

## Response to Consultation on 3D Printing: Proposed changes to regulations on diagnostic imaging devices



### About AbilityMate

AbilityMate is an Australian for-purpose enterprise. Our mission is to help children with disabilities access the equipment they need. Our vision starts by making custom-made 3D printed Ankle Foot Orthoses (AFOs) available to Australian children!

- Winner of 2016 NDIS National Emerging Technology Competition
- Winner of 2017 National Disability Awards “Excellence in Innovation”



Ankle Foot Orthoses increase mobility, increase independence, reduce pain, assist rehabilitation and correct or accommodate deformities for the children who wear them. Everytime we sell our product we deliver a positive impact for the end-user. What makes our approach different is the utilisation of child-friendly and cutting-edge technologies such as 3D scanning and 3D printing.

## The Problem We're Solving - A National and Global Problem



Every 15hrs an Australian child is born with cerebral palsy making it the most common childhood physical disability in Australia. Most of these children will need to wear Orthotics throughout their life.



Without access to orthotics services, people are often confined to their homes – excluded from participating in society, and locked into poverty and isolation.



The World Health Organisation (WHO) estimates that there are 100 million people who need Orthoses and currently only 1 in 10 receive them

## We are currently building technologies which directly address the following problems:



### Distressing experiences for children with disabilities

To replicate the physical form of a child's lower-limb, Orthotists take plaster casts.

It's a messy manual process feared by many children, dreaded by their parents and laborious for Orthotists.

Casting can take 25-35 mins per limb



### Shortage of Orthotists & Waiting Periods

Some families wait up to 8 months to get an appointment, there are many complex factors contributing to these waiting periods including the fact no state or territory in Australia currently meets the internationally recommended rates for optimal service provision. The sole published recommended rate for Orthotists is 3.0 practitioners per 100,000 population. Australia's national practitioner rate is 1.09 per 100,000 population.



### Manual Fabrication & Turnaround Times

Manufacturing turn-around times are anywhere between 4-8 weeks from successful cast to successful fitting. During that time Orthotists or Orthotic technicians embark on the laborious task of hand-crafting an AFO, using thermo-formed polypropylene.

# Response to Proposed TGA Changes

## Background

We have recently been made aware of the above consultation which formally closed in late December 2017. There are some aspects of the TGA proposals which would have a significant impact on medical devices under development by AbilityMate and we would appreciate TGA's consideration of the following feedback.

AbilityMate is developing a new process for manufacturing of custom-made 3D Printed Ankle Foot Orthoses. These are externally applied medical braces that support mobility for people with physical disabilities. The Orthoses are custom made and prescribed under the supervision of Allied Health Professionals.

The Orthoses are modelled based on a prescription by an Orthotist, after examination of the patient. As part of the manufacturing process, we have developed a low cost optical 3D Scanner that captures the shape of the patient's ankle and foot. The geometry is used to create a 3D model of the Ankle Foot Orthosis which is then sent to a 3D Printer for manufacture. Prior to the manufacturing process the Orthotists is required to review the 3D model and check that the Orthosis has been modelled to their specification. Manufacturing only occurs once sign off from the Orthotists has been established.

## Strongly Urge to Reconsider

We note that TGA's Consultation document includes a proposal to introduce a new classification which would place all scanners into Class IIa. We strongly urge TGA to reconsider such an approach, which presents an unnecessarily burdensome requirement which is not justified by the risks.

TGA compares such devices to X-Ray film. X-Rays are used for capture of images of internal anatomy to inform diagnosis and therapy which may be invasive (e.g. trauma surgery). Our manufacturing process uses optical scanners – which present negligible safety risk to the patient, and the information generated is used to produce low risk devices – which would be Class I if they were not exempted under the current custom manufacture provisions. The processes we have developed allows the low cost manufacture of personalised prescription devices to a group of patients who are frequently unable to afford alternates manufactured by more labour intensive manual customisation.

3D scanning also presents patients with an alternative to plaster casting techniques currently employed by Orthotists. The plaster casting process can be very distressing for children with physical and intellectual disabilities.

Additional to the potential costs savings and better experiences as mentioned above the use of 3D scanning in the application of custom made Orthoses also:

- Increases the productivity of the Orthotists by 400%-600% (international studies available on request).
- Reduces the rates of workplace accidents and incidents because Orthotist no longer have to use toxic materials and workshop tools to produce an Orthosis.
- Enables us to reach people in isolated communities who currently don't have access to Orthotics services

Furthermore, the proposed new classification departs from the current internationally harmonised framework for medical device classification and presents a unique Australian requirement which is not justified by the risks.

Under the proposed changes, the 3D Scanner would be classified as a Class IIa diagnostic medical device. We are not convinced that such a change would be justified even when scanners are used in development of implantable or other high risk devices, as regulatory review of the end use device already includes requirements for the manufacturer of the device to validate the manufacturing process, including the use of scanners. These requirements already address the risks arising from variability in the scanning process.

We argue that this up-classification is especially unjustified for such a low risk medical device as an external orthosis administered under direct clinical supervision. It would present a likely insurmountable burden to our business which has an objective to provide low cost disability aids to disadvantaged patients. Further it would be wasteful for the regulator whose efforts would be better deployed onto supervision of other higher risk devices.

We recommend that TGA reconsider this proposal for reclassification. We would prefer that it not be implemented at all, or at most implemented in such a way that its application be limited to devices used to inform preparation of high risk implantables.

Should TGA wish to explore the issues presented above in more detail or to receive additional feedback from us, we would be pleased to enter into further correspondence or discussions as required. Please do contact us directly should you wish to do so.

Best Regards,

**Johan du Plessis**

Co-Founder/CEO

[johan@abilitymate.com](mailto:johan@abilitymate.com)

0406 014 981