Orthotic & Prosthetic Entrepreneurship & Business Development on the Example of Tanzania

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TABLE OF CONTENTS

Foreword	4	2.3 Market Analysis – The Details	17
Chapter 1.0		2.3.1 Example for the Kilimanjaro Region – Method 1: 2.3.2 Evidence on Needs and Business Feasibility in O&P	17 21
Elements and Structure of a Business Plan	6	2.3.3 Disability – WHO, ISPO and Other information	23
Chapter 2.0 Background Information and How to Extract the Facts	7	 2.3.4 Disability – in Tanzania, National Data 2.4 Business Plan – Organization and Management 2.5 Business Plan – Sales Strategies 	24 25 27
2.1 The Executive Summary2.2 The Business Description2.2.1 Vision and Mission Statement for an O&P Business	7 7 7	 2.6 Business Plan – Funding Requirements 2.6.1 A Potential Funding Opportunity for Small and Medium Healthcare and O&P Enterprises in Tanzania 	29
2.2.2 The Business Model2.2.3 What is O&P?2.2.4 The Benefit of Special Relationships	8 8 10	 2.7 Financial Projections – Pricing/Budgeting/Accounting 2.7.1 Pricing 2.7.2 Budgeting 	34 34 37
2.2.5 Location 2.2.6 The Business Founder	10 11	2.7.3 Accounting	38
2.2.7 The Legal Structure and Legal RequirementsWho is a Resident?	11 12	Chapter 3.0 The Rest	40
 Legal Requirement: Certificate of Registration Legal Structure: Corporation (Limited Company) Legal Structure: Partnership Legal Structure: Trust Legal Structure: Charitable Organization 	13 13 14 14 15	 3.1 Final Remarks 3.2 References and Links 3.3 Attachments 3.4 About the Authors 3.5 About the Sponsor 	40 40 41 42 45
 Legal Requirement: Declaration of Estimated Income/Turnover Legal Requirement for: Investment in Tanzania – The TIC Legal Structure: Public / Private Partnerships or PPPs 	15 15 16		

Foreword

This document on Business Development (BD), BD-Planning and -Execution intents to support an understanding of most all of the business aspects of a new Orthotic & Prosthetic (throughout the text: O&P) business. All examples relate to the Republic of Tanzania, as it was requested for and written in Tanzania. However, most of the necessary steps are probably easily transferred to other African Nations with a few necessary corrections on national administrative and regulatory requirements.

The authors express sincere hope that it may support starting a business without taking unreasonable risk. It shall also help to have information available that many of the new entrepreneur's potential partners and lenders will ask, in order to reduce their own risk as business partners, family, bank – or whoever else who wants to support the new endeavor.

It is focused on looking for economic feasibility through business planning and strives to provide a reasonable overview of necessary steps to be taken.

Before starting with the actual content, it should be emphasized that local help is also available for most business questions. The local Chamber of Commerce (in Tanzania) can be found under link [*1].

In modern, computerized times much of the general information on health statistics and on business planning and on Orthotics/Prosthetics (O&P) can be found on numerous internet sites. This information is provided publically and free for anyone to look at and use it as deems appropriate. The authors have searched, evaluated and included some of this information in the document because they couldn't have said it any better. Resources, such as web links, are provided so that the business planner has an option to delve deeper into the topic and/or employ the web site provider's business to get actual busi-

ness help. Furthermore this document is not advertising or recommending one provider against the other – all the material used has impressed as being trustworthy and of value.

This O&P business planning document will therefore – in the last chapter – provide numbered links to references in the text.

It will also provide some rules, which may look like common sense.

They actually are – and once followed – facilitate planning and building the new business.

Disclaimer: This business planning document intends to cover most potential questions of new business planning for O&P (in Tanzania), but is not prepared to answer all individual questions that may arise in planning, financing and legal registration a particular new business. Therefore experienced local legal or administrative professionals may have to be consulted, to help finding the correct answers to local/regional questions.

6

Chapter 1.0 Elements and Structure of a Business Plan

The main elements of basically every business plan are:

- Executive Summary
- Business Description
- Market Analysis
- Organization and Management
- Sales Strategy
- Funding Requirements
- Financial Projections

These elements will be explained in detail in chapter 2 and its subchapters.

Chapter 2.0 Background Information and How to Extract the Facts

2.1 The Executive Summary

The Executive Summary is the first piece of information in a Business Plan but it makes sense to keep its design for last in the process of writing. Since it is going to be specific and meaningful, a summary of a **specific plan** must contain a concise statement of each element in the following business plan. It should not overload the reader with details to be expected in the plan itself and should not exceed a reasonable length of 1-2 pages.

2.2 The Business Description

2.2.1 Vision and Mission Statement for an O&P Business

Any business planner has their own mental plan on what his/her business should look like and what it should focus on. They might want to find the right concise wording to share that mental picture with the rest of the world. Such sharing is done in Vision- and Mission Statements or in one of them.

An O&P Vision Statement could be similar to this:

We (I) will thoroughly plan, design and build a successful, sustainable business for Orthotics and Prosthetics (O&P) that is appropriate in focus, size and technology to serve the needs of individuals with disabilities in our region.

AN O&P Mission Statement could be similar to this:

It is our mission to serve individuals with disabilities in our region with a focus on applying the most appropriate and affordable O&P technologies

to improve their functionality, their quality of life as well as to support their reintegration into families, society and work life.

These statements shall clearly communicate a specific intent and a difference when compared to other business.

Personal wording is required in both statements and it may be different than the provided example. The purpose is to make others perceive the strength of the planner's intentions.

2.2.2 The Business Model

An O&P business model is explainable based on two different sets of information and both of them are required.

One is: What kind of business is O&P? What is special about it?

The second one is: Which legal form will the business have?

The second one is – on the example of Tanzania – explained later and in detail. Here is the first one:

2.2.3 What is O&P?

The prospective business owner has been in O&P for a while. They should not take for granted that anyone else knows what O&P is.

