

mcompass® CLINICAL GUIDELINE TOOL

This document is designed to provide a generalized basis for reviewing mcompass® anorectal manometry results. This is intended as supplement to, but not a replacement for, appropriate medical training, experience, and levels of professional responsibility. Each case is unique, and your determinations must be based on individual evaluation and patient experiences.

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mcompass® DIAGNOSTIC ANORECTAL MANOMETRY

mcompass® Performs 6 Diagnostic Tests:

Resting
 Squeeze
 Expel Full
 Sensation
 Expel Empty
 Exhale (Cough)

Test	Purpose / Clinical Value
• Resting	Assess baseline sphincter pressure, which predominantly reflects internal anal sphincter (IAS) function.
• Squeeze	Assess the strength of the external anal sphincter (EAS) during voluntary squeeze.
• Expel Empty	Assess the rectal and anal sphincter pressure changes during an attempted defecation and their coordination with abdominal muscle contraction.
Expel Full	Assess the rectal and anal sphincter pressure changes during an attempted defecation and their coordination with abdominal muscle contraction, after IAS relaxation resulting from RAIR (recto anal inhibitory reflex).
• Sensation	Assess sensory thresholds in response to rectal balloon distension. Graphical representations for RAIR are evident during this test.
• Exhale (Cough)	Determine the integrity of the local reflex arc responsible for maintaining continence during an abrupt increase of intra-abdominal pressure.

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RESTING TEST

Clinical Significance

The IAS provides 80% of the resting anal sphincter pressure.

Considerations

- Are all four quadrants of the anal canal (Posterior, Left, Anterior, and Right) responding similarly?
- Is the anal mean pressure lower than normal?
- A low resting anal sphincter pressure may indicate weakness or disruption of the IAS. This may result in Incontinence.

Report Reference

Summary:				
Resting		Expel Empty		
Anal mean (mmHg)	11	Rectal Pressure (Gradient) (mmHg)	55	
Anal max (mmHg)	14	Anal Pressure (Gradient) (mmHg)	29	
Squeeze		Anorectal Gradient (mmHg)	26	
Anal mean (mmHg)	121	Expel Full		
Anal max (mmHg)	145	Rectal Pressure (Gradient) (mmHg)	47	
Squeeze Duration (sec)	20	Anal Pressure (Gradient) (mmHg)	27	
Sensation		Anorectal Gradient (mmHg)	20	
Rectal Capacity (cc)	110	Exhale		
RAIR (%)	See graph	Anal mean (mmHg)	36	
RB Volume at RAIR Threshold (cc)	See graph	Anal max (mmHg)	79	

Reference Normal Values

To	est	Male	Female < 50 years	Female ≥ 50 Years
Resting	Anal	64 – 88 mmHg	58 – 90 mmHg	44 – 59 mmHg

Relevant mcompass® Biofeedback Therapy Exercise

STRENGTH EXERCISE

This exercise is to help the patient increase pelvic floor strength and duration of squeeze in the anal sphincter.

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SQUEEZE TEST

Clinical Significance

This test assesses the strength of the EAS during voluntary squeeze.

The contraction of the EAS is usually associated with contraction of the puborectalis.

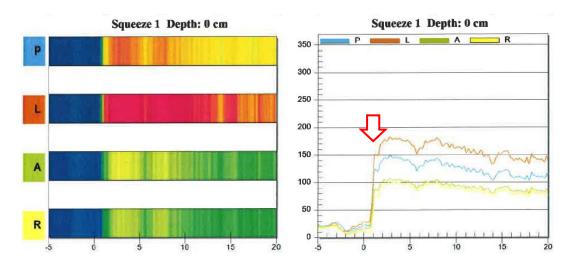
Squeeze Duration is the time interval in seconds during which the patient can maintain a squeeze pressure at or above 50% of the maximum squeeze pressure.

Considerations

- Are all four quadrants of the anal canal (Posterior, Left, Anterior, and Right) responding similarly?
- Is the anal mean pressure lower than normal?
- Are there consistent anal pressure increases across the three different squeeze and holds?
- How long can the patient maintain their pressure increase?
- A low anal squeeze pressure and/or short squeeze duration may indicate weakness or disruption of the EAS. This may result in Incontinence.

Report References

Summary:			
Resting		Expel Empty	
Anal mean (mmHg)	11	Rectal Pressure (Gradient) (mmHg)	55
Anal max (mmHg)	14	Anal Pressure (Gradient) (mmHg)	29
Squeeze		Anorectal Gradient (mmHg)	26
Anal mean (mmHg)	121	Expel Full	
Anal max (mmHg)	145	Rectal Pressure (Gradient) (mmHg)	47
Squeeze Duration (sec)	20	Anal Pressure (Gradient) (mmHg)	27
Sensation		Anorectal Gradient (mmHg)	20
Rectal Capacity (cc)	110	Exhale	
RAIR (%)	See graph	Anal mean (mmHg)	36
RB Volume at RAIR Threshold (cc)		Anal max (mmHg)	79



The squeeze pressure profile is biphasic with an initial sharp rise (maximum sphincter pressure) followed by a drop and a sustained pressure. The latter is important to maintaining continence.

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Test		Male	Female < 50 years	Female ≥ 50 Years	
Squeeze	Anal	174 mmHg & Higher	123 mmHg & Higher	99 mmHg & Higher	

Relevant mcompass® Biofeedback Therapy Exercise

STRENGTH EXERCISE

This exercise is to help the patient increase pelvic floor strength and duration of squeeze in the anal sphincter.

