Package 'bpAcc'

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Title Blood Pressure Device Accuracy Evaluation: Statistical Considerations

Maintainer Victor Miranda <victor.miranda@aut.ac.nz>

Depends R (>= 4.2.0), methods, stats

Description A comprehensive statistical analysis of the accuracy of blood pressure devices based on the method of AAMI/ANSI SP10 standards developed by the AAMI Sphygmomanometer Committee for indirect measurement of blood pressure, incorporated into IS0 81060-2. The 'bpAcc' package gives the exact probability 'of accepting a device D' derived from the join distribution of the sample standard deviation and a non-linear transformation of the sample mean for a specified sample size introduced by Chandel et al. (2023) and by the Association for the Advancement of Medical Instrumentation (2003, ISBN:1-57020-183-8).

License GPL-2

NeedsCompilation yes

BuildVignettes yes

Author Victor Miranda [cre, aut, cph],
Tanvi Chandel [aut],
Andrew Lowe [aut],
Tet Chuan Lee [aut],
Auckland_University_of_Technology (AUT) [cph, fnd]

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R topics documented:

`AcceptR` *Acceptance Region - ANSI/AAMI-SP10 standard.*

Description

Acceptance Region for a given sample size to comply with ANSI/AAMI-SP10 standard.

Usage

```
AcceptR(n,distribution = "normal",criteria = "SP10:2006")
```

Arguments

`n`	Sample size .
`distribution`	Underlying distribution the errors δ are pulled from. The default is `normal`, i.e. a normal distribution.
`criteria`	SP10 criteria used.

Details

Computes the revised probability of tolerable error i.e. the minimum probability of errors δ within tolerable error for a given sample size-`n`. The *tolerable error*, according to the ANSI/AAMI-SP10, is an error between -10 mmHg to 10 mmHg on a single person, using average of that person's readings. The revised probability of tolerable error varies for different sample sizes. Thus to meet the SP10 criteria, an acceptance region based on the sample size is provided by the package.

$$\int_{-\infty}^{\delta} f_N(x;\mu_0,\sigma) - \int_{-\infty}^{-\delta} f_N(x;\mu_0,\sigma)\, dx = \hat{p}$$

Complete details in Chandel, et al. (2023). The paper outlines he mathematical and statistical aspects behind `AcceptR`.

Value

It returns the acceptance region for a sample size i.e the upper limit of `sd` for a sample mean for a given `n`. This gives clinicians a flexible way to comprehend how the upper limit of the standard deviation -`sd` fluctuates depending on the sample size.

Author(s)

Tanvi Chandel, Tet-Chuan Lee, Andrew Lowe, Victor Miranda.

References

Chandel, T. and Lee, TC. and Lowe, A. and Miranda, V. (2023) Blood Pressure Device Accuracy Evaluation: Statistical Considerations with an Implementarion in R, *Statistics in Medicine* (under review).

Examples

```
## SP10-Acceptance Region for a sample size (n) = 85

AcceptR(n=85,distribution = "normal",criteria = "SP10:2006")


## SP10-Acceptance Region for a sample size (n) = 50

AcceptR(n=50,distribution = "normal",criteria = "SP10:2006")
```

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notDocumentedYetbpAcc *Not-documented functions and classes in* **bpAcc**.

Description

Those functions not documented yet in **bpAcc** are aliased to this file.

Details

These functions are still under review or being tested, and will be documented over time.

Value

Overall, these functions returns objects required by functions from **bpAcc**.

Further details will be given shortly.

Author(s)

T. Chandel, V. Miranda, A. Lowe, T. Lee

PAccept *Probability of acceptance - ANSI/AAMI-SP10 standard.*

Description

Probability of acceptance - ANSI/AAMI-SP10 standard.

Usage

```
PAccept(xbar,sd,N,distribution = "normal", criteria = "SP10:2006")
```

Arguments

xbar, sd	mean and standar deviation of the average errors distribution (normal).
N	Sample size (number of participants).
distribution	Underlying distribution the errors δ are pulled from. The default is normal, i.e. a normal distribution.
criteria	SP10 criteria used.

Details

Computes the *acceptance probability* of a device D for blood pressure measuring under the ANSI/AAMI-SP10 standards for a size-n sample of average errors from an asymptotically normal distribution with mean xbar and stadard deviation sd.

$$1 - \frac{1}{2}[1 + erf(\frac{0.78 - \hat{p}}{\sqrt(2)(\frac{\hat{p}(1-\hat{p})}{N})})]$$

The distribution is of the true probability of tolerable error p where the tolerable error according to the ANSI/AAMI-SP10, is an error between -10 mmHg to 10 mmHg on a single person, using average of that person's readings. Using the sampling distribution of sampling proportion, the probabilty of p>=0.78 is evaluated, which is called as the probabilty of acceptance or probability that for a given sample size n, sample mean xbar and sample standard deviation sd, the device is meeting the SP10 criteria.