When describing O&P, the following key points need to be considered:

- An O&P business is a medical/technical service provider, serving individuals
 with physical disabilities of the locomotor system with assistive mobility
 devices (artificial limbs and braces better designated as "prostheses and
 orthoses") and "Over the shelf devices, often called OTS devices. By definition all of them are part of the so-called "Assistive Mobility Devices".
- The potential customer is therefore any individual with a disability, which is a malfunction and/or deformity of the legs or the arms, or the spinal column.
- Disabilities may be congenital or acquired. Well known examples in the field are amputations, scoliosis, spina bifida, club feet or poliomyelitis, paraplegia, and other debilitating conditions. These provide samples for traumatic events, congenital deformity or acquired disease.
- The World Health Organization (WHO) estimates 2-4 % of the population experience significant difficulties in functioning. See link [*2]
- The ISPO/ WHO consider 0.5 % of the world's population in need of O&P services. See link [*3]
- SIDA estimates ca. 8 % of Tanzania's population to be disabled.
 See link [* 4]
- "O&P products" are custom made medical devices, fit to the individual client. The process requires optimal knowledge in physiology, pathology, anatomy, mechanics and biomechanics and highly developed professional skills.

2.2.4 The Benefit of Special Relationships

The business planner may have built such special relations already – if so they should be explained; if not so, it is highly important to build them carefully and professionally to facilitate starting a business:

Any business needs good relations with their clients. Once a client received a quality product or service, the client is the best promotor! Word of mouth is still an important aspect of building the O&P business in Tanzania.

An O&P business is not a standalone business that simply opens the doors and the customer walks in. O&P also needs healthy connections to medical centers, specialized rehab and to the clinical expert who may serve as a referral resource.

The planner may have other valuable relationships to professionals, national peers and organizations, international peers and organizations, medical experts, business experts, local or foreign industry and/or local or foreign markets. Which of them are already developed? Which need to be developed? Why are they considered to be of value?

2.2.5 Location

For the sake of building a sample for better understanding (see later) the authors will assume the new business is to be planned for the Kilimanjaro Region (that would be considered the business' "catchment area" for clients). In the example the new O&P business is located in close vicinity to the Kilimanjaro Christian Medical Center or in Moshi. The planner needs to describe where exactly the new business is going to be located and why that is important. Later that region shall be analyzed for population density, and patient density using official statistics for the calculations of client catchment and comparing these to existing reality.

2.2.6 The Business Founder

In a Business Plan it is important that the group, targeted to read the plan, understands O&P and the special professional education and career that the potential business founder has gone through to reach the point of starting their own business.

Stakeholders shall not be shy to present themselves and their special qualifications.

The founder is probably not going to run their business as a lonely, sole employee of their own. They will surround themselves with qualified colleagues, helpers, employees on administrative or technical levels. A detailed explanation who they are and what their benefits are for the new business is essential.

The special skills and gifts of partners, personnel and other stakeholders are after all, why they are chosen to participate in the first place and they might actually be one of the reasons why it will be possible to facilitate customer catchment.

2.2.7 The Legal Structure and Legal Requirements

The business model (for Tanzania) may follow any legal model that is permitted under the regulatory requirements of the Republic of Tanzania. Tanzania provides many options.

The following information (as of 2019) will provide the basic issues one needs to know to start up a business as an individual, a partnership, trust or a limited company. The planner will also find links for additional help and important contact addresses under the following link [*5]

Legal Structure: Individual

An individual, whether resident or nonresident, is required to visit the **Tanzania Revenue Authority (TRA)** regional or district office and fill TIN application form to apply for **Taxpayer Identification Number (TIN)**. The application can also be made online; the applicant must physically visit TRA offices for biometric scanning though, which involves taking photograph, finger prints and signature.

After obtaining their TIN certificate the applicant will be required to apply for a business license from the Trade office in the District, Municipal, City and the Ministry of Trade and Industry, depending on the type of business.

The registered name can be obtained before or after application for TIN through the **Business Registration and Licensing Authority (BRELA)**. A specific requirement for O&P by the Tanganyika Medical Council is to register with the **Association of O&P Tanzania (APOT)** of East Africa.

Who is a Resident?

A person qualifies to be a resident in the United Republic of Tanzania when:

- ...they have a permanent home in the United Republic and earn income in any part of the year.
- ...they are present in the United Republic during the year of income for a period or periods amounting in aggregate to 183 days or more.
- ...they are present in the United Republic during the year of income and in each of the two preceding years of income for periods averaging more than 122 days in each of such year of income.

- ...they are an employee or an official of the Government of the United Republic posted abroad during the year of income.
- ...they are a person holding a National ID-Card by the National Identification Authority (NIDA), a Tanzanian organization for the process of identification of its citizen.

• Legal Requirement: Certificate of Registration

An individual may opt to register the business name to the agency commissioned by Ministry of Trade and Industry known as Business Registration and Licensing Authority (BRELA). The registered name can be obtained before or after application for TIN. The registered business name shall be indicated on the TIN certificate together with an individuals' name showing the owners name trading as (T/A).

• Legal Structure: Corporation (Limited Company)

Starting a corporation requires a person to apply for the Certificate of Incorporation from Business Registration and Licensing Authority (BRE-LA). The promoters of the company are required to draw and submit the certificate and memorandum and articles of association.

The Certificate of Incorporation shall be attached to the TIN application enclosed with Memorandum and Articles of Associations when a person makes application to TRA.

The limited company shall apply for TIN certificate by filling TIN application forms as follows:

- Application for the business.
- Application for each shareholders/directors, in case any director has

already issued with TIN certificates for other purpose he/she cannot make another application. The same TIN number will be used.

 Non-citizen Directors are required to fulfill all immigration procedure and obtaining business permit from the Immigration Department working under Ministry of Home Affairs.

Legal Structure: Partnership

The partners have to register for the firm at BRELA and acquire the certificate of registration which shows the number and names of partners with their respective distribution ratio.

- In applying for TIN the partnership firm shall apply for its certificate by submitting the copy of certificate of registration obtained from BRELA.
- Each individual partner shall apply for TIN, in case any partner has already issued with TIN certificate for other purpose he/she cannot make another application. The same TIN will be used.

• Legal Structure: Trust

A trust is an arrangement under which the trustees hold assets but excludes partnership and a company.

A trust has to register for the firm at BRELA and acquire the certificate of registration which shows the names and addresses of trustees. Each trustee shall apply for TIN, in case any trustee has already been issued with TIN certificate for other purpose he/she cannot make another application. The same TIN will be used.

• Legal Structure: Charitable Organization

An entity will be recognized as charitable organization for tax purposes after been issued with a ruling by the Commissioner General. The applicant has to acquire all necessary documents from the Ministry of Home Affairs.

• Legal Requirement: Declaration of Estimated Income/Turnover

A business planner will be required to declare the estimated income or turnover for the provision of a tax assessment for the particular year. The tax officer at the TRA office may interview particulars of the applicant and the business in planning. A new requirement (2019) is an "Appointed Auditor" who is to present the required estimates to the TRA on behalf of the applicant. An auditor is a professional accountant or tax specialist, who is appointed by the government.

