and Articles in Contact with Food Stuffs. Test Method for the Resistance to Microwave Heating of Ceramic, Glass, Glass-Ceramic or Plastic Cookware.
EN50581:2012	Technical Documentation for the Assessment of Electrical and Electronic Products with Respect to the Restriction of Hazardous Substances

AND IF APPLICABLE, CONFORMS WITH THE FOLLOWING DIRECTIVES:

NUMBER	TITLE
MDR 2017/745	Medical Device Regulation
EC/1935/2004	Food Contact Directive
2014/30/EU	Electromagnetic Compatibility (EMC) Directive
2014/35/EU	Low Voltage Directive
2015/863	RoHS3 Directive
2012/19/EU	WEEE2 Directive
93/68/EEC	CE Marking Directive

ORIGINATED, REVIEWED AND APPROVED BY:

Jon Dekar; CEO, DESIN LLC

SIGNATURE: 

DATE (MM/DD/YYYY): 06/20/2023

APPENDIX VI: EU FOOD CONTACT DECLARATION OF COMPLIANCE

EU Food Contact Declaration of Compliance				
Manufacturer		DESIN LLC 7018 AC Skinner Parkway, Suite 270 Jacksonville, FL 32256		
Product covered by this declaration:		IFD-500-000, Obi		
Parts covered by this declaration		Utensil SM (IFD-400-025) Utensil LG (IFD-400-062) Plate (IFD-400-027)		
Date of declaration (mm/dd/yyyy):		04/20/2020		
Declaration of compliance with:				
<ul style="list-style-type: none"> • (EC) No. 1935/2004 (as amended) • (EC) No. 10/2011 (as amended) • (EC) No. 2023/2006 (as amended) 				
The monomer(s), additive(s) and processing aids used in the manufacture of the listed polypropylene parts are authorized by the Regulation.				
Information about the compliance of substances used that are subject to any restriction or specification				
Compliance with Overall Migration Limits (OML)		Overall migration is less than 1mg/dm ² (limit is 10mg/dm ²) under standard testing conditions laid down in Regulation (EC) No. 10/2011 (see Note#1).		
Parts	Resin Ingredient	Substance	Specific Migration Limits (SMLs)	Test results or calculated estimate (see Note#1)
Utensil SM & LG	Additive	Aluminum	1mg/kg	<1mg/kg
	Additive	Proprietary1	6mg/kg	
	Additive	Proprietary2	1.2mg/kg	
Plate	Polypropylene Homopolymer	DSTDP, CAS#693-36-7	5mg/kg	
	DSTDP Stabilizer	DSTDP, CAS#693-36-7	5mg/kg	
Information about the use of "dual use" additives in the material				
Plate	E470a, Calcium salts of fatty acids			
Conditions of use:				
Food Types		All		
Time & Temperature Limits		While in contact with foods:	70°C for 2 hours (do not exceed)	
		While stored in contact with food:	24 hours, <4°C (recommended)	
Information used to establish the compliance of the material or article				
The ratio of food contact surface area to volume		Utensil LG	107.83(cm ²): 11.52(cm ³)	
		Plate	1599.02(cm ²): 188.51(cm ³)	
Functional Barrier				
There is no functional barrier present.				
Note#1: Further information is available with a non-disclosure agreement in place. Reference the following certificate of analysis: DESIN LLC DESIN LLC 20-75343 CoA ver.01. Additionally, a comprehensive food contact report is available: IFD-DES-024, Obi Food Contact Report.				

APPENDIX VII: LIMITED WARRANTY

DESİN LLC (“DESİN”) guarantees, subject to the terms below, that if your Obi is verified to be defective in material or workmanship at the time of delivery, DESİN will, at its discretion, either: (i) repair Obi using new or refurbished parts or (ii) replace Obi with a new or refurbished device.

Terms: United States -the limited warranty expires 12 months from the date of shipment or after the first 400 hours of usage, whichever occurs first. Europe - for warranty information, please contact your distributor.

