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Prosthetics — Testing of ankle-foot devices and foot units — Guidance on the application of the test loading conditions of ISO 22675 and on the design of appropriate test equipment

Prothèses — Essais de mécanismes cheville-pied et unités de pied — Directives d'application des conditions de force d'essai selon l'ISO 22675 et de la conception d'équipement d'essai approprié

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Foreword

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ISO/TR 22676 was prepared by Technical Committee ISO/TC 168, *Prosthetics and orthotics*.

Introduction

This Technical Report is exclusively intended for use in connection with ISO 22675.

This Technical Report offers information that is closely related to the above International Standard but is not necessarily required for its application.

In order to confine the volume of ISO 22675 to the necessary, information with guidance character has been separated from it and compiled in this Technical Report.

Prosthetics — Testing of ankle-foot devices and foot units — Guidance on the application of the test loading conditions of ISO 22675 and on the design of appropriate test equipment

1 Scope

This Technical Report offers guidance on:

a) the specification of the test loading conditions of ISO 22675;

b) the design of appropriate test equipment.

The analytical work related to these items would have expanded the length of ISO 22675 without being directly required for its application. Most of the text of this Technical Report relates to the theoretical and technical background and the design of the equipment.

2 Guidance on the specification of the test loading conditions of ISO 22675

2.1 General

Although the concept of the tests on ankle-foot devices and foot units of ISO 22675 differs from that of the corresponding tests of ISO 10328, the relevant values of loads and dimensions are adopted where possible. Nevertheless, a few adaptations are unavoidable.

In order to confine the volume of ISO 22675 to the necessary, these and other matters relevant to the specification of the test loading conditions and test loading levels of ISO 22675 are dealt with in detail in this Technical Report.

2.2 Directions of static and maximum cyclic heel and forefoot reference loading

NOTE For the meaning of “reference” see also statements under “IMPORTANT” at the end of 2.4.1 and 2.4.2.

2.2.1 Basic relationships and conditions

The specification of the directions of static and maximum cyclic heel and forefoot reference loading is based on the relationships of a) and the conditions of b) and c) below.

a) According to Figure 1, for any instant of the loading period shown in Figure 2 there is a given relationship between the test force F and the forces at the foot platform, comprising the tangential (A-P) force component F_T, the perpendicular force component F_P and their resultant F_R. This relationship is determined by the angles α, β and γ.

The following Equations apply:

$$\alpha + \beta = \gamma \quad (1)$$

$$\beta = \arctan (F_T/F_P) \quad (2)$$

b) The values of the tilting angles γ_1 and γ_2 of the foot platform for static and maximum cyclic heel and forefoot reference loading are consistent with those specified in ISO 10328 for the separate structural tests on ankle-foot devices and foot units. These values are γ_1 = – 15° for heel loading and γ_2 = 20° for forefoot loading (see Table 10, Figure 7 and 17.2 of ISO 10328:2006 and Table 8 of ISO 22675:2006).

c) The ratio F_T/F_P of the values of the tangential and perpendicular force components at the foot platform according to Figures 1 and 2 for static and maximum cyclic heel and forefoot reference loading at the tilting angles according to b) is roughly ± 0,15.

NOTE The ratio addressed in c) is based on gait analysis data representative of normal level walking.

2.2.2 Lines of action of the resultant reference forces F_{R1} and F_{R2}

The relationships of 2.2.1 a) and the conditions of 2.2.1 b) and c) allow the inclination of the lines of action of the resultant reference forces F_{R1} and F_{R2} of static and maximum cyclic heel and forefoot reference loading to be specified as follows:

— from Equation (2) and the condition according to 2.2.1 c) β = arctan (F_T/F_P) = arctan (± 0,15) = ± 8,5°;

— from Equation (1) and the conditions according to 2.2.1 b) $\alpha_1 = \gamma_1 - \beta_1$ = – 15° + 8,5° = – 6,5° and $\alpha_2 = \gamma_2 - \beta_2$ = 20° – 8,5° = 11,5°.