Details of the necessary process can be facilitated by an experienced business law company. One possible example is given under link: [*6]

For support the planner may want to research and choose a consultant of personal preference – the obligatory auditor, however, might be sufficient because he is appointed for this purpose.

• Legal Requirement for: Investment in Tanzania – The TIC

This subchapter of investment may not reflect the typical business startup in O&P; but it could.

Therefore it shall be provided to make this guide complete. It refers to foreign entities wanting to start a business in Tanzania. It may also apply, if existing or new Tanzania business takes on partial foreign investment. Again, the help of specialized business lawyers is recommended.

Working directly with the TIC may facilitate the process:

The Tanzania Investment Centre (TIC) has been given the facilitative role to investors who want to establish business in Tanzania. In order to strengthen and expedite facilitation services, there are 7 senior officers from Government Departments and other Government Agencies permanently stationed and operating within Tanzania Investment Centre (TIC) premises. These are:

- 1. Lands Department
- 2. Tanzania Revenue Authority
- 3. Immigration Department
- 4. Labour Division
- 5. Directorate of Trade and
- 6. Business Registration and Licensing Agency

Upon submission of relevant documents, the above offices will process the application for different permits and approval. Further information is under link [*7]

• Legal Structure: Public / Private Partnerships or PPPs

For a new O&P business it may be worthwhile to brainstorm a public/private partnership. The private sector would have to be the executive arm in providing services and devices for the rehabilitation of Tanzania's disabled population, operating out of a government owned shop or a private entrepreneur could run a government installed O&P facility on behalf of the government efficiently.

Such endeavor would have to be discussed with the related government entities; it shall not be further discussed here, as it may not be a primary focus of new O&P business development in Tanzania.

Please find the National Public Private Partnership Policy of 2009 and further information under link [*8] and under [*9]

2.3 Market Analysis - The Details

When designing at a market analysis for O&P there are two alternative choices for the question on patient catchment:

- 1: Using the existing, most reliable regional statistics and converting them to the population in reach (this is the easy approach, see the example, and it is an acceptable planning tool) or
- 2: Doing specific market research on particular disabilities in the catchment region. This second one may be more exact, because it is working with exact regional numbers of exactly the disabilities the business is looking for. It would be an important approach if a business would want to specialize on serving the needs for a particular disability segment only. It is, however, a tremendous effort to do this kind of market research (or expensive to get it done by external professionals).

Whichever way is taken, it is important that numbers are credible and that, using them, that results can provide feasibility for (or against) the new project.

2.3.1 Example for the Kilimanjaro Region – Method 1:

The population of the Kilimanjaro Region is 1.64 Mio individuals (2012 Census). See link [*10].

It is certainly higher today (estimates say 1.75 Million). The calculations, however, will be based on the existing census, keeping in mind that the outcome would present higher numbers, if there were reliable numbers of the population today.

Knowing that the region is subdivided into 6 districts and not neglecting that they are of various size and population density, it is, however sufficient to calculate statistics for the Kilimanjaro region as one unit because – in the example – it will be proposed as the center of the so-called "catchment area".

It is allowed to do so, because of an existing and relatively well established transportation infrastructure of the Kilimanjaro region. Therefore it may be assumed a new O&P business (assumed as located in Moshi in this particular example) could reach 90 % of this potential client population, or vice versa the clients could reach the business.

The vicinity of an International Airport and good long distance road conditions allow to expand the catchment area far beyond the Kilimanjaro region (not done here). It has been confirmed by local business, that part of their clientele travels even from beyond Tanzania's borders!

A calculated 1.64 Million inhabitants of the region would lead to a result of 1.48 Mio reachable inhabitants under the assumptions of this 90% calculation model.

Looking at the average out of the WHO health statistics identifying $2-4\,\%$ of the population being severely restricted in function (see link [*11]), and the WHO/ISPO statement that 0.5 % of the population needing assistive devices (a number lacking evidence so far- see link [*12] and [*13] page 6), one might assume – probably without serious mistake – that any number between about 0.5 % and 2 % of the population would be in need of O&P assistive devices, which enhance function.

Using these numbers and assuming an average of a mid-level, somewhat conservative 1.5 % of the population, this calculation would lead to 22,200 individuals with disabilities, who would actually need one or the other assistive device (as artificial legs, braces and wheelchairs) about every 3 years in the Kilimanjaro Region.

This number can be split according to the districts within the Kilimanjaro region if a new business owner would intent to cover a specific region only.

The authors will not expand into further mathematics here, but leave this – if desired – to individuals planning their business.

Looking at these statistics from a business point of view one needs to be careful regarding economic strength of the population. The authors assume (not an evidence-based statement!), that only 25 % of the individuals numbered above would have the economic strength to pay out of pocket for O&P services.

Risk: This conservative assumption may be right or wrong, which could make a huge difference in the final results – statistics, however, were not found).

Under this assumption the O&P businesses of the region would share 5,600 individuals who can firstly: reach the business, who secondly: need O&P services and thirdly: are able to pay for it. This is the outcome of a market analysis, partially based on available data and (reasonable) assumptions.

If the new O&P business in the region would have to share this number with 2 competitors they each will end up with about 1,900 O&P clients for "large O&P" devices and many more for smaller, customizable "Off The Shelf" (OTS) products! O&P clients will return frequently, because disability is a lifetime condition.

Would that be a satisfactory client number for those businesses?

Yes, absolutely in Tanzania (manufacturing without automation by CAD CAM and similar tools), it would be providing a very good workload for a medium to large business in O&P.

If one of the businesses had the intent to grow their business beyond that number they would have to convince an additional number of patients within the existing pool to choose their particular business. This is called "competing", one of the typical and normal strategies in business life – thriving to be better in outcome and more convincing in client outreach, than the competition! Alternatively they could also serve patients (and this is a huge number!) who get their devices potentially paid by social services. This however is a cumbersome process taking administrative time with unknown outcome for each individual case, an effort for a business decision to make!

The calculations above do not yet consider a specific number for the OTS products. There are no health statistics in Africa for their use in the population. A reality check and one different possible step of getting a better "feeling" for the market is to look at existing O&P facilities. How many individuals with a disability does a regionally established O&P facility see per year for new O&P devices? How many repairs or repeat business for existing ones? How many for smaller items of care? What percentage of patients can pay for their services? How much is paid by whom for O&P services, if the patient is not able to do so (social services)? Is these numbers sufficient business-wise? Is there a patient overhang by the end of the year? A difficulty of this particular approach is that there is no answer to total patient availability in the region, but it helps to understand if established local facilities are extremely busy or "going slow".