Limitations: This Limited Warranty excludes Spoons, Plates, Placemats, and switches. Spoons, Plates, Placemats, and switches are non-returnable once used. Only manufacturing defects of materials or workmanship are covered when Obi is used properly and maintained in accordance to all included instructions. This warranty is void if Obi is improperly handled, dropped, put in a microwave, or exposed to excessive liquid(s), etc. In addition, any attempt(s) to open or dismantle Obi, including the Arm or Base assembly, will void this warranty. The warranty is limited to the initial purchaser of the Obi. The term of warranty identified above also operates to limit any implied warranties of merchantability or fitness under State law. Some States DO NOT allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you. DESİN will not be liable for any incidental or consequential damages as a result of customer use. Some States DO NOT allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.

Instructions: In order to obtain warranty service, deliver the Obi in either its original packaging or packaging with an equal degree of protection to the service center designated by DESİN or an authorized representative. An intact serial number or UPC is required for warranty claims. An issued RMA number may also be required by DESİN or an authorized distributor. The customer is responsible for all shipping and handling charges for the return of the Obi for warranty service, unless otherwise notified. For more information on how to obtain warranty service on your device in the US or Europe, please see “Contact Information”, or contact your distributor.

Other Terms and Conditions/Legal Rights: This warranty is issued pursuant to the terms and conditions of sale entered into when you purchased your Obi, the provisions of which govern this Limited Warranty. This Limited Warranty gives you specific legal rights, and you may also have other rights which vary from State to State.

Return Policy: An unopened, unused or lightly used Obi generally may be returned within 14 days of the shipping date for a refund. A restocking fee may apply.

Please contact 1-844-HelpObi or Service@MeetObi.com for return details.

APPENDIX VIII: TERMS AND CONDITIONS

1. **Acceptance:** All Purchase Orders (as defined below) or other proposed agreements for the sale of goods ("Goods") by DESIN LLC ("DESIN") are subject to acceptance, in writing, by DESIN and are not binding on DESIN unless so accepted. These Standard Terms and Conditions ("Standard Terms of Sale") are applicable to all purchase orders, quotations, schedules or ancillary agreements concerning the sale of Goods, of any nature (collectively, the "Purchase Order"), and are the only terms and conditions that apply to the sale of DESIN's Goods, except those specifically set forth in any Purchase Order and accepted in writing by DESIN. Any term or condition or standard of performance different from or in addition to these Standard Terms of Sale, whether set forth on the Purchase Order or otherwise proposed by Customer, must be agreed to, in writing, by DESIN in advance, and in the event of any conflict or inconsistency, between these Standard Terms of Sale and any Purchase Order or other document proposed by Customer, these Standard Terms and Conditions will control. Customer agrees that Customer's submission of a Purchase Order to DESIN or Customer's acceptance of any Goods provided by DESIN shall constitute Customer's irrevocable acceptance of these Standard Terms of Sale.
2. **Prices:** Prices for the Goods set forth in the Purchase Order, unless otherwise stated in writing, DO NOT include taxes, as set forth in these Standard Terms and Conditions, transportation or shipping charges, special packaging or other services unless otherwise set forth in the Purchase Order. Prices are all quoted in denominations of United States' Dollars. The price for custom items not otherwise available for sale will be quoted by DESIN on a job-by-job basis. DESIN reserves the right to correct any error in prices.
3. **Terms of Payment:** Unless otherwise specified in writing, payment shall be received by DESIN prior to any shipment of any Goods. Payment shall be made in denominations of United States currency.
4. **Customer Inspection:** Upon Customer's receipt of shipment, Customer shall immediately inspect the Goods. Unless Customer provides DESIN with written notice of any claim for shortages of or patent defects in the Goods within five (5) days after receipt of shipment, such Goods shall be deemed finally inspected, checked and accepted by Customer and in full compliance with these Standard Terms of Sale.
5. **Delivery/Packaging:**
 - a. DESIN shall use reasonable commercial efforts to make delivery of Goods or perform services within the time requested on Customer's Purchase Order. DESIN shall use its own discretion in choice of carrier and method of packing. DESIN has no obligation to obtain insurance for Customer covering Goods in transit to Customer.
 - b. Prices stated are based on DESIN's standard packaging. Packaging will be standard commercial packaging and acceptable to the commercial carrier.
6. **Cancellation and Returns:** Only unopened and unused Goods can be returned to DESIN for a refund of the Customer's purchase price, provided Customer returns such Goods to DESIN within 14 days after the date of shipment to Customer. All returns must be postmarked by the fourteenth day. Customer is responsible for all shipping costs to return any Goods. Prior to issuing any refund, DESIN reserves the right to inspect all returned Goods to determine whether such Goods remain unopened and unused. No other returns of Goods shall be accepted without the prior written approval of DESIN. DESIN may exclude special orders from this 14-day return policy if done so in writing prior to accepting Customer's order.
7. **Force Majeure:** DESIN will not be liable or otherwise responsible for any damage, loss, fault, or expenses arising out of delays in manufacturing, shipment or other non-performance of any Purchase Order caused or imposed by: strikes, fires, disasters, riots, acts of nature; intervention of government, war or threat of war, acts of terrorism, conditions similar to war, sanctions, blockades, embargoes; acts of Customer; shortages of labor, fuel, power, materials, supplies, transportation, or manufacturing facilities; governmental action, subcontractor delay or any other cause, condition or circumstance beyond DESIN's reasonable control (collectively, "Force Majeure"). If there is a delay or nonperformance due to Force Majeure, then DESIN may, at its option, and without liability, revoke all or any portions of its acceptance of Customer's Purchase Order and/or extend any date upon which any performance thereunder is due.
8. **Limited Warranty/Disclaimer of Warranties:** The parties expressly agree that Customer's sole and exclusive remedy against DESIN shall be for the repair and replacement of defective Goods as provided herein. THE WARRANTIES SET FORTH BELOW ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING THOSE OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, ALL OF WHICH ARE EXPRESSLY DISCLAIMED. NO AFFIRMATION OF DESIN, BY WORDS OR ACTION, OTHER THAN AS SET FORTH IN THIS SECTION, NOR ANY ADDITIONAL WARRANTIES, EXPRESS OR IMPLIED, MADE BY DESIN TO CONSUMER PURCHASERS OF THE GOODS SHALL CONSTITUTE A