Complete details in Chandel, et al. (2023). The paper outlines the mathematical and statistical aspects behind PAccept. The threshold probability for acceptance according to ANSI/AAMI-SP10 is 95% i.e.,Prob(p>=0.78) >= 0.95

Value

It returns the probability of a device meeting the SP10 criteria

Author(s)

Tanvi Chandel, Tet-Chuan Lee, Andrew Lowe, Victor Miranda.

References

Chandel, T. and Lee, TC. and Lowe, A. and Miranda, V. (2023) Blood Pressure Device Accuracy Evaluation: Statistical Considerations with an Implementarion in R, *Statistics in Medicine* (under review).

Examples

```
## Probability of acceptance of a device for a sample size (N) = 30 with sample
## mean (xbar) = 5, standard deviation = 5.
PAccept(xbar=5,sd=5,N=30,distribution = "normal", criteria = "SP10:2006")


## Probability of acceptance of a device for a sample size (N) = 60 with sample
## mean (xbar) = 2, standard deviation = 7.
PAccept(xbar=2,sd=7,N=60,distribution = "normal", criteria = "SP10:2006")
```

`ProbAccept` *Probability of device acceptance - AANSI/AAMI-SP10 standard.*

Description

Probability of device acceptance - AANSI/AAMI-SP10 standard.

Usage

```
ProbAccept(n, mu, sd, ptolerror = 0.85,
           distribution = "normal",
           criteria = "SP10:2006",
           simulate = FALSE, sim.count = 1e4,
           noshow = FALSE)
```

Arguments

`n`	Sample size (evaluated people, as defined by Chandel et al. (2022)).
`mu, sd`	mean and standar deviation of the average errors distribution (normal).
`ptolerror`	Probability of tolerable error. Default is 0.85
`distribution`	Underlying distribution the errors δ are pulled from. The default is `normal`, i.e. a normal distribution.
`criteria`	SP10 criteria used.

simulate	Logical. If TRUE, the acceptance probability is simulated from sim.count samples form a normal distribution. Else, the exact probability is returned. Default is FALSE.
sim.count	Integer, positive. Number of samples taken from normal distribution to estimate the probability of accepting the device.
noshow	Logical. If FALSE then results are prompted on terminal.

Details

Computes the *acceptance probability* of a device D for blood pressure measuring under the ANSI/AAMI-SP10 standards for a size-n sample of average errors from a normal distribution with mean mu and stadard deviation sd. The probability of tolerable error is set to 0.85, by default. A *tolerable error*, according to the ANSI/AAMI-SP10, is a an error of 10mmHg or less on a single person, using the average of that person's readings.

Fuller details in Chandel, et al. (2022). The paper outlines the mathematical and statistical aspects behind ProbAccept. Two random variables are involved: the sample standard deviation and a transformation of the sample mean, resulting in a double integral over a two-dimensional region.

Value

It returns the probability of accepting the device (either simulated or exact).

Author(s)

Tanvi Chandel, Tet-Chuan Lee, Andrew Lowe, Victor Miranda.

References

Chandel, T. and Lee, TC. and Lowe, A. and Miranda, V. (2022) Blood Pressure Device Accuracy Evaluation: Statistical Considerations with an Implementarion in R, *Statistical Methods in Medical Research* (under review).

See Also

ProbAccept psigmaami

Examples

```
## Probability of accepting a device with bias (mu) = 5, and true standard
## deviation = 5.
ProbAccept(n = 85, mu = 5, sd = 5, ptolerror = 0.85)


## Probability of accepting a device with bias (mu) = 5, and true standard
## deviation = 7.
ProbAccept(n = 85, mu = 5, sd = 7, ptolerror = 0.85)
```

`ProbTolError` *Probability of tolerable error - AAMI-SP10 standard.*

Description

Probability of tolerable error - AAMI-SP10 standard.

Usage

```
ProbTolError(distribution = "normal", mu, std.dev, delta)
```

Arguments

`distribution`	The errors distirbution. Default and only option is "normal".
`mu, std.dev`	Mean and standar deviation of the average errors distribution (normal).
`delta`	Maximum average error allowed for the device D.

Details

Computes the *probability of tolerable error* for a device D for blood pressure measuring under the ANSI/AAMI-SP10 standard for a size-`n` sample of average errors from a normal distribution with mean `mu` and stadard deviation `sd`. The maximum error accepted is 0.85, A *tolerable error*, according to the ANSI/AAMI-SP10, is a an error of 10mmHg or less on a single person, using the average of that person's readings.

