Consultation: Proposed refinements to the regulation of personalised medical devices

Introduction

This document has been created in collaboration with numerous global and national manufacturers utilising the LaserCAM Orthotics system in response to the regulatory requirements proposed in **personalised medical devices (including 3D-printed devices)**.

LaserCAM Orthotics is a computer-aided design/computer-aided manufacture (CAD/CAM) Medical Device Production System (MDPS) that has been developed in Australia and is currently utilised by leading Australian manufacturers and Universities. This system was developed by Cad Cam Orthotics. Our MDPS is provided on the terms that the manufactured devices are to be prescribed, dispensed and reviewed by an AHPRA registered health care professional, however, devices may be manufactured by non-professionals with the appropriate level of training.

Some of the Australian-based manufacturers that utilise our MDPS include The Orthotic Factory, Artisan Orthotics, Sole Performance Orthotics, Coastal Orthotics and Queensland University of Technology (QUT). QUT utilise our MDPS to deliver education for undergraduate podiatry students.

Classification

According to the TGA, the specific classification of devices produced using our MDPS is as follows:

TGA Categorisation: Patient-matched medical devices

GMDN Code: 62870

Name: Orthotic insole, custom-made

Description: A shoe insert intended to provide supplemental support for the sole, arch and/or heel of the foot. The device is specifically produced to meet an individual's special requirements, having been prescribed by a relevant healthcare professional. It is made of various materials (e.g., cork, rubber, foam, textile). This is a reusable device intended for single-patient use.

Class: Class I

Definition of Terms

For the purpose of understanding our response, we would like to define a series of terms. These terms may or may not be applicable to medical device production outside of our specific expertise. The TGA may find this section superfluous, however, we felt it necessary to provide context in relation to our response.

Positive Input

The term *positive input* defines a:

1. Digitised human foot, supplied by a health care professional; or
2. Direct impression captured of the patient's foot using plaster, fibreglass, foam, or any other media, supplied by a health care professional.

An example of a *positive input* is a three-dimensional (3D) scan of the human foot.

Prescriptive Modifiers

The term *prescriptive modifiers* defines:

1. Instructions provided by a health care professional to instruct device manufacture in the form of a:
    a. Digital or physical prescription form; or
    b. Instructions provided through other forms of communication

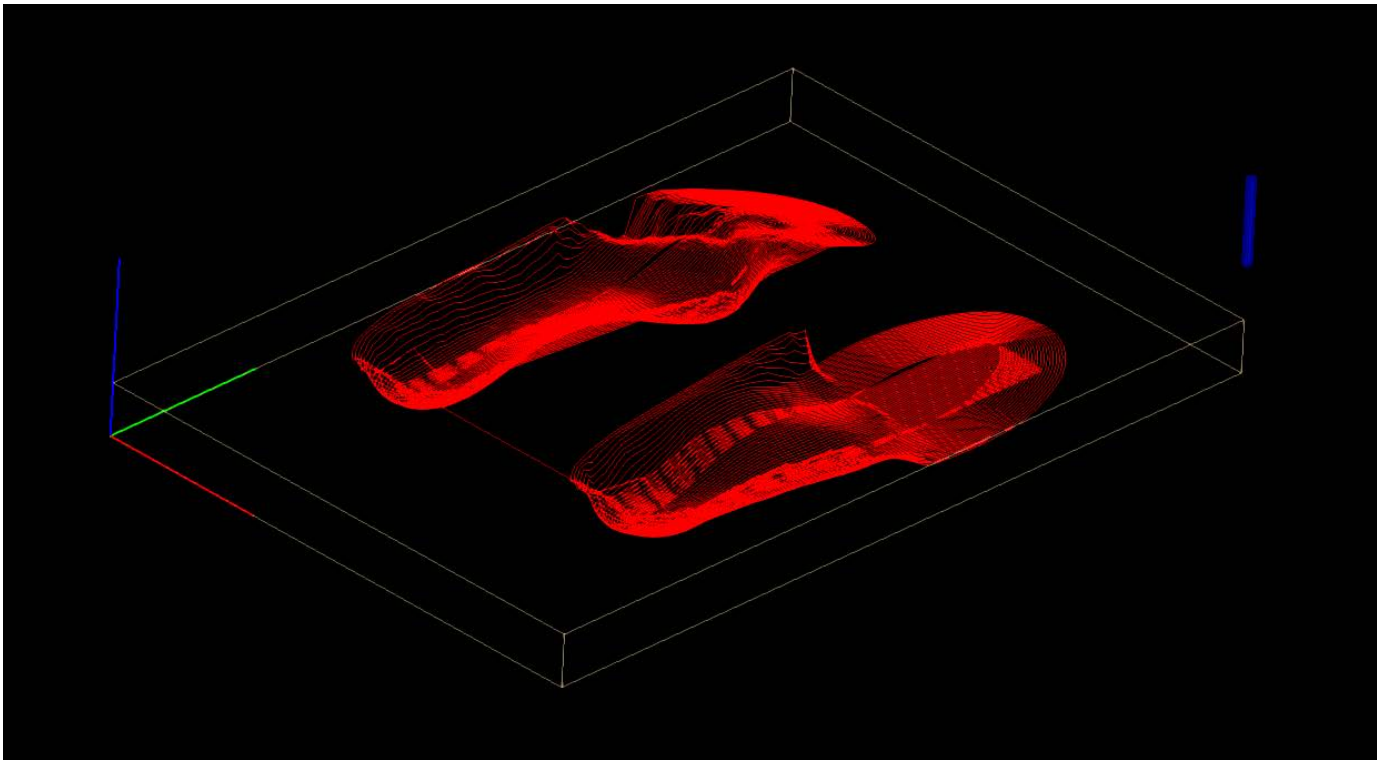
An example is a health care professional requesting a specific dimensional request that then informs device manufacture.

Negative Output

The term *negative output* defines a:

1. Digital file used for computer-aided manufacture such as:
    a. STL file for additive manufacturing; or
    b. A numerical control (NC) file for subtractive manufacturing
2. *Form* that is used in a thermoforming process.

