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(54) Title: IMPROVEMENTS IN CARDIOVASCULAR PERFORMANCE

(57) Abstract: A method to improve the cardiovascular performance and/or reduce the risk of cardiovascular disease in an individual exhibiting, or with an established risk of developing, the disease. The method subjects the individual to an individualized interval training programme whereby a safe maximum cardiovascular work load is first determined for the individual. This work load is measured as the maximum safe heart rate for the individual. The individual is then subjected to a series of alternating high and low intensity exercises for specific periods. The exercises are selected to ensure that the maximum safe heart rate of the individual is not exceeded. The programme is typically 3 sets of alternating exercises per day, 3 days per week for a 6 week period.

IMPROVEMENTS IN CARDIOVASCULAR PERFORMANCE

THIS INVENTION relates to improving the cardiovascular performance of an individual. In particular, it is directed to an improved method of exercising which can reduce the risk of cardiovascular and related diseases in an individual.

Heart disease is an increasing problem in today's society with tens of thousands of people in the 25-69 year age range dying annually from various forms of cardiac failure. A number of remedial factors are attributed to these deaths, including lack of exercise, being overweight, smoking and suffering from excessive stress.

The benefits of appropriate exercise are well documented to reduce heart disease and other problems. Exercise can, *inter alia*, improve work capacity (by increasing the oxygen consumption per kg of body weight (met)), reduce body weight, increase beneficial HDL cholesterol levels, reduce dangerous triglyceride levels, reduce hypertension and generally improve the overall well being of an individual.

For the most effective cardiac conditioning, it is appropriate for exercise to be undertaken at or around the anaerobic threshold. However, at this level of exercise, lactic acid accumulates in the blood from the breakdown of glucose resulting in a metabolic acidosis. It is not possible for exercise to continue at this level for any prolonged periods of time. Highly trained athletes training at high levels of intensity become conditioned to the rise in lactic acid, but untrained or no longer conditioned individuals are unable to undertake this level of exercise. Consequently, any exercise regime taken by the "average" individual is usually far from efficient and will soon be discontinued if that individual experiences significant discomfort.

Further, with increasing calls on the available time for exercising, any such exercise regime should ideally be enjoyable, capable of being undertaken without excessive health professional supervision, not require sophisticated and/or expensive equipment, be of a relatively short duration, capable of being undertaken in various environments and settings, but still be significantly effective in improving the overall fitness level and well being of the participant.

It is thus a general object of the present invention to overcome, or at least ameliorate, one or more of the above-mentioned disadvantages of known exercising regimes and to provide an effective cardiac conditioning programme for an individual.

The present inventor has established that this general objective can be achieved by subjecting a participant to an individualized anaerobic interval training programme.

Thus, according to a first aspect of the present invention, there is provided a method to improve the cardiovascular performance and/or reduce the risk of cardiovascular or other disease or other undesired symptoms in an individual, said method including:

determining a safe maximum cardiovascular work load for said individual;

exposing said individual to a high intensity first anaerobic regime at a level lower than said maximum load for a short first period;

at end of said first period, exposing said individual to a lower intensity second aerobic regime for a second period, said second period being shorter than said first period; and

multiply repeating alternating said first and second regimes over a given timeframe as required for said individual;

wherein, said first and second regimes are selected to substantially meet said safe work load of said individual.

Preferably, said safe work load is measured as the safe maximum heart rate of said individual.

Preferably, said first regime is at a level around 70-85% of said maximum heart rate of said individual.

Preferably, said maximum heart rate of said individual is determined by subjecting said individual to a short exercise regime during which the heart rate of said individual is monitored.

A typical short exercise regime is the repetitive exercise regime known as interval training.

Preferably, said first period is about five minutes.

Preferably, said second period is about one minute.

Preferably, said individual undertakes:

three sets of said repeating alternating said first and second regimes in a day (24 hours); and

three of said three sets in a seven day (168 hours) period.

Preferably, said individual undertakes said three of said three sets in every seven day (168 hours) period of a forty two day (1008 hours) period.