The authors did not delve into those details but have been informed that the largest O&P Facility in the region (KCMC O&P), with a number of qualified employees, handles a mixed patient load of about 2,000 per year and handles only a fraction of cases in need, which includes many of those that cannot pay (they are probably not a primary target group for new O&P businesses) and many that have to wait for service. This answer may serve as a "secondary evidence" that the calculations above are close to being reliable.

It may be interesting at this point to know that there are a few medical resources in the region who see patients beyond the patients seen at KCMC. These are:

- CCBRT Moshi
- · St. Joseph Hospital
- Mawenzi Regional Hospital
- Kibosho Missionary Hospital
- Machame Missionary Hospital

Also there are additional O&P facilities as service providers:

"USA River Rehab Center" in Arusha with their own orthopedic workshop and "Orthofit", a small but impressively functional specialist for prosthetics of the lower limb (only) and another one in planning. The authors do therefore not perceive a shortage of work in the region even if a patient load of about 2,000 seems to be "small" for a SME-size O&P company (2 – 6 employees) under European or USA standards (which do certainly not apply here!).

2.3.2 Evidence on Needs and Business Feasibility in O&P

Information can be anything from true evidence to wishful thinking. When using statistics and data to further a business reliable resources should be used exclusively. In O&P these are the World Health Organization, the ISPO, the national ministries of health or commerce, universities and NGO organizations that have done research in our field of interest. Evidence-based planning is harnessing the knowledge gained from official data and information and using it to optimize planning and to improve the reliability of results.

The "ISPO/WHO Guidelines for Training Personnel in Developing Countries for Orthotics and Prosthetics", see link [*13], page 6, states:

"Persons with physical disabilities, who have a need for prosthetics/orthotics and related rehabilitation services in developing countries, represent 0.5% of the population. In 2004 (!) there are 5.1 billion people in Africa, Asia and Latin America so there will be 25.5 million people in need of prosthetic/orthotic devices. The vast majority of these persons can remain functionally free of deformities or be re-established to function in society if provided with appropriate prosthetic/orthotic devices".

The requirement of evidence means that at least "the best available data, information and knowledge are used to make decisions".

Unfortunately the above ISPO/WHO statement does not show any reference to particular research (when, where, how), within the particular print, on the particular statement regarding need of assistive O&P devices or how it was calculated and extracted out of the more expansive WHO reports on disability. However, this guideline was written by experts in the field and in business planning one will have to be satisfied with the best evidence available. WHO and ISPO statistical health information – or a meaningful mix thereof – in regard to O&P is the best available evidence available to this profession.

Best evidence is required when the bank asks for patient load. How many accumulated clients are to be taken care of in the region that is reasonably covered? Which business value will that equate to? How can it be expanded?

In business terms this is relevant information and it is difficult to rely on data that does not present with the required evidence or proven reliable. Even a single professional consultant who may have had the task to travel a remote area and collect statistical information may provide valid and reliable information, as long as their methods were appropriate and their approach scientifically clean.

Rule: Not all information found is evident in the scientific sense. In O&P non-scientific information may provide a lower grade of evidence and

therefore it may still be valid for planning purpose as long as it is the best or only information available! Careful comparison of contradictory statements is indicated.

2.3.3 Disability - WHO, ISPO and Other information

WHO:

Excerpt of the World Health Organization's (WHO) World Report on Disability:

"About 15% of the world's population lives with some form of disability, of whom 2-4% experience significant difficulties in functioning". The global disability prevalence is higher than published previous WHO estimates, which date from the 1970s and suggested a figure of around 10%.

Regarding that the figure of $2-4\,\%$ of population with significant disabilities blindness, hearing loss and others, one may be permitted to calculate that $1-2\,\%$ of the population may turn up at the door of the new business earlier or later, needing O&P services. This number would be considered a conservative approach by some – or a slightly elevated number by others. At least the number is probable (see details of the market analysis above).

WHO Statistics, see link [*11], generalize the frequency of a particular disability in relation to population. These numbers are not necessarily 100% reliable, the situation may differ region to region but they are probably some of the best evidence one can get.

The International Society for Prosthetics and Orthotics, ISPO has been involved with O&P only since the 1970s and is therefore an excellent resource to find information needed for planning: For example if information on standards or education or international collaboration and consensus in

the field of O&P, is required, it is worthwhile to consider ISPO/WHO as a resource under link [*14]. In 2004 a working group has developed the ISPO guideline on: "Planning, Monitoring and Evaluation of O&P Service Projects". See link [*12].

This guideline was not designed for the planning of O&P enterprises with sole owners in mind, but it is excellently useable for that purpose. After all it does not make a huge difference, if an O&P service facility is run by an organization or by a sole owner company. Both build an appropriate O&P service and workshop, which has to prove efficiency and success. Both have an identical focus: quality patient service. The ISPO manual may be referred to more often. It can be downloaded (70 pages) from the internet.

2.3.4 Disability - in Tanzania, National Data

WHO and ISPO data were already mentioned. The Swedish International Cooperation Agency, SIDA is a government agency on behalf of the Swedish parliament and government with the mission to reduce poverty in the world. They have researched numbers in Tanzania. According to their national disability survey of 2008, 3.2 million Tanzanians (7.8%) of the population aged 7 years and above have some form of disability and up to 5.4 million (13.2%) are affected by disability. The Tanzania mainland has slightly higher prevalence of disability (13.3%) than Zanzibar (9.3%). It is more than 10 years old to date and it would be desirable to renew it and possibly shine a light on the requirements for assistive devices. However, as the WHO and ISPO statistics, it belongs to the best available evidence to date. It is referenced under [*15].

These numbers are considerably higher than those of the WHO and it would be interesting to compare both of their methods.

The Tanzanian SIDA numbers seem very encouraging for anyone who plans to start an O&P business in Tanzania. However, the authors cannot guarantee for accuracy as an O&P-only planning tool.

Rule: It is recommended to be critical with numbers on disabilities researched, even if they come from reputable organizations.

Risk: Not knowing or exaggerating the expected patient load for a new O&P business may cause serious miss-planning with undesirable consequences. Providing a range of reasonable probability is useful and builds trust.

2.4 Business Plan – Organization and Management

The business planner may have decided to be the President of the new company. Someone convincing might be the Executive Director – if the business really needs one. Is it going to be a participating active partner who will share in the company? Or is it going to be a highly skilled employee already found and willing to work for the new entity?