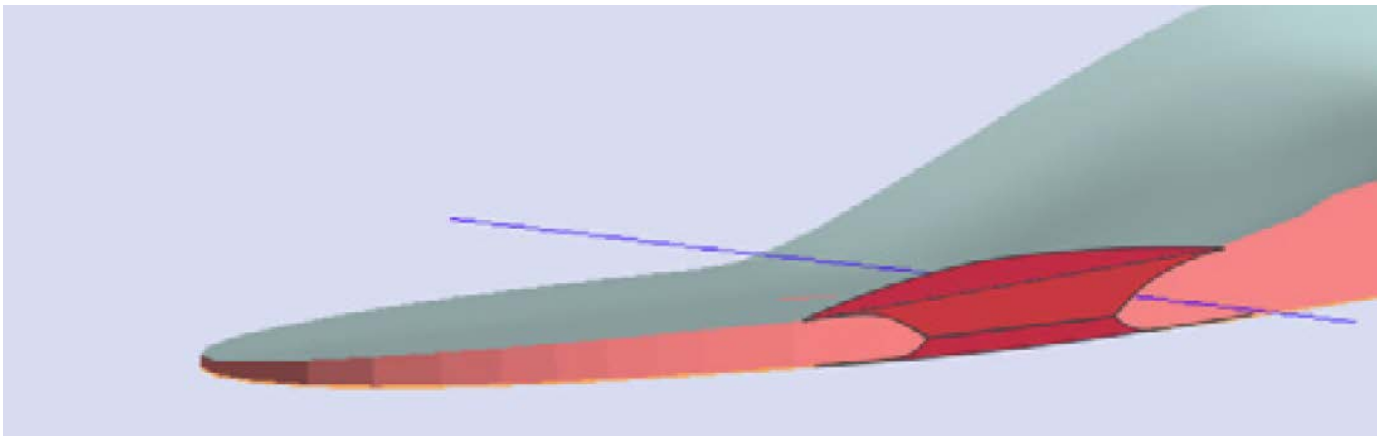
An example is a numerical control (*NC*) file that is generated within a CADCAM software that is then used as to CNC machine a *negative output*.



Manual Labour

The term *manual labour* defines any process completed by a human in a manufacturing environment that cannot, or is currently not completed using a computerised process.

An example of *manual labour* is an aperture, which is a lower density material integrated within a foot orthosis.



Foot Modelling Technique (FMT)

Foot Modelling Technique (FMT) defines *any* technique, method, or process used to produce a *positive input*. This *FMT* may be undertaken in a clinical environment and/or in a manufacturing environment (i.e. - when a physical *positive input* such as a plaster cast is provided to a medical device manufacturer).

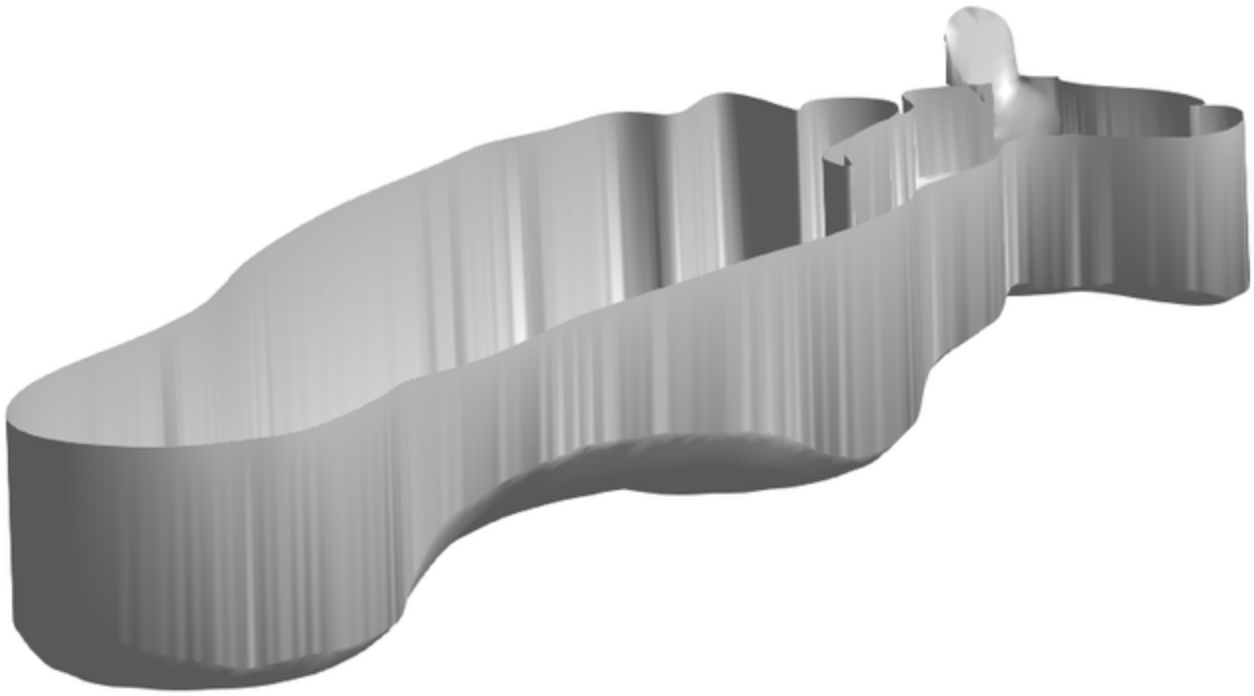
The *FMT* utilised in a clinical environment should always be based on the highest level of available clinical evidence in combination with the professional expertise of a suitably trained health care professional. There are currently a myriad of *FMT's* used in clinical practice, where any given *FMT* may result in significant changes to *positive input.*

An example of a *FMT* is the method of capturing a suspension plaster cast, which has been repeatedly described as the *gold standard method* for the capture of the human foot. Equipment that generates patient-specific anatomical models may be capable of complying with this *gold standard method* and therefore provide clinicians with the ability to capture a *positive input* using an evidence-based *FMT*.

The implementation of a *FMT* in a manufacturing environment is distinctly different, as its purpose is to generate a digital *positive input* from a physical *positive input* provided by a health care professional.

An example of a *FMT* implemented in a manufacturing environment is using a 3D scanner to scan a plaster cast provided by a health care professional.