The inclinations of the load lines of test loading conditions I and II of the principal structural tests of ISO 10328 do not correspond to these values, as the following calculation demonstrates. The inclination of their projection on the f-u-plane is defined by Equation (3).

$$\alpha_{I,\,II} = -\arctan\left[(f_K - f_A)/(u_K - u_A)\right] \tag{3}$$

The specific values of $\alpha_{I,\,II}$ calculated with the f- and u-coordinates specified for test loading level P5 (see Tables 5 and 6 of ISO 10328:2006) are α_I = – 11,31° and α_{II} = 6,52°. Together with the values β_I = – 3,69° and β_{II} = 13,48° calculated using Equation (1) and the values of γ according to 2.2.1 b) they determine the ratio of horizontal and vertical ground reaction force as

$$(F_T/F_P)_{I,\,II} = \tan \beta_{I,\,II} \tag{4}$$

giving the values $(F_T/F_P)_I$ = – 0,064 and $(F_T/F_P)_{II}$ = 0,24, which differ considerably from the ratio according to 2.2.1 c).

In order to approach the conditions illustrated in Figures 1 and 2, the inclination of the lines of action of the resultant reference forces F_{R1} and F_{R2} of static and maximum cyclic heel and forefoot reference loading according to ISO 22675 need to be determined by values of the angles α_1 and α_2 close to those calculated in the above.

This has been taken into account when establishing the full set of parameters required to specify the test loading conditions of the tests on ankle-foot devices and foot units of ISO 22675.

Figure 3 illustrates the profiles (curves) of the forces F_P, F_T, F_R and F as well as the profiles (curves) of the angles α, β and γ as a function of stance phase time.

Apparently, the values of the angles α and β for static heel reference loading or maximum cyclic heel reference loading at 150 ms after heel contact (α_1 = – 6,18°; β_1 = – 8,82°) and for static forefoot reference loading or maximum cyclic forefoot reference loading at 450 ms after heel contact (α_2 = 11,14°; β_2 = 8,86°) are close to the values of the angles α_1, α_2 and β calculated in the above (α_1 = – 6,5°; α_2 = 11,5° and β = ± 8,5°).

Based on these values, the directions of static and maximum cyclic heel and forefoot reference loading according to ISO 22675 can be specified <u>in part</u> as follows:

— The direction of static and maximum cyclic <u>heel</u> reference loading is defined as a straight line inclined to the u-axis by $\alpha_1 = -6{,}18°$.

— The direction of static and maximum cyclic <u>forefoot</u> reference loading is defined as a straight line inclined to the u-axis by $\alpha_2 = 11{,}14°$.

NOTE The angles α_1 and α_2 only determine the <u>inclination</u> to the u-axis of the lines of action of the resultant reference forces F_{R1} and F_{R2} of static and maximum cyclic heel and forefoot reference loading according to ISO 22675. In order to also determine their <u>position</u>, further parameters need to be specified, as for example the coordinates of specific reference points, through which they pass, as follows.

The different test loading conditions applicable to or particularly developed for ankle-foot devices and foot units, specified in ISO 10328 and ISO 22675, are illustrated in Figure 4 for test loading level P5. This figure illustrates:

1) the test loading conditions I and II of the principal structural tests of ISO 10328 (their projection on the f-u-plane);

2) the loading conditions of the separate structural tests on ankle-foot devices and foot units of ISO 10328;

3) the directions of static and maximum cyclic heel and forefoot reference loading of the tests on ankle-foot devices and foot units of ISO 22675.

The directions of static and maximum cyclic heel and forefoot reference loading according to ISO 22675 are specified in Cartesian coordinates as in test loading conditions I and II of the principal structural tests of ISO 10328.

For consistency at test loading level P5, the lines of action of the resultant reference forces F_{R1} and F_{R2} of static and maximum cyclic heel and forefoot reference loading according to ISO 22675 have the same f_A-offsets as in test loading conditions I and II of ISO 10328 (see Figure 4).