Possibly it is somebody that the business will have to search for. How does the business search for qualified partners/employees?

Orthotists and Prosthetist trained in Tanzania may present with different qualification levels:

- "Single Discipline Technologist" (ISPO Category III);
- "Orthopedic Technologist-Diploma" (ISPO Category II) and
- "B.Sc. in Orthotics and Prosthetics" (ISPO Category I).

 "M. Sc. Degrees in O&P" are not yet available in the Tanzanian education system. They may be acquired in online distance-learning, and they are offered by external universities (as by the University of Strathclyde, Glasgow, UK.)

Any O&P business has a number of title options available if that is important to the business and to the future employees:

Director, Manager, Lead Orthotist, Lead Prosthetist, Workshop Manager

and so on. Titles are not everything, they should be well considered before provided. They need to come within an employment contract and job description in writing. Both parties will agree on what is expected and what is provided. This creates bilateral commitment and option for control.

How many employees on which qualification levels will the new business need and when? How many employees in a simple maintenance function? How many short- or part-time employed or non-employed helpers?

The plan will have to describe everybody's function, their qualification, their main task and at which time in the business development process they are expected to be hired.

It is certainly difficult to plan for a number of employees as long as one does not know the actual work load the company will have available to start with. That's why there is the market analysis.

Now that the planner knows the volume of work to be reasonably expected they can – with some reliability – calculate how large or small of a business to start with. That leads also to the number of employees required for the task (assuming that the facilities are functional and ready to go, the employees need a work space).

To be remembered: Employees are an important business asset and also they create a high burden of cost for a new business. If the planner feels uncomfortable with taking on that responsibility from the start, they should start with one or two less employees and as the company grows, see if additional manpower needs to be hired.

It may be good to have an overview of employee recruitment on a clean document. A "Gantt Chart", as an example to be downloaded for free is referenced here: [*16]

2.5 Business Plan – Sales Strategies

Partners, lenders and recipients of the business plan need to know: O&P is not typically considered a sales-oriented business, and not to be compared with any sales-oriented trading business typically well-known in the general public.

O&P is a med-tech service dedicated to measuring, designing, casting, manufacturing, fitting of a device and training the recipient in appropriate, functional usage of their new custom device.

This is more than a sale, it is a complicated process, however, the outcome of any single O&P service is – in an important part – reflected in a single custom device, and a device is a product. In O&P typically all process reimbursement efforts are covered with the sale of the device.

Rule: For a better understanding of O&P business the planner and potential new business owner has the task to educate the client and the payers (if different) on the difference of the process-based O&P price calculation effort as compared to a product-based price of any simply traded resale product. This is one of the O&P self-explanation dilemmas world-wide!

As already explained, an O&P businesses' volume of sales depends mainly upon the number of patients it can attract.

In Europe and USA an O&P order, leading to a new "sale", is triggered by a specialized doctor (orthopedics, rehab and surgeons as well as PT and OT). He/she will perform a medical exam and come to a medical diagnosis, confirming the specific need for an orthopedic device (or wheelchair). Most of the clients (if health-insured) can see a specialized doctor for a small co-pay at any time (and not only after a surgery).

This creates a desirable side effect for everyone involved: The doctor, being a neutral professional expert, does their own diagnostic job and is – as a side-effect – simultaneously acting as a main sales promoter for O&P! Without a doctor's professional diagnosis and an objective "confirmation of need" in form of a prescription (which will land on the desk of one of the O&P businesses) there is no O&P sale.

In Tanzania things may be similar but they are certainly not the same. A Tanzania business needs to have referrals too. The easiest referral person would always be a healthcare provider seen by the client before they see O&P. It is not surprising that – over time – there is a special bond between a care provider and the client. So if they refer the client to O&P, basically what they say is: "I trust this O&P-company, as you (client) trust me, you are in very good hands there!"

Just as for Europe or the USA, Tanzania's O&P needs a "sales strategy" (it is not the most appropriate term in O&P because it is really more of a patient need satisfaction strategy!) that builds referrals. Any business – and O&P too – has to engage in PR with all potential referral resources. Any business has to make themselves well known and use any reasonable tool that comes to mind.

PR in O&P could be offering continuing education courses to referral resources, which is a benefit to the doctors/therapists and not just considered

"cheap advertising" with questionable arguments. The target group of medical experts needs to understand the work and results (demonstration of satisfied patients is a very successful tool) of O&P to become truly qualified referral resources! There are cases in which medical doctors have switched their careers to O&P because they were impressed with results achievable! O&P needs to utilize their chances of public involvement and public education!

Furthermore the combined use of printed brochures, newspaper, radio, TV, Instagram, Facebook and website advertising is recommended.

Once – or if – Tanzania's government agrees that health insurance should be available to everyone and pay for O&P services, they will simultaneously set controls in place in order to avoid abuse of the system. At that time a specialized doctor's prescription and referral to O&P will be mandatory. Once installed, it will facilitate any so-called "sales strategy" built on healthy, appropriate relations. It will also improve outcomes and outcome control as well as avoidance of fraud (which is an unfortunate truth of life!).

2.6 Business Plan – Funding Requirements

It can cost roughly between \$10,000 (if a small building is already owned, utility installation is already done and the new business owner is a do-it-your-self person) and \$300,000 to open an O&P company in Tanzania, depending on the chosen parameters of location, size, equipment technology installation, number of employees and start-up warehouse requirements (components and materials bought).

Calculated profit margins in O&P are typically only in the plus/minus 10 percent range, once all other factors are calculated appropriately.

There is no doubt that anyone starting a business will need seed money to get started!

Even if the entrepreneur has saved some money already, they need to calculate how much they will need beyond personal assets. Anyone, involved in providing funds, be it family, partners, donors, public programs or the local bank, need to know how much funding the new business needs and when they are going to have it paid back. This is common risk reduction and business sense on their end.

The new business needs also to consider finances for the start itself and to get over the starting hump of the first 6-12 months or more and consider all factors that contribute to the final amount they have to borrow. Here are examples:

Fix costs:

- Property (grounds)
- Property (buildings) to be purchased, leased or rented
- Property building functional re-design and renovation
- Property utility installations functional re-design and renovation
- Equipment and tools workshop
- Equipment and office tools administration
- Materials workshop
- · Materials administration
- Retail goods (prefab and assistive devices)
- Furnishing patient waiting and fitting rooms
- Furnishing administration
- Furnishing other
- Any other business related fixed cost

Flexible cost:

- All Personnel (depending on start-up needs)
- External planners, consultants
- Fees
- Taxes
- Any other business related flexible cost

Obviously it would be rather difficult to provide any specific planning examples in this document because there are too many factors influencing the numbers.