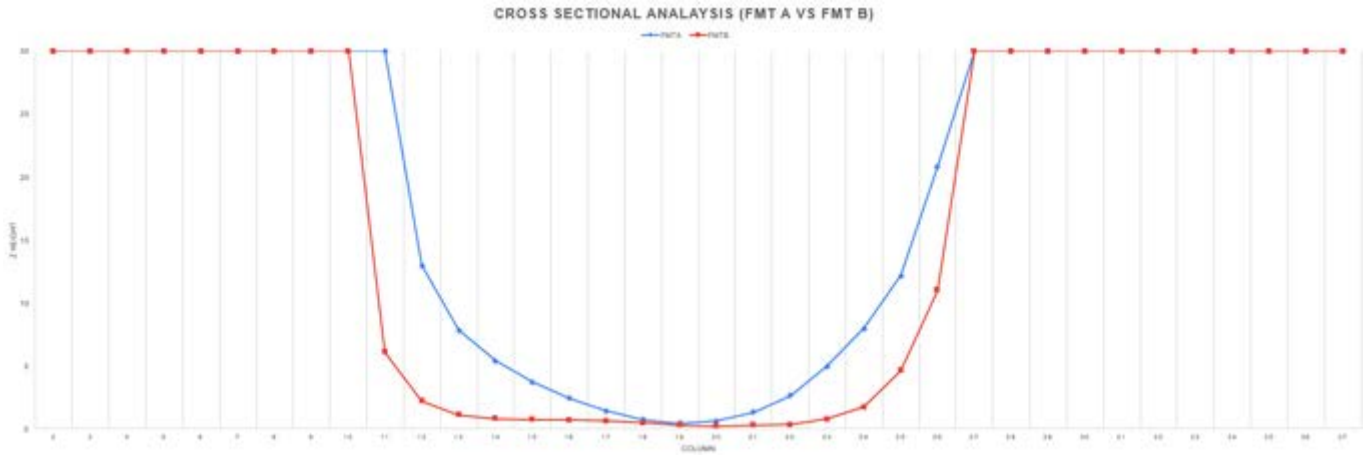
It is important to acknowledge that *FMT* has a significant impact on the manufacture of *morphology based devices,* but may have no impact on the manufacture of *non-morphology based devices.*

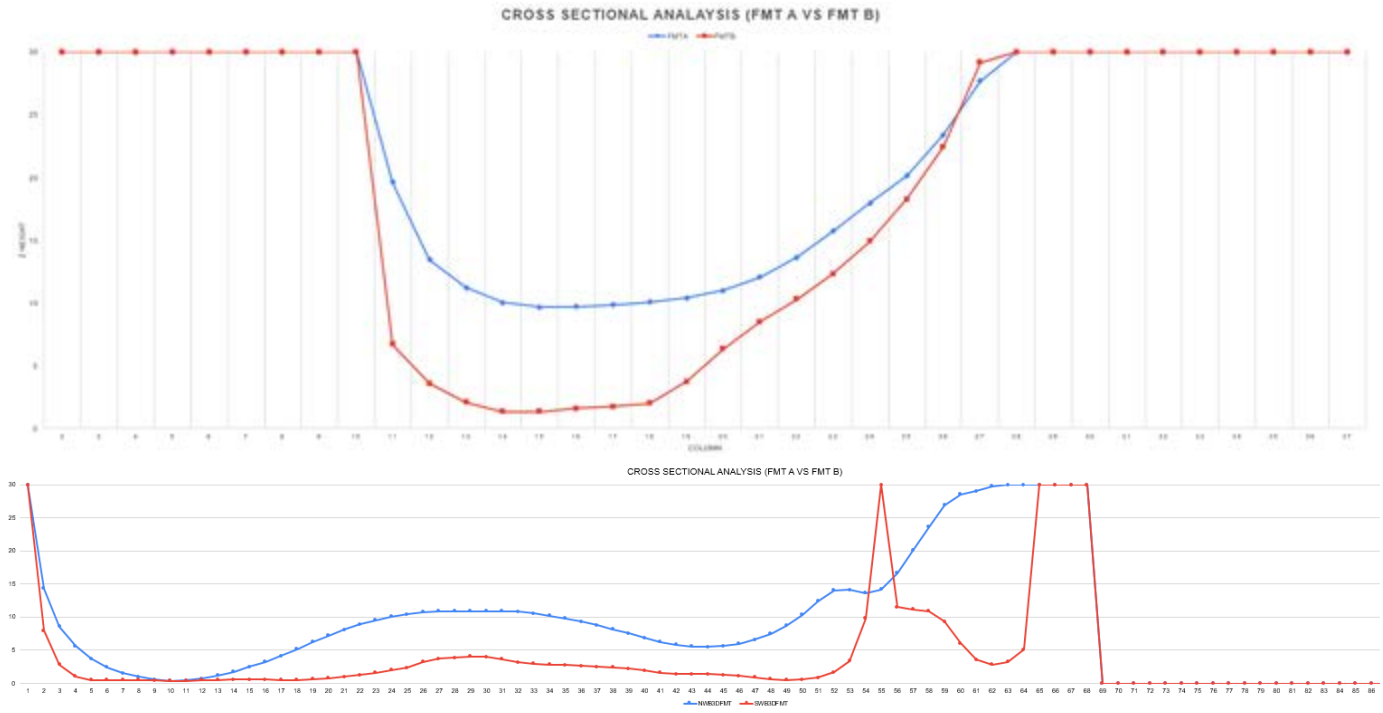


Please note that the above images represent two different *FMT* used to capture the same patient's foot. The resultant *positive input* is vastly different. Differences can be seen in the dataset below.

Comparative Differences of *FMT*

The images below show cross-sections from the same patient captured using two different *FMT's*. The selection of the appropriate *FMT* is made at the sole discretion of a health care professional. *FMT* selection, and subsequent *positive input* have significant implications on the manufacture of morphology based foot orthoses.





It should be noted that some cross sections have differences greater than 10mm in height. This shows the significance of *FMT* and should demonstrate the influence that this has on the manufactured device.

Morphology based devices

Morphology based devices are defined as devices that require a *positive input* to generate a *negative output* in combination with *prescriptive modifiers,* and cannot be produced without a *positive input* and *prescriptive modifiers.*

Morphology based devices with identical *prescriptive modifiers*, but a different *positive input* would have a different *negative output*.