With the values of the f_A-offsets at test loading level P5 specified in Table 7 of ISO 10328:2006 the above requirement allows the <u>complete</u> specification of the directions of static and maximum cyclic heel and forefoot reference loading according to ISO 22675 <u>at test loading level P5</u> as follows:

— the direction of static and maximum cyclic <u>heel</u> reference loading at test loading level P5 is defined as a straight line which passes the ankle level at $f_{A1} = f_{AI} = -32$ mm and is inclined to the u-axis by $\alpha_1 = -6{,}18°$;

— the direction of static and maximum cyclic <u>forefoot</u> reference loading at test loading level P5 is defined as a straight line which passes the ankle level at $f_{A2} = f_{AII} = 120$ mm and is inclined to the u-axis by $\alpha_2 = 11{,}14°$.

2.2.3 Position of the top load application point P_T

NOTE 1 The following is in accordance with Clause 6 and Figure 1 of ISO 22675:2006.

For the tests on ankle-foot devices and foot units of ISO 22675, the top load application point P_T is the point of intersection P_i of the lines of action of the resultant reference forces F_{R1} and F_{R2} of static and maximum cyclic heel and forefoot reference loading specified in 2.2.2.

The coordinates f_T and u_T of the top load application point P_T are calculated by determining at first the functions $u_1(f)$ and $u_2(f)$ of these lines of action from Equation (5)

$$u(f) = f \times \tan(90 - \alpha) + u_0 \tag{5}$$

and then determining their point of intersection P_i by putting $u_1(f) = u_2(f)$.

This method provides the following results:

— the functions of the lines of action of the resultant reference forces F_{R1} and F_{R2} are $u_1(f)_{P5} = 9{,}24 \times f + 375{,}53$ and $u_2(f)_{P5} = -5{,}08 \times f + 689{,}39$;

— their point of intersection is located at $P_{i,\,P5}$ ($f_{i,\,P5} = 22$; $u_{i,\,P5} = 578$).

The method for determining the functions $u_1(f)$ and $u_2(f)$ of the lines of action of the resultant reference forces F_{R1} and F_{R2} and their point of intersection P_i relates to test loading level P5. To apply this method to test loading levels P4 and P3, adaptations concerning the specific f_A-offsets are necessary, as described in the following.

According to 10.1.2.1 of ISO 10328:2006, "*For the principal structural tests on samples of prosthetic structures including an ankle-foot device or a foot unit […], the size of the foot selected shall allow the application of load in accordance with the combined bottom offset S_B specified for the test...*"

NOTE 2 The combined bottom offset S_{BII} determines the distance from the u-axis of the bottom load application point P_{BII} on the forefoot.

The selection of the correct size of foot providing the correct distance from the u-axis of the bottom load application point P_{BII} on the forefoot determines also the correct distance from the u-axis of the bottom load application point P_{BI} on the heel.

Assuming standard proportions for different sizes of feet, the values of S_{BII} and S_{BI} should show a similar scaling. According to the dimensions specified in Table 8 of ISO 10328:2006, this is, however, not the case. While the values of S_{BII} decrease from test loading level P5 to test loading level P3, as to be expected, the corresponding values of S_{BI} have the opposite trend. (Hence, for test loading levels P4 and P3, the bottom load application point P_{BI} of test loading condition I is likely to be located outside the heel portion of an ankle-foot device or foot unit of the size that provides the correct combined bottom offset S_{BII} of the load application point P_{BII} on the forefoot.)

The same applies, in principle, to the values of the offsets f_{BII}; f_{BI} and f_{AII}; f_{AI}.

For the determination of the reference test loading conditions for static and maximum cyclic heel and forefoot reference loading according to ISO 22675 adapted values of f_A- and f_B-offsets, identified by suffixes "1" and "2", can be established by the following conditions, which take account of the configurations described in 2.2.2 and illustrated in Figure 4.