Some of these are:

- Location of the business (local pricing)
- Size of the new business, (building, equipment, furnishing)
- Local planning, building, construction and related cost
- Other consultants needed
- Equipment sourcing, quality of machine/tool equipment and numbers
- Material needs on expanse of technologies covered (imported/local?)
- Volume of start-up stock and reserve stock needed workshop
- Volume of start-up stock and reserve stock needed for OTS retail
- Personnel cost level and numbers (depending on size/specialization)
- Level of government fees and initial taxation

For the technical component of workshop planning see the ISPO publication:

"Planning and Installation of Orthopedic Workshops in Developing Countries" by S. Heim, N.A. Jacobs and W.Kaphingst ISBN 87-98190201-0.

Not internet-based, see pdf attachment [*A1] in the electronic version of this document. Look at the website of the Tanzania Training Centre for Orthopaedic Technologists TATCOT (https://www.tatcot.org).

Unfortunately this valuable document was written already 1987, somewhat before every thought was published on the Internet, and any hard copy is out of circulation nowadays. It shall be attached, however, as a separate pdf file to the electronic version of this document. Even being 30 years old it is not outdated yet, except if a new business wants to invest in so called recent hi-tech (CAD CAM, 3-D printing), which the authors do not necessarily recommend for a start-up. Otherwise using the list above (including all the necessary small details not yet contained) and creating a tabulation (using MS Excel for example) is an easy way to get an answer for needs identified.

Risk: The funding need analysis is an important and big planning task – if not planned diligently, the new business may experience shortcomings in identified needs and unwanted surprises in their technical ability to provide services, as required by their clients.

Once the business planner has added up all needs and translated them into today's financial value, as well as knows the amount of their own finances available to invest, it is a simple mathematic action of subtraction to calculate the remaining funding requirements.

ALTERNATIVES:

The business planner may want to create two plans, one of them covering the bare minimum of an acceptable plan for slow growth and one covering a reasonable early investment in a representative, comfortable but still reasonable low to medium risk start-up size and the related plan. This may be a complex task to perform, in particular if the planner has not been involved in such projections and analyses before. Most of new business owners, however, have not been involved in such planning before! Feeling uncomfortable to find the required answers, is a good sign of a careful approach! It is recommended to ask for support by an experienced business planner if desired. They may not understand what the planned O&P items are needed for, but they understand how to compute their numbers/values correctly.

Risk: Fantastic numbers presented to a lender are not acceptable. Presenting fantasies can jeopardize the borrower's reputation much faster than they will be able to rebuild it!

Obviously anyone borrowing money will have to "sell" their plan with good arguments to those who desire to support. The planner must be prepared to answer all questions that might come up convincingly! A prospective new business owner must excite their listeners as much as they are excited themselves – personal appearance and professionalism increases trust and the chance for success – but the excitement must be based in the purest of realism! That is one of the reasons for the business plan!

2.6.1 A Potential Funding Opportunity for Small and Medium Healthcare and O&P Enterprises in Tanzania:

A funding opportunity (2019) that might fit the needs and conditions for small/medium healthcare enterprise and O&P is referenced under [*17].

The authors cannot guarantee that a potential application will fit all criteria. A potential recipient has to do their own specific research and communication. Another source of information on funding is the local Chamber of Commerce.

Failure is not a reason to give up! Bill Gates didn't get start-up funding but developed his business out of a garage!

2.7 Financial Projections – Pricing/Budgeting/Accounting2.7.1 Pricing

It was already stated that O&P is a service business not at all designed to "make a quick buck" but to serve the needs of people with disabilities with all necessary seriousness and with some social involvement.

That said, the business owner needs profits to sustain and grow a business because typically there is no government, NGO, or charitable organization to help them stay afloat:

No business will survive without revenue and profits.

Realistic sale prices for services and products need to be calculated. Better: Verified and agreed upon price lists obligatory for everyone in the field should be created. Unified price lists create trust in pricing in the health sector. See excel attachment [*A2] 04-19 Sample Calculation or see the VIET-COT/ISPO publication "Prosthetics/Orthotics for the Rehabilitation Team" by W. Raab and W. Kaphingst (in libraries, out of print). If unexperienced, it may be good to ask accounting experts (local business or Chamber of Commerce)

A sample for a price calculation path (see also electronic attachment): Direct Costs of Manufacturing:

The final calculation of any product, including orthoses and prostheses has to start with and cover all related Direct Costs of Manufacturing, such as:

raw materials, components, labor (all clinical processes to be included – not just the actual technical device manufacturing) and related overheads, (shipping cost of goods), and has to add a percentage for their handling, plus

Indirect Costs of Manufacturing, such as:

indirect labor (patient transport, accommodation if provided, store keeper, janitor, maintenance,) utilities, rent of the building or cost of the building, repairs, machine parts to be replaced and has to add a percentage for the effort related to govern these, plus the

Administrative Overhead, such as:

Accounting, Human Relations (HR), accounting, PR and marketing, Quality Control, Client Education and similar activities related to selling the previously manufactured device.

Direct Costs are easy to determine – the buyer had to pay for many of them to get the materials and components and their clinical and technical employees worked on creating the custom device for a certain amount of time. In order to have these times available for calculations they need to be properly recorded (clinical and technical), no part of the effort is to be neglected as "less important".

Indirect costs are a little more difficult because they are for example the total cost incurred over a month, distributed to be a justifiable part of the cost of a product manufactured. This can be expressed in man-hours per product (using hours one will get to different prices each time and will have to do a lot of single calculations) or in a justifiable percentage to be added to the direct cost (which provides a more stable manufacturing price, useable to lead to a price list). All direct and indirect costs including shall be added up and it will provide the "Cost of Manufacturing" or "Prime Cost". This indicates how much was invested to get it manufactured. No money is earned yet!

Now the product is ready for a sale and it is time to add the cost of sales. These are relatively small in O&P because the whole process until now was already related to the sale (the patient accepted the sale already when coming for their first or second appointment).

It is up to the business owner how segmented they calculate, they could also add some percentage points to cover the cost of sale and then add the profit at this time and they could even consider covering any cost of sales with it too.

Rule: If adding the profit is forgotten, a business will just "exchange money" without a profit it will be very short-lived!