Morphology based devices with identical *positive input*, but different *prescriptive modifiers* would have a different *negative output*. Assuming such *prescriptive modifiers* are non-aesthetic, *i.e. - colour*.

Example morphology based device workflow

The workflow below is simplified for the purpose of clarity and would likely describe what is currently recognised as a *custom foot orthosis* manufacturing workflow.

FMT POSITIVE INPUT PRESCRIPTIVE MODIFIERS NEGATIVE OUTPUT MANUAL LABOUR MBD CLINICAL DISPENSE

Morphology based devices:

- Can be produced within a *specified design envelope*;
- Are patient specific and intended for the sole use of the intended recipient;
- Require *positive input*;
- Are designed through the provision of *prescriptive modifiers* provided by a health care professional.

Non-morphology based devices

Non-morphology based devices are defined as devices that do not require a *positive input,* and may be manufactured with only *prescriptive modifiers*.

Non-morphology based devices with identical *prescriptive modifiers*, but a different *positive input* may have an identical *negative output*.

Example non-morphology based device workflow

The workflow below would likely describe what is currently recognised as a *non-custom foot orthosis*.

PRESCRIPTIVE MODIFIERS NEGATIVE OUTPUT MANUAL LABOUR NON-MBD CLINICAL DISPENSE

Devices produced using this workflow:

- Can be produced within a *specified design envelope*;
- Can be patient specific, and can be intended for the sole use of the intended recipient;
- Do not require *positive input;*
- Can be designed through the provision of *prescriptive modifiers* provided by a health care professional.

Morphology Based Devices vs. Non-Morphology Based Devices

In the context of foot orthoses, the provision of patient specific *positive input* determines whether a device is intended for a sole-recipient. We encourage the TGA to make a distinction between patient-matched medical devices that require a *positive input* and those that do not require a *positive input*.

Health care professionals involved in the prescription, design, dispense and review of prescription-only foot orthoses are expecting that *morphology based devices* be manufactured for their patients. Manufacturers that produce a *non-morphology based devices* when receiving a *positive input* from a health care professional are undertaking unethical practice. If this practice occurs, this essentially renders any efforts made to accurately capture *positive input* by the health care professional redundant. In such cases, therapeutic efficacy becomes extricated from a health care professionals judgement, which increases the associated risk.

Given the importance of patient specific *positive input*, this manufacturing practice needs to be discouraged in the foot orthosis industry from a regulatory level. We strongly encourage the TGA to take the necessary steps to provide distinction between *morphology based* and *non-morphology based* manufacturing pathways.

Responses

Exclusions

1. Do you agree with the rationale for the proposed exclusion of products? If not, why not?

Yes.

2. Are the risks posed by the products adequately managed if they are excluded from regulation by the TGA? Please explain your response, including by providing examples that illustrate and/or support your position.

Yes.

We ask that the answers to question 5 also be viewed in the context of potential arguments for exclusion. We have chosen to instead answer question 5 at length due to the context of the proposed exclusions and exemptions described by the TGA.

In summary the key points that adequately manage risk are:

- AHPRA registration;
- Continuing Professional Development;
- Professional Indemnity;
- Product Liability Insurance;
- MDPS Training

3. Are there further products that meet the principles proposed for exclusion? What are they and why should they be excluded? Please provide an explanation for why:

- the product represents no, or insignificant levels, of risk; or
- the product does not meet the definition of a medical device.

The TGA has proposed a change in the definition of Class IIa devices. This will result in 3D scanners that capture an anatomical foot model being classified as Class IIa devices.

The selection of an appropriate 3D scanner and appropriate *FMT* is based on the professional discretion of an AHPRA registered health care professional. 3D scanners that capture an anatomical foot model are intended to be used for the manufacture of Class I non-sterile, non-measuring patient-matched medical devices, and therefore pose an insignificant level of risk.

We recommend that all equipment including optical 3D scanners, computer-numerical control (CNC) routers, 3D printers, bench grinders, laboratory machinery, physical impression media and other inspection devices be considered for exclusion when being used for the manufacture of Class I non-sterile, non-measuring patient-matched medical devices that are prescribed, dispensed and reviewed by an AHPRA registered health care professional.

Risks associated with 3D scanners are extremely low, and the proposed regulatory burden is excessive. 3D scanners comply with pre-existing electrical safety requirements and Australian standards.

Manufacturers are already bound by the requirements to correctly comply with advertising standards when making claims regarding the accuracy of 3D scanners. It is the responsibility of a health care professional to assess new 3D scanning technologies and determine the appropriateness to clinical practice.

The health care professional utilises this equipment, which is one step in the process of manufacturing a low-risk device, whose risk is further mitigated through the involvement of the health care professional during all stages of direct patient contact.

We believe that the classification of a 3D scanner that matches the description as a Class IIa device is excessive given the low-risk associated with the use of the 3D scanner and resultant manufactured device. This highlights the importance of accurate and reliable 3D scanners as if measurements are grossly incorrect then the risk of subsequent adverse events is increased.

In addition, we believe categorisation of such devices will not improve clinical efficacy of resultant products, nor effectively mitigate the minimal risks associated with prescription-only foot orthoses.

Exemptions

4. Do you agree with the rationale for the proposed exemption of Class I non-sterile, non-measuring patient-matched devices when produced under the circumstances listed in this consultation paper? If not, why not?

Yes.

5. Can the risks posed by the Class I non-sterile, non-measuring patient-matched medical devices when produced under the circumstances listed in this consultation paper be adequately managed if they are exempted from inclusion in the ARTG? Please explain your response, including by providing examples that illustrate and/or support your position.

Yes. Class I non-sterile, non-measuring patient-matched medical devices have been studied within the scientific literature. Adverse reactions with the use of these devices are rare (Woodburn, 2002) and this includes for vulnerable populations (Rome K, 2010) and in comparison with sham versions designed for no therapeutic benefit (Burns J, 2007).

We can also consider the level of risk posed by Class I non-sterile, non-measuring patient-matched medical devices utilising a risk matrix. The consequence of an adverse reaction to this device is predicted to be insignificant, whereas the likelihood is possible (i.e. blister in the arch). Devices in this category are predicted to be no more than low risk.