Preferably, at the end of each said seven day period, said individual is subjected to a short exercise regime during which the current maximum heart rate of said individual is monitored, and said first and second regimes and/or said first and second periods are subsequently adjusted, if necessary, such that said current maximum heart rate of said individual is not exceeded during a subsequent practice of said method.

Once again, a typical short exercise regime is the repetitive exercise regime known as interval training.

In some instances, it may not be required to significantly improve cardiovascular performance, but one merely wishes to monitor that performance when an individual is subjected to certain cardiovascular work loads.

Therefore, as a second aspect of the present invention, there is provided a method to monitor the cardiovascular performance of an individual, said method including:

assessing the initial fitness level of said individual, said fitness level being determined by subjecting said individual to a short exercise regime and calculating the product of the maximum measured heart rate and systolic blood pressure of said individual divided by the maximum oxygen consumption of said individual during said exercise regime;

exposing said individual to a high intensity first anaerobic regime at around 70-85% of said maximum heart rate for a short first period;

at end of said first period, exposing said individual to a lower intensity second aerobic regime for a second period, said second period being shorter than said first period;

multiply repeating alternating said first and second regimes over a given timeframe as required for said individual; and

re-determining the fitness level of said individual at end of said timeframe.

As hereinbefore discussed, it is advantageous for an individual to undertake an exercise programme that reduces the accumulation of lactic acid in his/her blood, thus, as a third aspect of the present invention, there is provided a method to reduce the accumulation of lactic acid in the blood of an individual while said individual is engaged in anaerobic exercise, said method including:

determining a safe maximum heart rate for said individual;

restricting said individual to a high intensity first anaerobic exercise at around 70-85% of said maximum heart rate for a short first period;

at end of said first period, restricting said individual to a lower intensity second aerobic exercise for a second period, said second period being shorter than said first period; and

multiply repeating alternating said first and second exercises over a given timeframe as required for said individual.

While it is not necessarily too difficult for an individual to determine the necessary cardiovascular parameters for the successful operation of the

present invention through the use of various cardiovascular-reading devices that are now readily available through health shops and sports stores, if that individual is already suffering from a perceived cardiovascular risk(s), then it is advisable for one or more health professionals to assist in establishing and monitoring the required said first and second regimes.

Accordingly, as a fourth aspect of the present invention, there is provided a method to improve the cardiovascular performance and/or reduce the risk of cardiovascular or other disease or other undesired symptoms in an individual, said method including:

obtaining the medical history of said individual;

assessing data of said individual, said data at least being selected from one or more of the group comprising personality, anxiety and depression assessment, any said medical history, and dietary history;

if required, undertaking appropriate test(s) to determine initial physiological parameters of interest to said individual;

determining a safe maximum cardiovascular work load for said individual;

exposing said individual to a high intensity first anaerobic regime at a level lower than said maximum work load for a short first period;

at end of said first period, exposing said individual to a lower intensity second aerobic regime for a second period, said second period being shorter than said first period, said first and second regimes being selected to substantially meet said safe work load of said individual;

multiply repeating alternating said first and second regimes over a given timeframe as required for said individual;

at the end of each predetermined multiply repeating of said first and second regimes, re-assessing said data and, if required, modifying said first and/or second regimes; and

at end of said timeframe, if required, undertaking appropriate test(s) to determine final said physiological parameters of interest to said individual.

Embodiments of the present invention will now be described with reference to the following examples which illustrate the results from a number of individuals that have practised the present invention.

General Example

Typically, an intending participant completes a questionnaire which determines the participant's general health, dietary habits and the outcome(s) sought by the participant (for example, relief from a specific cardio-related medical problem, increased fitness, weight loss, etc.)

If necessary, a report from the participant's usual health practitioner is also obtained.

Also, additional pathology and/or psychological tests are undertaken to determine the suitability of the intending participant to undertake the present invention and to provide initial parameters which will be re-determined after a participant has concluded the present invention for comparison purposes.