Currently, only normally distirbuted errors are handled. Further choices will be implemented over time.

Fuller details in Chandel, et al. (2022).

Value

It returns the probability of tolerable error based on a normal distribution.

Author(s)

Tanvi Chandel, Tet-Chuan Lee, Andrew Lowe, Victor Miranda.

References

Chandel, T. and Lee, TC. and Lowe, A. and Miranda, V. (2022) Blood Pressure Device Accuracy Evaluation: Statistical Considerations with an Implementarion in R, *Statistical Methods in Medical Research* (under review).

See Also

ProbAccept psigmaami

Examples

```
## Probability of tolerable error, mu = 4, sd = 5, delta = 10 (ANSI/AAMI-SP10)
ProbTolError(mu = 4, std.dev = 5, delta = 10)
```

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psigmaami *Distribution function of the sigma-aami transformation (not vectorized).*

Description

Distribution function of the sigma-aami transformation (not vectorized).

Usage

```
psigmaami(sigmaami, mu, std.dev, n, ptolerror = 0.85, lower.tail = TRUE)
```

Arguments

sigmaami	A single, positive, quantile. See below for further details.
mu, std.dev	mean and standar deviation of the average errors distribution (normal).
n	sample size
ptolerror	Probability of tolerable error, Default is 0.85
lower.tail	logical; it *TRUE* (default), probabilities are $P[sigmaami \leq x]$ otherwise, $P[sigmaami > x]$.

Details

This is the distribution function of the sigmaami transformation.

A size-n sample of blood pressure average errors (average of the difference between three *device* measurements and the three corresponding reference readings) is drawn from a normal distribution with mean mu and standard deviation std.dev. The r.v. sigmaami results from transforming $xbar$, the sample mean, assuming the proportion of drawn errors lie in (-delta, delta) with probability ptolerror, that is sigmaami$= sigmaami(xbar)$.

Value

`psigmaami` gives the distribution function.

Author(s)

Tanvi Chandel, Tet-Chuan Lee, Andrew Lowe, Victor Miranda.

References

Chandel, T. and Lee, TC. and Lowe, A. and Miranda, V. (2022) Blood Pressure Device Accuracy Evaluation: Statistical Considerations with an Implementarion in R, *Statistical Methods in Medical Research* (under review).

See Also

`ProbAccept`

Examples

```
## Sample of n = 85 average errors from a normal distribution with mean 3 and st.dev = 2.
psigmaami(sigmaami = 4, mu = 3, std.dev = 2, n = 85)
```

`Supplementary functions`

Supplementary fuctions of the package **bpAcc**.

Description

Supplementary function required to compute the acceptance probability of a device for BP measurement.

Usage

```
fsup1(mu, sd.aami, ptolerror)
fsup2(mu.aami, sdev, ptolerror)
toint(xbar, mean, sd, n)
```

Arguments

`mu`	True mean error (bias). This is 'mu' of the errors distribution (normal).
`sd.aami`	Standard deviation of a normal distribution meeting the ANSI/AAMI-SP10 standards.
`ptolerror`	Probability of tolerable error. Default is 0.85.
`mu.aami`	Mean of a normal distribution meeting the ANSI/AAMI-SP10 standards.
`sdev`	True standard deviation of the errors (normal distribution).
`xbar, mean, sd, n`	Auxiliary arguments.

Details

Supplementary functions to compute the *probability of accepting the device D*. The errors (average of the differences from three *device* measurements and the three corresponding reference readings) are by default normally distributed with mean `mean` and `sd`. Function `fsup1` is called by `root`, `fsup2` is needed by `rootinv`, and `toint` is required by `psigmaami`.

See `psigmaami` for further details on `ptolerror`.

Value

No value returned. These are funtcion internally called by `ProbAccept`.

Author(s)

Tanvi Chandel, Tet-Chuan Lee, Andrew Lowe, Victor Miranda.

References

Chandel, T. and Lee, TC. and Lowe, A. and Miranda, V. (2022) Blood Pressure Device Accuracy Evaluation: Statistical Considerations with an Implementarion in R, *Statistical Methods in Medical Research* (under review).

See Also

`ProbAccept` `psigmaami`

Examples

```
#### 'sd' that meets the AAMI-sp10 standars
root(mu = 5, ptolerror = 0.9)
# root(mu = 11, ptolerror = 0.85) # Error

#### 'mu' that meets the AAMI-sp10 standars
rootinv(sdev = 3, ptolerror = 0.9)
# rootinv(sdev = 2, ptolerror = 0.85) # Error
```

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