It may be useful to compare this risk to that non-medical footwear (i.e. running shoes). Both of these items are worn on the feet and can result in minor adverse reactions.

AHPRA Registration (Pre-Existing Risk Mitigation Mechanism)

The most important factor that mitigates risk is that the biomechanical assessment, prescription, dispense and review of prescription-only foot orthoses is undertaken by a health care professional that is registered with AHPRA. It is important to recognise that AHPRA registered health care professionals are responsible for all direct patient contact, and that a manufacturer generally never has direct patient contact.

AHPRA partners with National Boards to improve professional standards alongside public and private professional bodies to protect public safety. In the context of prescription-only foot orthoses, The Podiatry Board of Australia develop codes and guidelines that provide guidance to the Podiatry profession about professional conduct and practice, including but not limited to:

- Codes of conduct;
- Advertising guidelines;
- Clinical record requirements;

- Continuing Professional Development (CPD);
- Recency of practice;
- Infection control;
- Endorsement of scheduled medicines;
- Insurance requirements;
- Criminal history;

In combination, these professional standards adequately mitigate the risk associated with the provision of prescription-only foot orthoses, which are a very low-risk device.

Our current concerns with the regulation relate to the allocation of design liability on the manufacturer, even when such a design is determined by an AHPRA registered health care professional. We believe the regulation places an unreasonable liability on the manufacturers of prescription only Class I non-sterile, non-measuring patient-matched medical devices.

Additionally, we believe the TGA should provides legislative clarity on the distinction between patient-matched medical devices that are *morpholo gy based* and *non-morphology based.* The current definition of a patient-matched medical device needs refinement, or further stratification devices manufactured with significantly different manufacturing philosophies are included in the same category.

Professional Indemnity Insurance (Pre-Existing Risk Mitigation Mechanism)

Professional Indemnity (PI) insurance indemnifies the *adviser* against specific liabilities that arise out of a result of professional practice. This includes the liability to compensate clients for professional failures. A health care professional can and must be insured for civil liabilities arising as a result of the performance of any activities within a defined scope of practice.

AHPRA stipulates that all health care professionals who undertake any form of clinical practice in their respective profession(s) must have PI insurance arrangements that comply with the relevant registration standard, for all aspects of their practice. As part of this requirement health care professionals must make an annual declaration as part of their renewal of registration stating that they have the appropriate PI insurance arrangements.

Associations across all health care professions work closely with AHPRA to ensure that the reputation of professional medical services are protected, as well as the reputation of individual members. PI insurance is critical to upholding this reputation as it ensures that patients with valid claims arising from the use of professional medical services are fairly compensated for their losses.

Learned Intermediary Doctrine

The *learned intermediary doctrine* is worth exploring as it highlights the relationship between medical device manufacturers, health care professionals and patients. *Learned intermediaries* have the duty to warn patients (as consumers), giving them access to informed consent and the voluntary assumption of risk. This concept states that manufacturers have no duty to warn patients of the potential hazards regarding prescription products that are accessible only through health care professionals, but only to provide adequate warnings to prescribers. This doctrine helps to distinguish liability issues surrounding prescription only medical products, and correctly determines that a health care professional is the most appropriately positioned individual to assess the benefits and risks associated with the provision of a prescription-only medical device.

PI Insurance Considerations

We highlight the following excerpt of **personalised medical devices (including 3D-printed devices)**:

> "The definition of a patient-matched medical device means a medical device that:
>
> (b) is designed by the manufacturer (even if the design is developed in consultation with a health professional);
>
> The specified design envelope is the limits of design that a manufacturer can be confident (with the support of objective evidence) will result in a medical device that is safe, and will meet the intended recipient's requirements (i.e. design validation). "

A health care professional that is a *prescriber*, is responsible for the design of prescription-only foot orthoses.

A health care professional acting in the role of a *learned intermediary* is responsible for determining the relevant benefits and risks associated with prescription medical devices.

The safety of a prescription-only foot orthosis cannot be determined by a manufacturer, but the manufacturer can produce a devices that match each prescription.

Manufacturers should not provide discretionary professional services (e.g. - *lab discretion*). This is especially important as manufacturers almost always never have direct patient contact.

We highlight the following excerpt of **consultation: proposed refined to the regulation of personalised medical devices**:

> "It is considered that where a medical device has been "prescribed" by a registered health professional and is manufactured by a qualified or accredited professional according to the specifications provided by the healthcare practitioner, risks can be adequately mitigated."

The vast majority of manufacturers employ non-professional technicians that produce devices according to health care professional prescriptions. Such technicians are not "*qualified or accredited professionals*". They also have no obligation, and are unable to assess the safety of a prescription-only foot orthosis.

We believe the staff of Cad Cam Orthotics are *qualified,* as we provide extensive on-the-job training and instruction. Practical skills are assessed daily to determine the propensity of an individual to work in a non-supervised capacity and there are policies and procedures in place to carefully monitor and address errors when they occur.

It is helpful to consider the analogy of a complex production line containing various stages of *manual labour* completed by non-professionals that are provided with practical on-site training. If the TGA considers exemption for prescription-only foot orthoses, then this must extend to those manufactured by individuals that are not "*qualified or accredited professionals"*; this is provided that such devices are prescription-only.

The imposition of PI insurance on health care professionals is possible as the insurance market is willing and able to provide cover on terms that are affordable and meet the cover specification. This is as a result of a range of converging factors, including the fact that individuals registered with AHPRA are regarded as professionals (*learned intermediaries*) that are able to provide professional advice.

In any insurance negotiation an insurer's commercial interests must be considered, and it is a meaningless exercise to specify a level of cover that is likely to be met with significant resistance and excessive financial imposition. The vast majority of manufacturers employ non-professional technicians that manufacture according to health care professional prescriptions. Such non-professionals are often highly skilled and experienced, but are unable to obtain PI insurance.