NOTE 3 The offsets f_{AI} and f_{AII} of test loading level P5 and the offset f_{AII} of test loading levels P4/P3 of ISO 10328:2006 have been adopted as f_{A1} and f_{A2} of P5 and f_{A2} of P4/P3 without adaptation of their values.

$$(f_{A,\,P5} - f_{i,\,P5})/(u_{i,\,P5} - u_{A,\,P5}) = (f_{B,\,P5} - f_{i,\,P5})/(u_{i,\,P5} - u_{B,\,P5}) \tag{6}$$

$$f_{A1,\,P5}/f_{A2,\,P5} = f_{A1,\,P4/P3}/f_{A2,\,P4/P3} \tag{7}$$

$$f_{B1,\,P5}/f_{B2,\,P5} = f_{B1,\,P4/P3}/f_{B2,\,P4/P3} \tag{8}$$

$$(f_{B2,\,P5} - f_{B1,\,P5})/(f_{A2,\,P5} - f_{A1,\,P5}) = (f_{B2,\,P4/P3} - f_{B1,\,P4/P3})/(f_{A2,\,P4/P3} - f_{A1\,P4/P3}) \tag{9}$$

using Equation (6) $f_{B1,\ P5} = (-\ 32 - 22)/(578 - 80) \times (578 - 0) + 22 = -\ 41$ and

$f_{B2,\ P5} = (120 - 22)/(578 - 80) \times (578 - 0) + 22 = 136$.

using Equation (7) $f_{A1,\ P4/P3} = -\ 32/120 \times 115 = -\ 31$.

using Equation (8) $f_{B1,\ P4/P3}/f_{B2,\ P4/P3} = -\ 41/136 = -\ 0{,}3$ or

$f_{B1,\ P4/P3} = -\ 0{,}3 \times f_{B2,\ P4/P3}$.

using Equation (9) $f_{B2,\ P4/P3} - f_{B1,\ P4/P3} = (136 + 41)/(120 + 32) \times (115 + 31) = 170$ or

$f_{B2,\ P4/P3} + 0{,}3 \times f_{B2,\ P4/P3} = 1{,}3 \times f_{B2,\ P4/P3} = 170$, giving

$f_{B2,\ P4/P3} = 170/1{,}3 = 131$ and

$f_{B1,\ P4/P3} = -\ 0{,}3 \times f_{B2,\ P4/P3} = 39$.

Since it is desired that for static and maximum cyclic heel and forefoot reference loading the ratio F_T:F_P of the values of the tangential and perpendicular force components (see 2.2.1) is the same for all test loading levels, the inclinations of the lines of action of the resultant reference forces F_{R1} and F_{R2}, determined by the angles $\alpha_1 = -\ 6{,}18°$ and $\alpha_2 = 11{,}14°$ (see 2.2.2) also need to be the same for all test loading levels.

The point of intersection $P_{i,\ P4/P3}$ of the lines of action of the resultant reference forces F_{R1} and F_{R2} for the specific f_A-offsets related to test loading levels P4 and P3 illustrated in Figure 5 in the style applied to Figure 4 can, therefore, be calculated in the manner described in the above for test loading level P5, using the functions determined by application of Equation (5), modified by a coordinate transformation that regards parallel shifting determined by the differences

$(f_{A1,\ P5} - f_{A1,\ P4/P3})$ for $u_1(f)$ and $(f_{A2,\ P5} - f_{A2,\ P4/P3})$ for $u_2(f)$.

The resulting coordinates of the point of intersection $P_{i,\ P4/P3}$ are

$P_{i,\ P4/P3}(f_{i,\ P4/P3} = 21;\ u_{i,\ P4/P3} = 554)$.

The different positions of the point of intersection P_i of the lines of action of the resultant reference forces F_{R1} and F_{R2} determined in the above are dependent on the size of foot determined by the foot length L rather than on the test loading level. This can be shown as follows.

Assuming again, standard proportions for different sizes of feet, the values of f_{A2}, f_{A1} or $(f_{A2} + f_{A1})$ can be expected to show a scaling that is proportional to the size of foot.

Indeed, the scaling of the f- and u-coordinates of $P_{i,\ P5}$ by the quotient $f_{A2,\ P4/P3}/f_{A2,\ P5} = 115/120$ gives exactly the same position of $P_{i,\ P4/P3}$ as calculated in the above.