WARRANTY HEREUNDER. DESIN's warranty does not apply to any Goods that have been subjected to misuse, mishandling, misapplication, neglect (including but not limited to improper maintenance), accident, improper installation, modification (including but not limited to use of unauthorized parts or attachments), or adjustment or repair performed by anyone other than DESIN or one of DESIN's authorized agents. In no event shall DESIN be responsible for the quality or performance of any goods manufactured by other parties; such Goods shall carry only the warranty of the manufacturer.

Except as otherwise set forth below, any claim by Customer with reference to the Goods sold pursuant to the Purchase Order shall be deemed waived by the Customer unless submitted in writing to DESIN within the earlier of (i) five (5) days following the date Customer discovered, or by reasonable inspection should have discovered, any claimed breach of the foregoing warranty, or (ii) thirty (30) days following the date of shipment. Any legal dispute for breach of the foregoing warranty shall be initiated within one (1) year from the date the alleged breach was discovered or should have been discovered, whichever occurs first.

Subject to the provisions of these Standard Terms of Sale, the Limited Warranty that applies to all Goods sold is as follows:
SEE LIMITED WARRANTY.

9. Limitation of Liability: DESIN WILL IN NO EVENT BE LIABLE FOR ANY CONSEQUENTIAL, SPECIAL, INCIDENTAL, INDIRECT, PAIN AND SUFFERING, OR PUNITIVE DAMAGES TO ANY PERSON, WHETHER BASED UPON BREACH OF WARRANTY, NEGLIGENCE, STRICT LIABILITY, TORT, BREACH OF CONTRACT OR ANY OTHER THEORY, REGARDLESS OF WHETHER THE REPLACEMENT OR REFUND REMEDY SET FORTH ABOVE FAILS OF ITS ESSENTIAL PURPOSE OR FOR ANY OTHER REASON WHATSOEVER. "CONSEQUENTIAL DAMAGES" FOR PURPOSES HEREOF SHALL INCLUDE, WITHOUT LIMITATION, LOSS OF USE, INCOME OR PROFIT, OR LOSSES SUSTAINED AS THE RESULT OF INJURY (INCLUDING DEATH) TO ANY PERSON OR LOSS OR DAMAGE TO PROPERTY (INCLUDING, WITHOUT LIMITATION, PROPERTY HANDLED OR PROCESSED BY THE USE OF THE GOODS).