The participant is then subject to a short exercise regime, for example, the Bruce Protocol. From this regime, a fitness level ratio is calculated from the product of the maximum measured heart rate and systolic blood pressure of the participant divided by the maximum oxygen consumption of the participant during the exercise regime. The initial fitness level of that participant is then determined from the following scale: <10 very fit; 10.1-15.0 fit; 15.1-20.0 average; 20.1-25.0 poor; >25.1 very poor.

From all of this information, a safe maximum cardiovascular work load for the participant is determined and an exercise regime is established. A person, usually a paramedical graduate, is assigned to the participant to monitor the performance of the participant and to determine any appropriate alterations to the regime that may be required as the participant undertakes the present invention.

The exercise regime, typically, is selected from one or more of the following stationery bike riding, motorized treadmill, arm ergometry or walking.

The participant then undertakes three sessions per week for six weeks.

Each session typically comprises a 4 minute warm up, followed by a 3-5 minute high intensity exercise such as stationery bike riding, walking on a motorized treadmill, or undertaking arm ergometry exercises, followed by a 1 minute low intensity exercise, typically, being resting. The alternating high and low intensity exercises are repeated twice more and are then followed by a 4 minute cool down.

After each third session (which is usually at the end of each week), the participant's heart rate is re-determined and the safe workload re-calculated. If the safe heart rate can be increased at that time, this is achieved either by increasing the duration or the work load of the high intensity exercise. Once the maximum target heart rate is achieved as measured at a re-determination, the remaining sessions within the six week period are completed at that particular intensity.

Optionally, face to face contact between the participant and the paramedical graduate is not necessarily compulsory as telemetry monitoring of a participant's heart rate and other physiological parameters can be undertaken for remote downloading and assessment.

After all sessions have been completed, the required parameters are re-determined and compared against the initial determinations.

Group Example 1

Of a first group of 176 males, 45% were assessed to be of average or above fitness levels (average fitness ratio 15.7). After 6 weeks of undertaking the present invention in accordance with the general example above, 76% now had an above average fitness level with their average fitness ratio increasing to a good 12.3.

Group Example 2

Of a second group of 68 males, 47% were assessed to be of average or above fitness levels (average fitness ratio 17.6). After 6 weeks of undertaking the present invention in accordance with the general example above, 69% now had an above average fitness level with their average fitness ratio increasing to a good 12.9.

Group Example 3

Of a third group of 111 males, 60% were assessed to be of average or above fitness levels (average fitness ratio 14.5). After 6 weeks of undertaking the present invention in accordance with the general example above, 80% now had an above average fitness level with their average fitness ratio increasing to a good 11.9.

Group Example 4

Of a first group of 110 females, 50% were assessed to be below average fitness levels (average fitness ratio a poor 21.7). After 6 weeks of undertaking the present invention in accordance with the general example above, only 16% had a below average fitness level, all the remaining improving their average fitness ratio to a good 14.4.

Group Example 5

Of a second group of 76 females, again 50% were assessed to be of below average fitness levels (average fitness ratio 21.9). After 6 weeks of undertaking the present invention in accordance with the general example above, only 17% had a below average fitness level, all the remaining improving their average fitness ratio to a good 14.6.

Group Example 6

Of a third group of 34 females, again 53% were assessed to be of below average fitness levels (average fitness ratio 21.1). After 6 weeks of undertaking the present invention in accordance with the general example above, only 15% had a below average fitness level, all the remaining improving their average fitness ratio to a good 13.9.

Specific Example 1

JM, a 74yo male with known ischaemic cardiomyopathy, was admitted with chest pain. The regime commenced with a 4 minute warm up. The interval training initially comprised 3 minutes on a stationary bicycle to target heart rates followed by 1 minute rest. This training was repeated twice more and then

followed by a 4 minute cool down. This regime was continued for 3 days a week for 3 weeks whereat the time on the bicycle was increased to 4 minutes. No increase in workload was required as heart rate was within the required range. The amended regime continued for 3 weeks.

Various parameters were measured pre-, immediate post- and up to 48 months post-regime which are summarized in Table 1.

JM exhibited a very significant improvement in weight loss and physical fitness. He was able to double the amount of physical activity after the regime. HDL levels improved over time. No further hospital admissions were required.