If manufacturers are not able to be adequately insured, then it is not unreasonable to expect that:

- Prescription-only foot orthosis prices will increase;
- Manufacturers may operate without appropriate insurance;
- Prescription-only foot orthoses may become less patient specific;
- Newly assumed liability may have negative impacts on innovation

Manufacturer Obligations (Pre-Existing Risk Mitigation Mechanism)

Product Liability Insurance

Manufacturers are generally covered by product liability insurance, which protects manufacturers against liability resulting from defects in manufactured products. Liability provisions of the Australian Consumer Law (ACL) generally apply to manufacturers that permit a health care professional to promote medical devices directly to patients as being their own manufactured product. To our knowledge, this is the most common relationship between medical device manufacturers and health care professionals in the Australian market.

It is generally accepted that manufacturers of prescription-only foot orthoses owe a duty of care to health care professionals and that manufactured products:

- Correspond to the prescriptive requests provided by the health care professional;
- Are of acceptable quality;
- Are non-defective

A manufacturer of prescription-only foot orthoses should be subject to liability for harm to persons caused by a lack of adherence to the general principles of duty of care described above. However, claims arising from the manufacture of prescription-only foot orthoses cannot impose liability on the manufacturer if such claims are the result of incorrect product design. To re-iterate, this is because in the context of prescription-only foot orthoses, the prescription explicitly determines the design.

Our insurer has provided advice that we (as a manufacturer) are not able to be covered by professional indemnity insurance. We do have product liability insurance, which provides coverage against manufacturing error, *e.g. - not correctly following a prescription.*

Independent Education

Private and public businesses manufacture according to non-proprietary or proprietary techniques, with such techniques not being subjected to rigorous scrutiny by any independent authority. Manufacturers of prescription-only foot orthoses play an important role in providing health care professionals with product information relating to their manufactured devices. This allows a health care professional to improve their capacity to act in their role as a *learned intermediary.*

Product information can be provided in the form of workshops, conferences, print media, or other forms of communication. A manufacturer will commonly detail at great length their *specified design envelope*, provide technical information about products, and allow health care professionals

to receive in-depth insight into manufacturing processes. Health care professionals, in their role as '*gate-keeper*' must then critically assess the provided information and determine the appropriateness of a manufacturer products for their patients.

In the case of our MDPS, we provide training to undergraduates, health care professionals, academics and non-health care professionals.

Technicians that operate our MDPS equipment and follow manufacturing instructions are rarely professionals, nor are they required to be. The completion of the manufacturing stages by a "*qualified or accredited professional*" does not mitigate risk. Risk mitigation is associated with an AHPRA registered health care professional providing *prescriptive modifiers* and *positive input,* and undertaking the assessment, fitting and review stages, i.e. - the stages of direct patient interaction.

Manufacturers that adopt our MDPS are provided with a minimum of 38 hours training. This training comprehensively covers the appropriate use of our MDPS. Training is often tailored to an individual's pre-existing skill. From our extensive experience, it is common for non-professionals to have a higher level of practical skill than professionals. Non-professionals are able to receive training in the manufacturing stages, where there is no direct patient contact. Health care professionals are able to receive training in any stage.

We have developed a knowledge base that details each individual available *prescriptive modifier* (our specified design envelope).

LaserCAM Orthotics - Prescription Guides

Our prescriptive platform **LaserCAM Prescribe** also provides information about each individual *prescriptive modifier* in real-time during prescription.

⚠ It is critical to remember that our MDPS provides information on *what* the *prescriptive modifiers* are, and *how* they alter the morphology of the prescription-only foot orthosis. Our MDPS never provides information as to *when*, *for who*, *why*, or *how much* regarding any individual *prescriptive modifiers*, and we do not make any therapeutic claims. This would be inappropriate as we have not assessed the patient, therefore cannot effectively assess the patient specific benefits and risks.

Our MDPS

Manufacturers utilising our MDPS have been operating for decades. To our knowledge, all Australian Universities that offer a Podiatry degree, teach students how to prescribe prescription-only foot orthoses to manufacturers that employ non-professional technicians. Additionally, Australian Universities have at times providing training to students in how to prescribe to manufacturers that use our MDPS.

In many cases health care professionals (and even Universities) seek manual labour training from non-professional that utilise our MDPS, due to the incredibly vast difference in manual labour skill between health care professionals and non-professionals. This difference in manual labour skill can be attributed to the fact that non-professionals are far more likely to be employed to perform manual labour tasks in a full-time capacity, compared with health care professionals.

We would now like to provide a detailed look at our specific MDPS. This should demonstrate how risk is effectively mitigated during various stages of the prescription-only foot orthosis manufacturing pipeline.

A detailed view of the stages of manufacture using the LaserCAM Orthotics MDPS.

Stage 1: Patient Assessment CLINICAL STAGE

This stage involves the direct assessment of a patient by an AHPRA registered health care professional. This health care professional makes a professional determination that prescription-only foot orthoses are applicable to the management of the pathology of the specific patient.

The health care professional acts in their role as a *learned intermediary* in an initial capacity to convey the proposed treatment approach, which involves providing the patient with a summary of the expected benefits and risks.

- Direct patient contact
- Undertaken by AHPRA registered health care professional
- AHPRA registered health care professional acting within scope of practice
- Professional service and advice provided to patient
- The provision of this professional service is covered by PI insurance
- Manufacturing service selected based on professional discretion of health care professional

Risk Mitigation

AHPRA REGISTRATION PI INSURANCE

Stage 2: Foot Modelling Technique CLINICAL STAGE

This stage involves *any* technique, method, or process used to produce a *positive input*. The selection of an appropriate *FMT* for a specific patient is based on the professional discretion of an AHPRA registered health care professional. This selection should be based upon the highest level of available clinical evidence.

- Direct patient contact
- Undertaken by AHPRA registered health care professional
- AHPRA registered health care professional acting within scope of practice
- Professional service provided to patient
- The provision of this professional service is covered by PI insurance
- 3D scanning equipment complies with pre-existing electrical safety standards

⚠️ It is important to acknowledge that the selected *FMT* has a significant impact on the manufacture of *morphology based devices*.

Risk Mitigation

AHPRA REGISTRATION PI INSURANCE

Stage 3: Positive Input CLINICAL STAGE

This stage involves an AHPRA registered health care professional using a 3D scanner, or physical impression media to capture an anatomical model (*positive input)* of the patient's foot. The appropriateness of this captured *positive input* is determined by the professional discretion of an AHPRA registered health care professional.