10. Safety Information: DESIN has supplied or made available to Customer certain information relating to safety conditions and procedures concerning the Goods, and Customer acknowledges receipt thereof and further acknowledges that it has reviewed and understands same. Customer agrees to abide by all safety procedures and warnings provided by DESIN, and further agrees to use the Goods only in conformity with the instructions provided and the intended use(s) of the Goods.

11. Trademarks: The purchase of Goods from DESIN does not entitle Customer to use, register, or otherwise identify Customer or its business with the name, trademark, service mark or other identity of DESIN or the name Obi or its likeness without express written permission from DESIN. All such marks and goodwill associated with such marks remain the sole and exclusive property of DESIN.

12. Taxes: Unless otherwise specifically provided on the face of any Purchase Order, the price for the Goods purchased does not include sales, use, excise or similar taxes, whether tariffs, duties, special assessments. The amount of any such taxes, tariffs, duties and special assessments applicable to the Goods shall be paid by Customer in the same manner and with the same effect as if originally included in the purchase price.

13. Additional Charges: If substitute or additional Goods, or repair parts, are purchased by Customer from DESIN, the provisions of these Standard Terms of Sale shall be applicable to such purchase, the same as if such substitute or additional Goods or repair parts had been originally purchased hereunder.

14. Entire Agreement: These Standard Terms of Sale, together with the terms and conditions contained on the face side of DESIN's invoice or quotation, constitute the entire agreement between DESIN and Customer with respect to the matters contained therein, and supersedes all prior oral or written representations, proposals, correspondence, discussions, negotiations and agreements. No course of prior dealings, acceptance or acquiescence in a course of performance and no usage of the trade shall be relevant to supplement, explain or modify any terms contained herein. All representations, promises, warranties or statements by an agent or employee of DESIN that differ in any way from the terms and conditions hereof shall be given no effect or force. No waiver or alteration of terms herein, including any added or different terms identified on any invoice, quotation, or Purchase Order, shall be binding unless in writing signed by an executive officer of DESIN.

15. Priority: In the event of any inconsistency among the provisions in these Standard Terms of Sale or the Purchase Order, precedence shall be given first to these Standard Terms of Sale, and second, to the special terms and conditions contained on the face of the Purchase Order and accepted, in writing, by DESIN.

16. Governing Law: The sale of Goods pursuant to the Purchase Order shall be subject to and construed in accordance with the laws of the State of Michigan, United States of America, applicable to contracts made and performed in the State of Michigan without giving effect to any

choice or conflict of law provision or rule (whether of the State of Michigan or any other jurisdiction) that would cause the application of the laws of any jurisdiction other than the State of Michigan. Exclusive jurisdiction and venue for any action arising between the parties with respect to the Goods shall lie in the Courts of Oakland County, Michigan or in federal courts situated in the Eastern District of Michigan (Southern Division) if federal court jurisdiction is invoked. The parties irrevocably consent and submit to the personal jurisdiction of said courts and agree not to challenge or assert any defense to the exclusive jurisdiction and venue of said courts including, without limitation, forum non conveniens. Customer and DESiN agree that, notwithstanding these exclusive jurisdiction and venue provisions, the parties intend to be bound by the mandatory arbitration clause articulated in these Standard Terms of Sale. The parties hereby exclude the application of the United Nations Convention on Contracts for the International Sale of Goods.

17. Severability: If any provision of these Standard Terms of Sale is deemed invalid or unenforceable by any court of competent jurisdiction or under any statute, regulation, ordinance, executive agreement or other rule of law, such provision shall be deleted or modified, at the election of Customer and DESiN, but only to the extent necessary to comply with such ruling, statute, regulation, ordinance, agreement or rule, and the remaining provisions of these Standard Terms of Sale and the Purchase Order shall remain in full force and effect.