The typical profit in O&P is calculated with 10 - 15 % on the Manufacturing Cost or Prime Cost. A percentage for business risk factors can also be added (a can of resin dries out, rats eat a role of leather or there is a power outage in the middle of a sensitive process) or for a specific singular effort (a quadruple amputee requires much more involvement or work than 4 single amputees!).

Last not least the government wants to participate and cash in on the VAT, or sales tax, which has to be added again. If a country follows the VAT taxing, a business is allowed to deduct the tax initially paid on the materials/ components going into the product – it is important to not forget that! (VAT = value added tax; tax of a product is only to be paid for the outgoing value, not for the incoming value! The incoming tax already paid in purchasing is deducted as an accounting activity).

Risk: Reasonable prices are the one most important starting aspect of business success for the creation of revenue. Any miss-calculation is a stepping stone to painful business failure!

2.7.2 Budgeting

A business cannot spend more money than they own (or at least not for long!).

If it needs to do that on a temporary basis, they will need to borrow and lenders will charge interest for the money borrowed. Unfortunately borrowing cannot be avoided at all times.

Once the cost of business and the related revenue have been recorded for one or several representative months, it is easy to calculate a projection on how much money may be needed in advance for a year of purchasing and manufacturing.

Rule: Control of the cash flow situation every single day and in a planning control by the end of every month provides early answers of business success or warning signs if success cannot be achieved yet.

Risk: Businesses die for three reasons: Either they spend too much or they do not earn enough or both. The control tool to avoid this from happening is budget control.

Budgeting, however is more. It is a thorough plan what amounts of money to spend for which purpose at which time. It can be derived out of prospective planning (items needed) and out of the financial realities of cash available for the purpose.

The budget will show where compromises or reduction of investment is necessary.

2.7.3 Accounting

The following information may seem less important for the start-up planning, however – it is going to be important – as soon as the business starts. Therefore the prospective new business owner must be prepared and knowledgeable now!

The required information and more is kindly provided under the link [*16]:

Rule: Accounting is a government enforced business requirement:

Appropriate bookkeeping (accounting) is necessary in any business. As a small business owner, it's important to recognize that the best practices apply also to them. Following basic accounting principles is essential for success in any size business; savvy record-keeping and financial analysis is key to not only monitoring expenses, but to discovering new avenues of growth. In addition, it ensures to stay responsible for tax obligations to the government and to employees.

Accounting entails more than just managing credits and debits, and it comes into play more often in everyday business decisions than one may realize. A few examples include:

- Closely monitoring accounts receivable to illustrate trends or behaviors in the customer base. The safest approach is to be paid in full at the day of device delivery!
- It can also cut down on the costs incurred by pursuing late payers.
- Establishing a detailed budget to discover inefficiencies in operations.
- Sudden changes in costs or revenues can alert to important changes.
- Understanding the company's financial position in order to spot problem areas that could interfere with credit rating and loans.

Risk: Experts agree that one of the most common reasons why small business fail is because cash flow runs dry. To prevent this disaster, the business should implement policies for efficient record-keeping and a sound financial strategy.

Rule: Remember: Taxes are unavoidable and the government is unforgiving!

Regional office contact data can be found under the following link: [*19]

40

Chapter 3.0 – The Rest

3.1 Final Remarks

No information is ever 100% perfect, in particular not, if conditions researched or taken for granted so far are in flux and change constantly. This document was written in 2019.

As a fact of life: Nothing is more constant than change!

If the document provided deems wrong in parts or lacking in particular information, the authors would like to know about it.
For the authors, March 2019

Wieland Kaphingst, Dipl.-Ing Biomedical Engineering, CPO wkaphingst@gmail.com

3.2 References and Links

- *1: http://www.tccia.com/tccia/monummy/
- *2: https://www.who.int/disabilities/world_report/2011/report/en/
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- *17: http://www.funds4africa.org/en/small-and-growing-business-fund/
- *18: https://www.accounting.com/resources/accounting-basics-small-business/
- *19: http://www.tccia.com/tccia/monummy/

3.3 Attachments

- *A1: "Planning and Installation of Orthopedic Workshops in Developing Countries by S. Heim, N.A. Jacobs and W. Kaphingst ISBN 87-98190201-0 is attached as a pdf version to the electronic version of this document.
- *A2: Excel Calculation Aid Sheets

3.4 About the Authors

Wieland Kaphingst is a Biomedical Engineer and Certified Prosthetist/Orthotist (CPO), certified in Germany, Europe and the United States.

His global O&P career, covering 53 years, ended with retirement from a very creative US-based medical technology company, Tamarack Habilitation Technologies, covering O&P clients and wheelchair user's needs for quality care worldwide.

For the immigration to the USA he retired (in 1994) from the position of

 Director of the Federal School for Orthopaedic Technology, Dortmund Germany

And started a new career in the USA.

Starting final retirement in 2018, he finished his eight year career as

• Director for (global) Business Development for Tamarack.

His experience and activities cover acknowledged positions in O&P projects of Education, Clinical Research, Education and of Business in 26 countries over the last 40 years.

He was active as a member of ISPO and AAOP, and is a Rotary Club member. He is known for valuable worldwide professional presentations and publications to the benefit of the profession.

Wieland has been awarded with a

Fellowship of the American Academy of Orthotists and Prosthetists

Harold Shangali is a Certified Orthotist Prosthetist (Orthopaedie Meister), certified at the Federal School for Orthopedic Technology Dortmund Germany and holds a M Sc degree in Prosthetics & Orthotics awarded by the University of Strathclyde, Glasgow, UK. He holds the position of Dean of the Faculty for Rehabilitation Medicine at the Kilimanjaro Christian Medical University College (KCMU-College), Tumaini University Makumira in Moshi Tanzania.

Harold is a certified Prosthetist/Orthotist and Orthopaedic Engineer with knowledge, skill and hands-on practice in patient care, orthopaedic engineering and last not least vast experience as a lecturer in teaching future generations of qualified O&P specialists.

During his career he held positions of:

- Chairman of ISPO World Congress Committee 2004 2006.
- President of International Society of Prosthetics and Orthotics (ISPO)
 2004 2007
- Chairman of FATO International Congress Committee, Arusha, Tanzania,
 2012
- Co-Investigator on Survey on the Impact of trained O&P Professionals in East African National & International Affiliation
- Principal-Tanzania Training Centre-Orthopaedic Technologists (TATCOT) 1985–2014
- Dean Faculty of Rehabilitation Medicine, KCMU-College 2012 2019
- and several high level supervisory research positions.