- Direct patient contact
- Undertaken by AHPRA registered health care professional
- AHPRA registered health care professional acting within scope of practice
- Professional service provided to patient
- The provision of this professional service is covered by PI insurance

⚠️ It is important to acknowledge that manufacturers have very little control over the provided *positive input*. The *positive input* has a significant influence on the morphology of the manufactured *morphology based device* and resultant benefits and risks.

Risk Mitigation

AHPRA REGISTRATION PI INSURANCE

Stage 4: Prescriptive Modifiers CLINICAL STAGE

This stage involves an AHPRA registered health care professional developing a set of *prescriptive modifiers* based upon their professional discretion. These *prescriptive modifiers* are selected from a *specified design envelope* that is virtually limitless. This professional discretion will be informed by the patient assessment and perceived benefits and risks, which have been conveyed to the patient.

LaserCAM Orthotics MDPS - Prescriptive Modifier Guides

- Direct patient contact
- Undertaken by AHPRA registered health care professional
- AHPRA registered health care professional acting within scope of practice
- Professional service provided to patient
- The provision of this professional service is covered by PI insurance

⚠️ An AHPRA registered health care professional provides these instructions (*prescriptive modifiers)* that **explicitly** determine the design. This is in direct conflict with *Section 1.1 - Overview of* the regulation - **personalised medical devices (including 3D-printed devices)** that states that a patient-matched medical device is:

"*(b) is **designed by the manufacturer** (even if the design is developed in consultation with a health professional)"*

⚠️ A manufacturer **cannot be responsible** for the design, nor be insured for such a responsibility.

Risk Mitigation

AHPRA REGISTRATION PI INSURANCE MDPS TRAINING

Stage 5: Prescription Receipt MANUFACTURING STAGE

This stage involves a manufacturer receiving a *positive input* in combination with *prescriptive modifiers*.

- No direct patient contact
- Can be completed by non-professional
- Data entry task
- Start of manufacturing service
- Insured by manufacturers product liability insurance

Risk Mitigation

PRODUCT LIABILITY INSURANCE MDPS TRAINING

Stage 6: Computer-Aided Design - Alignment MANUFACTURING STAGE

This stage involves aligning *positive input* data in frontal, sagittal and transverse planes according to a set of defined *prescriptive modifiers* that our MDPS terms *Clinical Measures*. These *prescriptive modifiers* are provided by an AHPRA registered health care professional.

LaserCAM Orthotics MDPS - Clinical Measures

- No direct patient contact
- Can be completed by non-professional
- Objective process
- Easily validated and repeatable
- Well documented policies and procedures
- Insured by manufacturers product liability insurance
- Utilises *prescriptive modifiers* provided by an AHPRA registered health care professional
- Utilises *positive input* provided by an AHPRA registered health care professional

Risk Mitigation

AHPRA REGISTRATION PRODUCT LIABILITY INSURANCE PI INSURANCE MDPS TRAINING

Stage 7: Computer-Aided Manufacture - NC/STL Generation MANUFACTURING STAGE

This stage involves generating a *negative output* based explicitly on the alignment of the *positive input* in combination with a set of defined *prescriptive modifiers* that our MDPS terms *Intrinsic Adjustments*.

This stage generates a file that may be used in additive or subtractive manufacturing processes. Manufacturing equipment utilised is non-proprietary and variable in accuracy. Manufacturers should state the accuracy of their specific additive or subtractive manufacturing equipment so that health care professionals can exercise appropriate clinical judgement.

⚠️ Our CNC routers have a positional accuracy of 0.01mm.

⚠️ Our recommended 3D scanners have an accuracy of <1mm.

LaserCAM Orthotics MDPS - Intrinsic Adjustments

- No direct patient contact
- Can be completed by non-professional
- Objective process
- Easily validated and repeatable
- Well documented policies and procedures
- Insured by manufacturers product liability insurance
- Utilises *prescriptive modifiers* provided by an AHPRA registered health care professional
- Utilises *positive input* provided by an AHPRA registered health care professional
- Manufacturing equipment complies with pre-existing electrical safety standards

Risk Mitigation

AHPRA REGISTRATION PRODUCT LIABILITY INSURANCE PI INSURANCE MDPS TRAINING

Stage 8: Manual Labour MANUFACTURING STAGE

This stage involves generating completing any required *manual labour* tasks that may not be completed using a digital additive or subtractive manufacturing process. These *manual labour* tasks are requested using a defined set of *prescriptive modifiers* that our MDPS terms *Device Options*, *Off-Loading Options, Shoe-Fitting Options* and *Material Options*.

🟩 **LaserCAM Orthotics MDPS - Device Options**

🟩 **LaserCAM Orthotics MDPS - Off-Loading Options**

🟩 **LaserCAM Orthotics MDPS - Shoe Fitting Options**

🟩 **LaserCAM Orthotics MDPS - Material Options**

- No direct patient contact
- Can be completed by non-professional
- Objective process
- Easily validated and repeatable
- Well documented policies and procedures
- Insured by manufacturers product liability insurance
- Utilises *prescriptive modifiers* provided by an AHPRA registered health care professional
- Utilises *positive input* provided by an AHPRA registered health care professional
- Material specifications available to AHPRA registered health care professional
- Manufacturing equipment complies with pre-existing electrical safety standards

Risk Mitigation

AHPRA REGISTRATION PRODUCT LIABILITY INSURANCE PI INSURANCE MDPS TRAINING

⚠️ It is widely acknowledged in the industry than non-professionals working in manufacturing environments possess far greater *manual labour* skill.

Stage 9: Manufacturer Quality Control MANUFACTURING STAGE

This stage involves a delegated manufacturing technician completing a series of checks to ensure that the manufacturing stages have been completed in accordance with *prescriptive modifiers* requested by an AHPRA registered health care professional.

🔢 Our MDPS recommends that individuals involved with manufacturing stages are designated with unique identifiers. These unique identifiers are used in the logging of specific manufacturing tasks, which allows for improved tracking of manufacturing error. This helps to provide the necessary targeted training in order to minimise associated risks, and highlight processes that can be implemented to reduce error.