Specific Example 2

JS, a 62yo female, was admitted for post coronary artery bypass grafting. Exhibited mild aortic valve stenosis. The regime commenced with a 4 minute warm up. The interval training initially comprised 3 minutes on a stationary bicycle to target heart rates followed by 1 minute rest. This training was repeated twice more and then followed by a 4 minute cool down. This regime was continued for 3 days a week for 6 weeks during which the time on the bicycle was gradually increased to 4 and then to 5 minutes and the workload gradually increased.

Various parameters were measured pre-, immediate post- and up to 18 months post-regime which are summarized in Table 2.

JS exhibited a very significant improvement in weight loss and physical fitness.

TABLE 1

Parameter	Pre Programme	Post Programme	3 month	6 month	12 month	18 month	24 month	36 month	48 month
Ratio	34.9	18.6	16.3	14	15.1	16.3	15.1	17.4	15.1
Met	2	4	4	4	4	4	4	4	4
Wgt (kg)	108.2	97.7	97.3	93.8	95.9	95.8	97.8	96.4	93.8
BMI	36.6	33	32.9	31.7	32.4	32.4	33.1	32.6	32.5
Total Cholesterol	4.6	4.3	4.3	4.4	5.1	4.0	4.5	4.6	4.3
HDL Cholesterol	0.98	0.92	1.06	1.08	1.05	1.1	1.13	1.27	1.1
LDL Cholesterol	2.22	1.98	2.14	2.35	3.23	2.22	2.77	2.95	2.6
Tryglycerides	1.9	1.6	1.6	1.5	1.7	1.6	1.6	1.27	1.4

TABLE 2

Parameter	Pre Programme	Post Programme	3 month	6 month	12 month	18 month
Ratio	23.1	9.3	11.9	9.3	8.8	10
Met	4	7	7	7	10	7
Wgt (kg)	83.9	74.5	73.4	75	78.2	77.2
BMI	30.8	28.7	27	27.5	30.5	29.1
Total Cholesterol	6.7	4.4	4.2	4.5	4.5	4.6
HDL Cholesterol	1.16	0.96	1.17	1.16	1.02	1.09
LDL Cholesterol	3.45	2.39	2.66	2.90	2.79	3.14
Tryglycerides	6.8	2.6	2.1	1.6	1.7	1.7

Specific Example 3

KB, a 36yo female, was referred because of atypical chest pain - non cardiac, but associated with gall bladder pathology. The initial exercise assessment established that KB was less fit than she believed despite her exercising daily and being an avid surfer. The regime commenced with a 4 minute warm up. The interval training initially comprised 3 minutes of working to target heart rates followed by 1 minute rest. For the second set, the duration of walking was increased to 4 minutes and, for the third set, to 5 minutes. This regime was continued for 3 days a week for 6 weeks.

Various parameters were measured pre-, immediate post- and 6 months post-regime which are summarized in Table 3.

KB improved her fitness level and cholesterol profile.

Specific Example 4

AF, a 58yo male, had three previous myocardial infarcts and had been refused surgery due to a very poor prognosis. He was a cigarette and social drug user. He was clinically obese, depressed and had ceased medications due to this depression. The regime commenced with a 4 minute warm up. The interval training initially comprised 3 minutes on a stationary bicycle to target heart rates followed by 1 minute rest. This training was repeated twice more and then followed by a 4 minute cool down. This regime was continued for 3 days a week for 6 weeks during which the time on the treadmill was increased to 4 minutes and the workload gradually increased.

Various parameters were measured pre- and immediate post-regime which are summarized in Table 4.

AF improved in all parameters. His depression levels and anxiety state also improved markedly.