Harold has been awarded with fellowships:

- Fellow International Society of Prosthetics and Orthotics (ISPO)
- Fellow Federation of African Technical Orthopaedics (FATO)

Wilfried Raab is a Certified Orthotist/Prosthetist (Orthopaedic Meister)

His expansive O&P career, covering 53 years of intensive involvement in the field, was mainly focused on teaching O&P in Low Income Countries, sponsored by the German International Cooperation (GIZ). He was teaching and providing clinical services in Algeria, Tanzania, China and Vietnam.

His experience and activities cover Clinical Practice as well as Prosthetic and Orthotic Science in education and training for Diploma and Degree students for more than 25 years. He was involved in establishing sustainable O&P Training Centers in

- Tanzania,
- China and
- Vietnam.

As an active member of the ISPO, he held the position as a

• Task officer for Community Based Rehabilitation over a triennium.

He started his retirement in Tanzania in 2015 and is presently working parttime as

Lecturer and Project Coordinator for O&P

at the Kilimanjaro Christian Medical University College, Tumaini, Makumira, in Moshi Tanzania.

3.5 About the Sponsor

The Saar-Lor-Lux Umweltzentrum (Saar-Lor-Lux Environmental Center – UWZ) was founded in 1995 and is a subsidiary of the Saarland Chamber of Skilled Crafts and 24 craft guilds.

The five business segments of UWZ are environmental and energy consulting, management systems, regional development, development cooperation and further education. Target groups of the consultancy and projects are national and international enterprises, companies as well as representatives of public structures such as counties, federal and state governments.

In development cooperation, UWZ primarily works in the "Business membership organization Partnerships" (KVP) and "Vocational Education and Training Partnerships" (BBP) funding programs of the Federal Ministry for Economic Cooperation and Development (BMZ) as well as in other projects of the Federal Government and in EU projects. At present, UWZ is coordinating projects in Tunisia, Benin, Côte d'Ivoire and Tanzania. sequa gGmbH is the official implementing agency of the KVP and BBP programs.

In its partner countries, UWZ carries out vocational training measures with a focus on environmental protection, renewable energies and energy efficiency and develops a range of services for chambers of trade and commerce, vocational training centers and universities.

UWZ sponsored this publication on "Entrepreneurship and Business Development in O&P in Africa" in the framework of the Vocational Training Partnership between UWZ and Kilimanjaro Christian Medical University College (KCMUCo) which is financed by the Federal Ministry for Economic Cooperation and Development (BMZ).

Project Coordinator in Germany was Nora Jankowski.

Sepp Heim an obituary by three of his colleagues

Sepp Heim, OMM died on April 23rd 2019 at the age of 84 years. He was born into the middle of an existing first generation of the German "orthopedic technician Heim-family". Representing the second O&P generation he created an early personal and intensive connection with orthopedic technology; basically from the time of birth to the day of his passing away. He never saw it differently and he never questioned it.

Even in the younger years of Sepp's life, no day passed being full of information, experiences, events, and important contacts to those involved with orthopedic technology. Later this was true on the level of consulting the German and other global governments and International Aid Organizations, on developing programs for basic and advanced O&P education, continuing education and hands-on training in orthopedics technology. No other individual had the trust and has been given responsibility and the means to create as many O&P schools in countries of need, as Sepp Heim did.

For a phase of his life Sepp Heim was – on behalf of the German government (BMZ/GTZ) – the founding Expert Manager of the "Tanzania Training Center for Orthopedic Technologists" TATCOT. Later he was employed as the Director of the German O&P School "Bundesfachschule" (BUFA), by the German Professional O&P Association. In another phase, he was elected President of the "International Society for Prosthetics and Orthotics" (ISPO) by its global member representatives (2001 – 2004).

During his early involvement at TATCOT he had a vision of appropriately sized and equipped O&P workshops to be established as patient service centers in Tanzania. His vision was far ahead of the economic realities of that time – but the ISPO publication triggered in 1984 – on modular workshop design is deservedly attached as an important part of this document for O&P Business Development in Africa and has basically the same meaning today as it had when designed 34 years ago.

In addition to the O&P constancy within the family (also the next generation is involved in orthopedic technology), Sepp had many individuals in his life, who accompanied him each on a section of the way, who knew him, who had the same goals by the same means or the same goals pursued with different means.

Both genres were welcome to him, the one for the immediate, mutual "rolling up of the shirt sleeves" (Sepp was a "doer"), the other for extensive discussion about the supposedly only factual truth, but always in tolerance of the diversity of opinions and experiences of his communication partners. Sepp Heim both understood himself and his potential opponents, always as the winners of any subject discussion, either he gained approval or he made existing differences very clear. Both results have always been understood as a win-win for both sides! He knew to motivate others and to support them in their own development.

Sepp Heim's enormous work and the results of developing and establishing O&P Training and Education as well as O&P Services in countries under economic development will always be remembered. His work triggered not only government awareness for the need to install P&O Services, but also to integrate such services by political decision processes into many a National Health Care system.

Sepp Heim's companions included, over a different number of years, many good and famous colleagues in orthopedic medicine, technology and education. Among this large number are three humble colleagues with whom he worked, directly and indirectly, very closely and for decades in the international development of O&P training on numerous continents and countries and on international professional policy.

Among many others these three were:

Harold Shangali, Wilfried Raab and Wieland Kaphingst.

Here is our specific memory of Sepp Heim:

Sepp was a leader who also wanted to be (quietly) led, an instructor who could also learn, a role model with his own role models, a stimulator who was easy to excite himself, a critic and a recognizer of value created. He was a new sponsor of new ideas, a creative person who was able to develop more effective ideas himself in one month than others in a year. In short, as a strong leader Sepp was by no means a "simple" or totally "flawless" personality. He would have never claimed that for himself either. On the contrary, his motto was: "He who does nothing does not make any mistakes," and doing nothing was not only alien to him, but inconceivable.

His life's work, O&P education, was infinite in his own imagination and the fruits of his work suggest that he was not entirely wrong. His work has brought movement to where there was a standstill, and his work is continuing steadily with every new generation of young orthopedic technicians on numerous continents.

Sepp was a personality, a man who knew to judge the strength of his opponents correctly, but did not fear them.

In recognizing strength, he was also someone who recognized the strengths of his co-workers and as a leader made maximum use of them for the benefit of each project, but someone still, who is considered "Papa Heim" among many of his students on different continents.

We are proud that we not only knew Sepp Heim, but also worked with him day in day out for a fruitful period of our lives.

Harold Shangali

Wilfried Raab

Wieland Kaphingst