- No direct patient contact
- Can be completed by non-professional
- Objective process
- Easily validated and repeatable
- Well documented policies and procedures
- Insured by manufacturers product liability insurance
- Utilises *prescriptive modifiers* provided by an AHPRA registered health care professional
- Utilises *positive input* provided by an AHPRA registered health care professional

Risk Mitigation

AHPRA REGISTRATION PRODUCT LIABILITY INSURANCE MDPS TRAINING PI INSURANCE JOB TRACKING

Stage 10: Clinical Quality Control CLINICAL STAGE

This stage involves an AHPRA registered health care professional assessing the manufactured product. The manufacturer will provide a copy of the requested *prescriptive modifiers,* which includes a log of the technicians involved in specific manufacturing stages. The AHPRA registered health care professional may also perform a standardised quality control process, which seeks to determine the appropriateness of the manufactured device with respect to the individual patient.

- Direct patient contact
- Undertaken by AHPRA registered health care professional
- AHPRA registered health care professional acting within scope of practice
- Professional service provided to patient
- The provision of this professional service is covered by PI insurance
- AHPRA registered health care professional validates that the manufactured device is fit for purpose via:
    - Assessment with respect to requested *prescriptive modifiers;*
    - Assessment with respect to the patient
- Benefits and risks conveyed to patient
    - Informed consent provided

Risk Mitigation

AHPRA REGISTRATION PI INSURANCE

Stage 11: Clinical Adjustment CLINICAL STAGE

Devices are often modified by an AHPRA registered health care professional according to professional discretion, which may include, but is not limited shoe fitting, comfort, gait analysis and biomechanical considerations.

⚠ A prescription-only foot orthosis may be modified at this stage according to the discretion of an AHPRA registered health care professional. The manufacturer therefore cannot be liable for any losses incurred to the intended recipient that occur as a result of such modification.

- Direct patient contact
- Undertaken by AHPRA registered health care professional
- AHPRA registered health care professional acting within scope of practice
- Professional service provided to patient
- The provision of this professional service is covered by PI insurance
- Manufactured product morphology can be significantly altered

Risk Mitigation

AHPRA REGISTRATION PI INSURANCE

Stage 12: Review CLINICAL STAGE

This stage involves an AHPRA registered health care professional assessing the manufactured product, it's clinical efficacy and determining whether the benefits of using the device outweigh any apparent risks.

- Direct patient contact
    - Performed by health care professional
    - Review of efficacy of device according to professional judgment
- Devices can be modified - see **Stage 7: Clinical Adjustment**
- Benefits and risks conveyed to patient
    - Informed consent provided
- Professional service provided to patient
- The provision of this professional service is covered by PI insurance

Risk Mitigation

AHPRA REGISTRATION PI INSURANCE

6. Are there further circumstances where Class I non-sterile, non-measuring patient-matched devices could be exempt? If so, what measures are in place to manage the risks associated with the devices?

Please provide details:

- describe the specific circumstances that are in place (such as qualifications, accreditation, certification, etc) to ensure that the risks associated with the manufacture of the devices have been managed and the Australian regulatory requirements for medical devices have been met before they are supplied.

We encourage the TGA to provide an exemption for prescription-only foot orthoses that are manufactured by non-professionals, provided that such devices are prescribed, reviewed and dispensed by an AHPRA registered health care professional working within their defined scope of practice. We consider that there are sufficient third-party mechanisms of oversight in place to suitably manage the risk posed by prescription-only foot orthoses under such circumstances, and that the exemption should therefore be extended.

A lack of exemption for such manufacturers would be highly anti-competitive, have no impact on the mitigation of risk, and potentially result in the closure of countless small and medium-sized enterprises within Australia. We are hopeful that our answer to question 5 has already demonstrated how risk is effectively mitigated, regardless of whether devices are "*manufactured by a qualified or accredited professional*".

Over 10 Australian SME's utilise our MDPS to manufacture prescription-only foot orthoses. Almost all do not employ professionals, and do not have direct interaction with patients. These SME's manufacture prescription-only products according to an AHPRA registered health care professionals prescription. The terminology proposed by the TGA indicates that additional and unreasonable liability will be placed upon these SME's, which is of concern, and puts into question their viability.

Inclusion in ARTG using alternative conformity assessment procedures

7. Do you agree with the rationale for the proposed alternative conformity assessment procedures for Class IIa patient-matched devices when produced under the circumstances listed in this consultation paper? If not, why not?

Not applicable.

8. Do you agree that the risks associated with the proposed Class IIa patient-matched devices when produced under the circumstances listed in this consultation paper could be adequately managed through the proposed alternative conformity assessment procedure? Please explain your response, including by providing examples that illustrate and/or support your position.

Not applicable.

9. Are there further circumstances where an alternative conformity assessment procedure for Class IIa patient-matched devices would be appropriate? If so, what measures are in place to manage the risks associated with the devices?

Not applicable.

10. Are there any Class IIa patient-matched devices that should not be subject to an alternative conformity assessment procedure? What are they and why not?

Not applicable.

General question

11. Are there alternative mechanisms for reducing the regulatory burden for patient-matched medical devices without compromising patient health and safety that you would like to propose?

We hope that our response to question 5 has highlighted alternative pre-existing mechanisms that mitigate risk and demonstrates how exemption for prescription-only foot orthoses is appropriate. We also hope that the TGA will demonstrate a capacity and willingness for regulatory innovation by considering the following:

1. Amendments to the terminology regarding design responsibility;
2. Clarity regarding sub-classifications of patient-matched medical devices with regards to:
    a. morphology based devices vs. non-morphology based devices;
    b. prescription-only devices vs. non-prescription devices;

3. Additional exemptions for non-professionals involved in manufacturing prescription-only devices;
4. Additional exemption for optical 3D scanning equipment and other ancillary equipment utilised exclusively for the manufacture of exempted devices;
5. Providing specific examples of liability regarding prescription-only devices;
6. ISO certification will not provide additional risk mitigation when considering the pre-existing mechanisms of oversight;
7. ISO certification will be pose a risk to the viability of small manufacturing businesses

We welcome the TGA to contact us in regards to our response. If further detail will assist in developing more effective regulatory mechanisms then we are happy to provide further comment.