TABLE 3

Parameter	Pre Programme	Post Programme	6 month
Ratio	14.5	10.6	9.3
Met	7	10	10
Wgt (kg)	64.3	58.8	59.6
BMI	23.6	21.6	21.9
Total Cholesterol	4.9	4.2	4.9
HDL Cholesterol	1.42	1.44	1.73
LDL Cholesterol	2.67	2.36	2.6
Tryglycerides	1.0	0.7	0.6

TABLE 4

Parameter	Pre Programme	Post Programme
Ratio	11.7	8.0
Met	4	7
Wgt (kg)	91.6	87.6
BMI	31.7	30.3
Total Cholesterol	5.1	3.7
HDL Cholesterol	1.1	0.93
LDL Cholesterol	3.39	1.89
Tryglycerides	1.4	1.0

From all of the above results, the following observations were apparent:

participants significantly lowered their blood pressure;

participants improved their cardio-respiratory function regardless of their fitness levels or presence of obesity; those participants that were obese or morbidly overweight still exhibited an improved fitness level to the same extent as the less weighty participants;

participants reduced their total cholesterol level;

participants increased their levels of "good" cholesterol (HDL);

participants exhibited a reduction in their triglyceride level;

participants exhibited a significant reduction in "bad" cholesterol (LDL);

participants exhibited a significant reduction in the high sensitivity C-reactive protein (its level in a person is a predictor of risk for a heart attack);

a risk factor in heart disease is the level of fibringen, the clotting factor in blood; participants exhibited a decline in fibringen levels;

participants could undertake same level of work at a lower heart rate or more physical work at their previous heart rate.

As an individual undertakes the present invention, the increased physical activity will result in one or more benefits known to flow from such activity. These benefits include:

reduced risk of premature death, heart disease, stroke, Type II diabetes and colon cancer;

weight control;

blood pressure control;

builds and maintains bones, muscles and joints;

reduces feelings of depression and anxiety; and

promotes psychological well being;

all of the above leading to an overall improved quality of life for the individual.

The above benefits are available to any participant and being initially overweight and unfit does not mean that a person cannot exercise and benefit from the present invention.

It will be appreciated that the above described embodiments are only exemplification of the various aspects of the present invention and that modifications and alterations can be made thereto without departing from the inventive concept as defined in the following claims.

CLAIMS

1. A method to improve cardiovascular performance and/or reduce the risk of cardiovascular disease in an individual exhibiting, or with an established risk of developing, said disease, said method including:

   determining a safe maximum cardiovascular work load for said individual;

   exposing said individual to a high intensity first anaerobic regime at a level lower than said maximum load for a short first period;

   at end of said first period, exposing said individual to a lower intensity second aerobic regime for a second period, said second period being shorter than said first period; and

   multiply repeating alternating said first and second regimes over a given timeframe as required for said individual;

   wherein, said first and second regimes are selected to substantially meet said safe work load of said individual.

2. A method as defined in Claim 1, wherein, said safe work load is measured as the safe maximum heart rate of said individual.

3. A method as defined in Claim 2 wherein, said first regime is at a level around 70-85% of said maximum heart rate of said individual.

4. A method as defined in Claim 2 wherein, said maximum heart rate of said individual is determined by subjecting said individual to a short exercise regime during which the heart rate of said individual is monitored.

5. A method as defined in any one of Claims 1 to 4 wherein, said first period is about five minutes.

6. A method as defined in any one of Claims 1 to 5 wherein, said second period is about one minute.

7. A method as defined in any one of Claims 1 to 6 wherein, said individual undertakes:

three sets of said repeating alternating said first and second regimes in a day (24 hours); and

three of said three sets in a seven day (168 hours) period.

8. A method as defined in Claim 7 wherein, said individual undertakes said three of said three sets in every seven day (168 hours) period of a forty two day (1008 hours) period.

9. A method as defined in Claim 8 wherein, at the end of each said seven day period, said individual is subjected to a short exercise regime during which the current heart rate of said individual is monitored, and said first and second regimes and/or said first and second periods are subsequently adjusted, if necessary, such that said safe work load of said individual is not exceeded during a subsequent practice of said method.