For test loading level P5 test loading condition II the most appropriate size of foot meeting the condition of 10.1.2.1 of ISO 10328:2006 quoted in the above is size 26 (foot length L = 26 cm).

Consequently, the most appropriate size of foot meeting this condition for test loading levels P4 and P3 shall be size 26 scaled by either of the quotients

$(f_{A2,\ P4/P3} - f_{A1,\ P4/P3})/(f_{A2,\ P5} - f_{A1,\ P5}) = (115 + 31)/(120 + 32)$ or

$(f_{B2,\ P4/P3} - f_{B1,\ P4/P3})/(f_{B2,\ P5} - f_{B1,\ P5}) = (131 + 39)/(136 + 41)$,

which give identical values (0,96) indicating size 25 (foot length L = 25 cm).

In this relation it is important to realize that straight lines drawn from the points of intersection $P_{i,\ P5}$ or $P_{i,\ P4/P3}$ to the points on the f-axis at $f_{B1,\ P5}$ and $f_{B2,\ P5}$ or $f_{B1,\ P4/P3}$ and $f_{B2,\ P4/P3}$ determine reference triangles of identical proportions (see Figure 5).

Since the ratio of f-offsets/foot length L is identical for both sizes of foot, triangles determined by straight lines drawn from the points of intersection $P_{i,\ P5}$ or $P_{i,\ P4/P3}$ to the points on the f-axis determined by the posterior heel edge and the point of foot of the reference feet of sizes 26 (foot length L = 26 cm) and 25 (foot length L = 25 cm) will also have identical proportions (see Figure 6).

The dependence of the position of the point of intersection P_i of the lines of action of the resultant reference forces F_{R1} and F_{R2} on the foot length L described in the above has been established in the concept of the tests of ISO 22675 in the following manner.

- The point of intersection P_i of the lines of action of the resultant reference forces F_{R1} and F_{R2} of static and maximum cyclic heel and forefoot reference loading is referred to as top load application point P_T. If appropriate, the dependence of the position of the top load application point $P_T(f_T, u_T)$ on the foot length L is indicated by the additional suffix 'L' in the form $P_{T,\ L}(f_{T,\ L}, u_{T,\ L})$. If appropriate, general suffix 'L' is replaced by specific values.

- The f- and u-coordinates determining the position of the top load application point P_T are specified in Table 8 of ISO 22675:2006 for a wide range of foot lengths L. In addition, that table includes the Equations that determine these coordinates for any other foot length.

- As is illustrated in Figure 6, the proportion of the reference triangle described in the above uniformly applies to all sizes of foot, independent of the test loading level. In principle, this allows ankle-foot devices and foot units of any size of foot to be tested at any of the test loading levels specified.

For feet of different lengths L, positioned within the coordinate system as illustrated in Figure 6, the related top load application points $P_{T,\ L}$ are located on a straight line directed to the origin of the coordinate system. The distance D_{PT} between load application points $P_{T,\ L}$ relating to two successive values of foot length L has a fixed value determined by the Equation

$$D_{PT} = \frac{\sqrt{\left(f_{T,26}^{\ 2} + u_{T,26}^{\ 2}\right)}}{26} \tag{10}$$

which gives a value of D_{PT} = 22,2.

2.3 Magnitudes of static and maximum cyclic heel and forefoot reference loading

The specification of the magnitudes of static and maximum cyclic heel and forefoot reference loading is based on the following general condition.

The specific values F_{R1x} and F_{R2x} of the resultant reference forces F_{R1} and F_{R2} (see Figure 1) are consistent with the corresponding values F_{1x} and F_{2x} of the test forces F_1 and F_2 specified in ISO 10328 for the separate tests on ankle-foot devices and foot units (see Tables 12 and D.3 of ISO 10328:2006). The specific values F_{R1x} and F_{R2x} of the resultant reference forces F_{R1} and F_{R2} are listed in Table 1.

The specific values F_{1x} and F_{2x} of the test forces F_1 and F_2 related to the specific values F_{R1x} and F_{R2x} of the resultant reference forces F_{R1} and F_{R2} (see Figure 1) are determined by the following Equation, derived from the relationship described in 2.2.1 a):

$$F_{1,\ 2} = F_{R1,\ R2} \times \cos \alpha_{1,\ 2} \tag{11}$$

The specific values F_{1x} and F_{2x} of the test forces F_1 and F_2 calculated using Equation (11) for α_1 = – 6,18° and α_2 = 11,14° (see 2.2.2) are listed in Tables 10 and C.2 of ISO 22675:2006.

Table 1 — Magnitudes of resultant reference forces F_{R1x} and F_{R2x}

Resultant force F_{R1x}, F_{R2x}	Related test forces F_{1x} and F_{2x} of the separate tests on ankle-foot devices and foot units specified in ISO 10328 (see Tables 12 and D.3 of ISO 10328:2006)								
	Symbol	Numerical values for heel and forefoot loading F_{1x} and F_{2x} at test loading level P_y							
		P6		P5		P4		P3	
		Heel	Forefoot	Heel	Forefoot	Heel	Forefoot	Heel	Forefoot
		N							
F_{R1sp},	F_{1sp},	2 800	—	2 240	—	2 065	—	1 610	—
F_{R2sp}	F_{2sp}	—	2 800	—	2 240	—	2 065	—	1 610
$F_{R1su, lower level}$,	$F_{1su, lower level}$,	4 200	—	3 360	—	3 098	—	2 415	—
$F_{R2su, lower level}$,	$F_{2su, lower level}$	—	4 200	—	3 360	—	3 098	—	2 415
$F_{R1su, upper level}$,	$F_{1su, upper level}$,	5 600	—	4 480	—	4 130	—	3 220	—
$F_{R2su, upper level}$	$F_{2su, upper level}$	—	5 600	—	4 480	—	4 130	—	3 220
F_{R1cmax},	F_{1cr},	1 600	—	1 280	—	1 180	—	920	—
F_{R2cmax}	F_{2cr}	—	1 600	—	1 280	—	1 180	—	920
F_{R1fin},	F_{1fin},	2 800	—	2 240	—	2 065	—	1 610	—
F_{R2fin}	F_{2fin}	—	2 800	—	2 240	—	2 065	—	1 610

2.4 Reference test loading conditions of static and cyclic tests

2.4.1 Static tests

According to the statements of 2.2 and 2.3, the reference test loading conditions for static (and maximum cyclic; see NOTE) heel and forefoot loading according to ISO 22675 are determined by the parameters listed in a) to d). (For the meaning of “reference” see IMPORTANT.)

a) The position of the top load application point P_T, determined by the coordinates f_T and u_T relevant to the foot length L of the test sample (see 2.2.3); these are specified as offsets $f_{T, L}$ and $u_{T, L}$ in Table 8 of ISO 22675.

b) The direction of the lines of action of the resultant reference forces F_{R1} and F_{R2}, determined by the coordinates of the top load application point P_T [see a)] and their inclinations to the u-axis, determined by the angles $\alpha_1 = -6{,}18°$ and $\alpha_2 = 11{,}14°$ (see 2.2.2).

c) The magnitudes of the resultant reference forces F_{R1} and F_{R2}, specified in Table 1, and the related test forces F_1 and F_2 to be applied in the top load application point P_T [see a)] as illustrated in Figure 1, determined by Equation (11) for $\alpha_1 = -6{,}18°$ and $\alpha_2 = 11{,}14°$. These are specified in Table 10 of ISO 22675:2006.

d) The tilting angles $\gamma_1 = -15°$ and $\gamma_2 = 20°$ of the foot platform for static (and maximum cyclic; see NOTE) heel and forefoot loading. These are specified in Table 9 of ISO 22675:2006.

IMPORTANT — The inclinations of the lines of action of the resultant reference forces F_{R1} and F_{R2} to the u-axis addressed in b) are only relevant to the reference test loading conditions of the static (and cyclic; see NOTE) tests, since the concept of the tests of ISO 22675 allows each sample of ankle-foot device or foot unit to develop its individual performance under load corresponding to its individual design.