18. Non-Waiver: No change, modification or waiver of any provision of these Standard Terms of Sale shall be valid or binding unless it is accepted in writing, by DESiN. A waiver by either party of any breach or failure to enforce any term or condition of these Standard Terms of Sale shall not in any way affect, limit or waive such party's right at any time to enforce strict compliance with that or any other term or condition of these Standard Terms of Sale.

19. Binding / Non-Assignment: This contract shall be binding upon and shall inure to the benefit of the successors, and permitted assigns of Customer and DESiN, provided, however, that Customer may not assign any portion of its rights or delegate any portion of its obligations hereunder or under any Purchase Order without in each instance obtaining DESiN's prior written consent. Any attempted assignment by Customer or assignment by Customer of this contract without DESiN's prior written consent is void.

20. DESiN's Performance Excused Upon Customer's Breach: In addition to the rights and remedies conferred upon DESiN by law or in equity, DESiN shall not be required to proceed with the fulfillment of any Purchase Order or the performance of any contract if Customer is in default in the performance of any order or contract with DESiN, and in cases of doubt as to Customer's financial responsibility, shipments under this order may be suspended or sent sight draft with bill of lading attached by DESiN. Additionally, in the case of subsequent orders or, in the case of open Purchase Orders, DESiN is not required to proceed with the fulfillment of any subsequent order or perform such open Purchase Order if Customer is in breach with regard to any prior fulfilled orders, including, without limitation, non-payment.

21. Binding Arbitration: Any controversy or claim arising out of or relating to the Goods, these Standard Terms of Sale, or any related agreement between Customer and DESiN shall be settled by binding arbitration in accordance with the following provisions:

- a. The agreement of the parties to arbitrate covers all disputes of every kind relating to or arising out of these Standard Terms of Sale and the goods, as well as any claim based on tort or any other causes of action relating to the transactions contemplated by of these Standard Terms of Sale, such as claims based on an allegation of fraud or misrepresentation and claims based on a federal or state statute. In addition, the arbitrators selected according to procedures set forth below shall determine the arbitrability of any matter brought to them, and their decision shall be final and binding on the parties.
- b. The forum for the arbitration shall be Oakland County, Michigan (USA).
- c. The governing law for the arbitration shall be the laws of the State of Michigan, as more fully provided for in the "Governing Law" section of these Standard Terms of Sale.
- d. There shall be three arbitrators, unless the parties are able to agree on a single arbitrator. In the absence of such an agreement within 10 days after the initiation of an arbitration proceeding, each party shall select one arbitrator, and those two arbitrators shall then select, within 10 days, a third arbitrator. If those two arbitrators are unable to select a third arbitrator within that 10-day period, a third arbitrator shall be appointed through the Arbitrator Selection Process facilitated through the American Arbitration Association. The decision in writing of at least two of the three arbitrators shall be final and binding on the parties.
- e. The rules of arbitration shall be the Consumer Arbitration Rules of the American Arbitration Association, as modified by any other instructions that the parties may agree on at the time, except that each party shall have the right to conduct discovery in any manner and to the extent authorized by the Federal Rules of Civil Procedure as interpreted by the federal courts. If there is any conflict between those rules and the provisions of this Section 21, the provisions of this Section shall prevail.

- f. The arbitrators' decision shall provide a reasoned basis for the resolution of each dispute and for any award. The arbitrators shall not have the power to award damages in connection with any dispute in excess of actual compensatory damages and shall not multiply actual damages or award consequential or punitive damages or award, pain and suffering, or any other damages that are excluded under the provisions of these Standard Terms of Sale.
- g. Each party shall bear its own fees and expenses (including attorney fees) regarding the arbitration and any related proceeding, and the parties shall share equally the fees and expenses of the arbitrators.
- h. The arbitrators shall have power and authority to award any remedy or judgment that could be awarded by a court of law in the state of Michigan consistent with these Standard Terms of Sale. The award rendered by arbitration shall be final and binding on the parties, and judgment on the award may be entered in any court of competent jurisdiction in the United States.



Designed, manufactured and distributed by:

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