10. A method to monitor the cardiovascular performance of an individual exhibiting, or with an established risk of developing, cardiac disease, said method including:

assessing the initial fitness level of said individual, said fitness level being determined by subjecting said individual to a short exercise regime and calculating the product of the maximum measured heart rate and systolic blood pressure of said individual divided by the maximum oxygen consumption of said individual during said exercise regime;

exposing said individual to a high intensity first anaerobic regime at around 70-85% of said maximum heart rate for a short first period;

at end of said first period, exposing said individual to a lower intensity second aerobic regime for a second period, said second period being shorter than said first period;

multiply repeating alternating said first and second regimes over a given timeframe as required for said individual; and

re-determining said fitness level of said individual at end of said timeframe.

11. A method to reduce the accumulation of lactic acid in the blood of an individual exhibiting, or with an established risk of developing, cardiac disease, while said individual is engaged in anaerobic exercise, said method including:

determining a safe maximum heart rate for said individual;

restricting said individual to a high intensity first anaerobic exercise at around 70-85% of said maximum heart rate for a short first period;

at end of said first period, restricting said individual to a lower intensity second aerobic exercise for a second period, said second period being shorter than said first period; and

multiply repeating alternating said first and second exercises over a given timeframe as required for said individual.

12. A method to improve the cardiovascular performance and/or reduce the risk of cardiovascular disease in an individual exhibiting, or with an established risk of developing, said disease, said method including:

obtaining the medical history of said individual;

assessing data of said individual, said data at least being selected from one or more of the group comprising personality, anxiety and depression assessment, any said medical history, and dietary history;

if required, undertaking appropriate test(s) to determine initial physiological parameters of interest to said individual;

determining a safe maximum cardiovascular work load for said individual;

exposing said individual to a high intensity first anaerobic regime at a level lower than said maximum work load for a short first period;

at end of said first period, exposing said individual to a lower intensity second aerobic regime for a second period, said second period being shorter than said first period, said first and second regimes being selected to substantially meet said safe work load of said individual;

multiply repeating alternating said first and second regimes over a given timeframe as required for said individual;

at the end of each predetermined multiply repeating of said first and second regimes, re-assessing said data and, if required, modifying said first and/or second regimes; and

at end of said timeframe, if required, undertaking appropriate test(s) to determine final said physiological parameters of interest to said individual.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2009/000031

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.

A63B 22/00 (2006.01)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
GOOGLE, EPOQUE: EPODOC & WPI: IPC/EC A63B/IC/EC and Keywords: Fitness, Exercise, Training, Anaerobic, Aerobic, Repetition, Repeat, Alternate, Time, Length, Duration, Period, Cycle, Intensity, Endurance) and similar terms.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	PATON et al, 'Effects of High-intensity training on Performance and Physiology of Endurance Athletes', Sportscience, Vol. 8, 25-40, 2004, Retrieved from the internet on 14 April 2009 at URL: http://sportsci.org/jour/04/cdp.htm See Whole Document	
A	STEVENS et al, 'Interval training: alternating periods of high- and low- intensity exercise for maximum benefit – includes continuing education test', American Fitness, July-August, 1997, Retrieved from the internet on 14 April 2009 at URL: http://findarticles.com/p/articles/mi_m0675/is_n4_v15/ai_19575697 See Whole Document	
A	LINDSAY et al, 'Improved athletic performance in highly trained cyclists after interval training', Med Sci Sports Exercise, Vol 28(11), 1427-1434, 1996, Retrieved from the internet on 14 April 2009 at URL: http://www.ncbi.nlm.nih.gov/pubmed/8933495 See Whole Document	
A	FINN, 'Effects of High-Intensity Intermittent Training on Endurance Performance', Sportscience, Vol 5(1), 2001, Retrieved from the internet on 14 April 2009 at URL: http://sportsci.org/jour/0101/cf.htm See Whole Document	

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

* Special categories of cited documents:

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INTERNATIONAL SEARCH REPORT

International application No.
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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2005/082471 A1 (KONINKLIJKE PHILIPS ELECTRONICS, N.V.) 09 September 2005 See Whole Document	
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/AU2009/000031

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

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		EP	0975396	IL	132294	MX	PA99009210
		US	5879270				
US	5803870	NONE					
US	5435799	NONE					

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX