GIMA

PROFESSIONAL MEDICAL PRODUCTS

MONOFILAMENTO
MONOFILAMENT
MONOFILAMENT
EINZELFADEN
MONOFILAMENTO
MONO-FILAMENTO
ΜΟΝΟΜΗΜΑΤΙΟ
ديحولا طيخلا

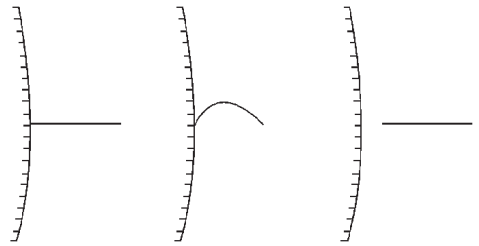
È necessario segnalare qualsiasi incidente grave verificatosi in relazione al dispositivo medico da noi fornito al fabbricante e all'autorità competente dello Stato membro in cui si ha sede.
All serious accidents concerning the medical device supplied by us must be reported to the manufacturer and competent authority of the member state where you registered office is located.
Il est nécessaire de signaler tout accident grave survenu en relation avec le dispositif médical que nous fournissons au fabricant et à l'autorité compétente de l'État membre dans lequel il est basé.
Es necesario notificar cualquier accidente grave que se produzca en relación con el producto sanitario suministrado por nosotros al fabricante y a la autoridad competente del Estado miembro en el que se encuentre.
É necessário comunicar qualquer acidente grave que ocorra em relação ao dispositivo médico fornecido por nós ao fabricante e à autoridade competente do Estado-Membro em que está sediado.
Jeder schwerwiegende Unfall im Zusammenhang mit dem von uns gelieferten Medizinprodukt ist dem Hersteller und der zuständigen Behörde des Mitgliedstaats, in dem es seinen Sitz hat, zu melden.
Είναι απαραίτητο να αναφερθεί οποιοδήποτε σοβαρό ατύχημα που συνέβη σε σχέση με το ιατροτεχνολογικό προϊόν που παρέχεται από εμάς στον κατασκευαστή και στην αρμόδια αρχή του κράτους μέλους στο οποίο βασίζεται.
من الضروري الإبلاغ عن أي حادث خطير يقع فيما يتعلق بالجهاز الطبي المقدم من قبلنا إلى الشركة المصنعة والسلطة المختصة في الدولة العضو التي يوجد بها.

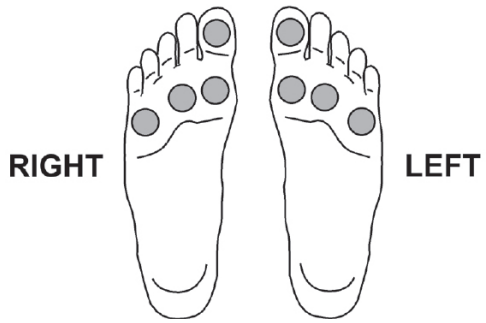
Gima S.p.A.
Via Marconi, 1 - 20060 Gessate (MI) Italy
gima@gimaitaly.com - export@gimaitaly.com
www.gimaitaly.com
Made in China

MD

CE REF 31282

GIMA





ENGLISH

MONOFILAMENT

Show the filament to the patient and touch it to his/her hand or arm so that he/she knows it does not hurt.
Use the 10 gram filament to test sensation at the indicated sites on each foot as shown. Apply the filament along the perimeter of, and NOT directly on, an ulcer, callus, scar or necrotic tissue.

The monofilament is an instrument for a preliminary diagnosis of sensory neuropathy which can be caused, for example, by diabetes. The foot is one of the parts of the body which are affected by the damage caused by neuropathy as the peripheral sensory perception is compromised; the monofilament can detect a patient's ability to perceive moderate pressures.

The MONOFILAMENT bends at a pressure of 10 grams for at least 50/60 times before bending to a lower force; it is recommended to change the wire after the use on 6/15 patients and allowed to rest for at least 24 hours before being reused. It can work optimally at a temperature of 20/26°C

GIMA

with humidity 30/50% without deforming. With temperature higher then 33°C and with humidity ar 80%, the filament can be deformed and make the diagnosis less accurate. The filament was tested to determine the accuracy of bending to 10 grams and the deformation force has been recognized at +/- 10%. Substitute definitely the filament after 150/200 bendings.

Hold the filament by exercising a moderate pressure perpendicular to the skin an use a smooth motion when testing.
Hold the filament perpendicular to the skin and use a smooth motion when testing. Use a 3-step sequence that includes (1) touch the skin, (2) bend the filament, and (3) lift from the skin (See Figures 1- 3). Do not use rapid movement. The approach, skin contact, and departure of the filament should be approximately 1.5 seconds in duration.
Ask the patient to respond "yes" when the filament is felt. If the patient does not respond when you touch a given point on the foot, continue on to another site.
When you have completed the sequence, REPEAT on the area(s) where the patient did not indicate feeling the filament.
Use the filament in a random sequence.

