



SPEECH THERAPY DEVICE
DADDY
USE AND MAINTENANCE MANUAL



Read this leaflet carefully before using the Daddy device, it contains important information for the correct performance of the speech therapy treatment.

DADDY is a medical device specifically designed for use in speech therapy: it must not be used for any other purpose. The goal is the rehabilitation of sensoriality and oral motor skills both verbally and non-verbally. In particular, the rehabilitation objectives consist of: enhancing mandibular stability, promoting independent movements between the oral districts, regulating sensory perception, increasing proprioception and tonic motor control of the jaw muscles, facilitating the emergence of new phonemes.

Intended use environment: there are no restrictions.

Intended user: the device can be used by people with oral sensory and motor problems. The device can only be used under the responsibility of an adult. The device was designed to be used on the patient by a speech therapist or by an adult trained by the speech therapist who prescribed its use. Brief training is required for users orally or in writing with specific methods and times of use or autonomously by viewing the online procedures in the video tutorial (after prescription, access the reserved area at <https://gruppotom.it/area-reserved/> or using the QR code.

Treatable areas/ Part of the body with which the medical device interacts: dental arches, upper and lower lips, tongue. The device is intended to come into contact with the intact mucosa of the mouth, do not use in case of damaged mucosa.

Application of the device: the device may only be used for its intended purpose. During use, the patient must be seated with feet firmly on the ground. Show the patient the incompressible nature and hardness of the device before introducing it into the mouth to avoid the patient exerting excessive pressure with the teeth. Before placing the device between the teeth, make sure that there are no lesions on the oral mucosa or teeth, that there are no pathological oral reflexes. The device must be for personal use only for each patient to avoid contamination. Do not expose to continuous heat sources above 80°C.

Times of use: the times of use foreseen for the therapy vary from a single session to 3/4 sessions per week. For each session the times (minimum-maximum) are: from a few seconds to a few minutes, at the discretion of the speech therapist who prescribes their use.

Undesirable effects: DADDY speech therapy devices do not produce undesirable effects when used in a compliant manner. You must report any serious incidents that have occurred in relation to the device to the manufacturer and the Competent Authority.

Contraindications: each device is personal, it should not be exchanged with others. Do not use or replace the device if there are any signs of material degradation on it. Do not use the device in contact with injured parts.

Cleaning and conservation: the device must be cleaned after each use with disinfectant products. The device can then be washed with running water at a temperature not exceeding 80°C. The device must be manipulated by the therapist exclusively by touching the central part with the thumb and forefinger after carefully sanitizing the hands. Store inside a clean package.

Disposal: the device, being made up exclusively of PMMA material, and therefore being in line with the IPPC guidelines, is completely recyclable. Therefore, it must be disposed of and recycled according to the directives of your municipality of residence.

It has no time or use limit, the device is personal and has unlimited duration for each patient.



Made by:

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