LOSS OF PROTECTIVE SENSATION AT ANY ONE OF THE EIGHT SITES (shown on the diagram above) INDICATES A FOOT AT HIGH RISK.
It is recommended to disinfect the product after each use on a patient by using a non-alcoholic antibacterial disinfectant.

GIMA WARRANTY TERMS
The Gima 12-month standard B2B warranty applies.

M31282-M-Rev.7-12/21

GIMA

REF	**GB -** Product code **FR -** Code produit **IT -** Codice prodotto **DE -** Erzeugniscode **ES -** Código producto **PT -** Código produto **GR -** Κωδικός προϊόντος **PL -** Numer katalogowy **SE -** Produktkod **RO -** Cod produs **HU -** Termékkód **SA -** كود المنتج
LOT	**GB -** Lot number **FR -** Numéro de lot **IT -** Numero di lotto **DE -** Chargennummer **ES -** Número de lote **PT -** Número de lote **GR -** Αριθμός παρτίδας **PL -** Kod partii **SE -** Satsnummer **RO -** Număr de lot **HU -** Tételszám **SA -** رقم الدفعة
	GB - Keep in a cool, dry place **FR -** À conserver dans un endroit frais et sec **IT -** Conservare in luogo fresco ed asciutto **DE -** An einem kühlen und trockenen Ort lagern **ES -** Conservar en un lugar fresco y seco **PT -** Armazenar em local fresco e seco **GR -** Διατηρείται σε δροσερό και στεγνό περιβάλλον **PL -** Przechowywać w suchym miejscu **SE -** Förvara på svalt och torrt ställe **RO -** A se păstra într-un loc răcoros și uscat **HU -** Száraz, hűvös helyen tárolandó **SA -** يحفظ في مكان بارد وجاف
	GB Keep away from sunlight **FR** À conserver à l'abri de la lumière du soleil **IT** Conservare al riparo dalla luce solare **DE** Vor Sonneneinstrahlung geschützt lagern **ES** Conservar al amparo de la luz solar **PT** Guardar ao abrigo da luz solar **GR** Κρατήστε το μακριά από ηλιακή ακτινοβολία **PL** Przechowywać z dala od światła słonecznego **SE** Skyddas från solljus **RO** A se păstra ferit de razele soarelui **HU** Napfénytől védve tárolandó **SA -** يحفظ بعيدا عن أشعة الشمس
	GB - Manufacturer **FR -** Fabricant **IT -** Fabbricante **DE -** Hersteller **ES -** Fabricante **PT -** Fabricante **GR -** Παραγωγός **PL -** Producent **SE -** Tillverkare **RO -** Producător **HU -** Gyártó **SA -** الشركة المصنعة

CE	**GB** Medical Device compliant with Regulation (EU) 2017/745 **FR** Dispositif médical conforme au règlement (UE) 2017/745 **IT** Dispositivo medico conforme al regolamento (UE) 2017/745 **DE** Medizinprodukt im Sinne der Verordnung (EU) 2017/745 **ES** Producto sanitario conforme con el reglamento (UE) 2017/745 **PT** Dispositivo médico em conformidade com a regulamento (UE) 2017/745 **GR** Ιατρική συσκευή σύμφωνα με την ΚΑΝΟΝΙΣΜΟΣ (ΕΕ) 2017/745 **PL -** Wyrób medyczny zgodny z Rozporządzenie (UE) 2017/745 **SE -** Den medicintekniska produkten överenss-tämmer med förordning (EU) 2017/745 **RO -** Dispozitiv medical realizat în conformitate cu prevederile regulamentul (UE) 2017/745 **HU -** A 2017/745/EU rendeletnek megfelelő orvostechnikai eszköz **SA -** جهاز طبي يتوافق مع التوجيه (UE) 2017/745
	GB - Date of manufacture **FR -** Date de fabrication **IT -** Data di fabbricazione **DE -** Herstellungsdatum **ES -** Fecha de fabricación **PT -** Data de fabrico **GR -** Ημερομηνία παραγωγής **PL -** Data produkcj **SE -** Tillverkningsdatum **RO -** Nu conține latex **HU -** Gyártás dátuma **SA -** تاريخ التصنيع
MD	**GB** Medical Device **FR** Dispositif médical **IT** Dispositivo medico **DE** Medizinprodukt **ES** Producto sanitario **PT** Dispositivo médico **GR** Ιατροτεχνολογικό προϊόν **PL -** Wyrób medyczny **SE -** Medicinteknisk produkt **RO -** Dispozitiv medical **HU -** Orvostechnikai eszköz **SA** جهاز طبي
	GB - Consult instructions for use **FR -** Consulter les instructions d'utilisation **IT -** Leggere le istruzioni per l'uso **DE -** Gebrauchsanweisung beachten **ES -** Consultar las instrucciones de uso **PT -** Consulte as instruções de uso **GR -** Διαβάστε προσεχτικά τις οδηγίες χρήσης **PL -** Przeczytaj instrukcje użytkowania **SE -** Läs bruksanvisningen **RO -** Citiți instrucțiunile de utilizare **HU -** Olvassa el a használati utasításokat **SA -** اقرأ بدقة وحرص تعليمات الاستخدام