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EXPEL EMPTY TEST

Clinical Significance

This test assesses the rectal and anal sphincter pressure changes during an attempted defecation and their coordination with abdominal muscle contraction. The contraction of the EAS is usually associated with contraction of the puborectalis.

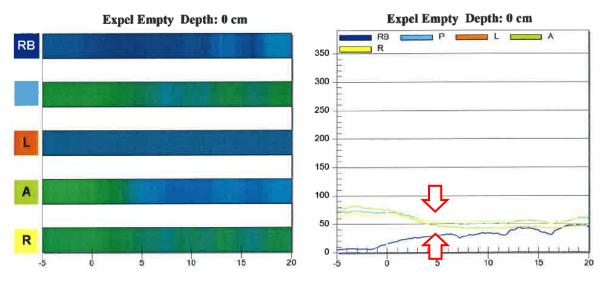
When performed with the rectal balloon empty, the IAS will not have the benefit of RAIR to induce relaxation, although the patient should be able to relax the EAS.

Considerations

- Is there an increase in rectal pressure and a <u>coordinated</u> decrease in anal sphincter pressure?
- The inability to perform this coordinated maneuver may lead to functional obstruction to the passage of stool and is termed *dyssynergic defecation*. This may result in Constipation.

Report References

Summary:			
Resting		Expel Empty	
Anal mean (mmHg)	11	Rectal Pressure (Gradient) (mmHg)	55
Anal max (mmHg)	14	Anal Pressure (Gradient) (mmHg)	29
Squeeze		Anorectal Gradient (mmHg)	26
Anal mean (mmHg)	121	Expel Full	
Anal max (mmHg)	145	Rectal Pressure (Gradient) (mmHg)	47
Squeeze Duration (sec)	20	Anal Pressure (Gradient) (mmHg)	27
Sensation		Anorectal Gradient (mmHg)	20
Rectal Capacity (cc)	110	Exhale	
RAIR (%)	See graph	Anal mean (mmHg)	36
RB Volume at RAIR Threshold (cc)	See graph	Anal max (mmHg)	79



In these graphs the rectal pressure (RB dark blue) is increasing as the anal pressures (P, L, A, R blue, orange, green, yellow) decrease.

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To	Test Male Female < 50 years			Female ≥ 50 Years
Expel	. Nectai		22 – 49 mmHg	40 – 71 mmHg
Empty	Anal	55 – 86 mmHg	56 – 81 mmHg	52 – 76 mmHg

Relevant mcompass® Biofeedback Therapy Exercise

EXPEL FULL EXERCISE

This exercise is to help the patient visualize muscle contractions associated with defecation and improve muscle strength and coordination and abnormalities.

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EXPEL FULL TEST

Clinical Significance

This test assesses the rectal and anal sphincter pressure changes during an attempted defecation and their coordination with abdominal muscle contraction. The contraction of the EAS is usually associated with contraction of the puborectalis.

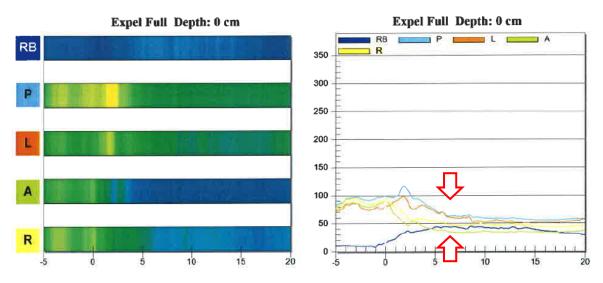
When performed with the rectal balloon full beyond the point of *sensation*, the IAS will experience relaxation due to RAIR, and the patient should be able to relax the EAS.

Considerations

- Is there an increase in rectal pressure and a <u>coordinated</u> decrease in anal sphincter pressure?
- The inability to perform this coordinated maneuver may lead to functional obstruction to the passage of stool and is termed *dyssynergic defecation*. This may result in Constipation.

Report References

Summary:			
Resting		Expel Empty	
Anal mean (mmHg)	11	Rectal Pressure (Gradient) (mmHg)	55
Anal max (mmHg)	14	Anal Pressure (Gradient) (mmHg)	29
Squeeze	_	Anorectal Gradient (mmHg)	26
Anal mean (mmHg)	121	Expel Full	
Anal max (mmHg)	145	Rectal Pressure (Gradient) (mmHg)	47
Squeeze Duration (sec)	20	Anal Pressure (Gradient) (mmHg)	27
Sensation		Anorectal Gradient (mmHg)	20
Rectal Capacity (cc)	110	Exhale	
RAIR (%)	See graph	Anal mean (mmHg)	36
RB Volume at RAIR Threshold (cc)	See graph	Anal max (mmHg)	79



In these graphs the rectal pressure (RB dark blue) is increasing as the anal pressures (P, L, A, R - light blue, orange, green, yellow) decrease.

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Te	est	Male	Female < 50 years	Female ≥ 50 Years
Expel Full	Adjusted Rectal	65 – 127 mmHg	35 – 83 mmHg	65 – 130 mmHg
Expel Full	Anal	51 – 81 mmHg	47 -75 mmHg	45 – 70 mmHg

Relevant mcompass® Biofeedback Therapy Exercise

EXPEL FULL EXERCISE

This exercise is to help the patient visualize muscle contractions associated with defecation and improve muscle strength and coordination and abnormalities.

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SENSATION TEST

Clinical Significance

This test assesses sensory thresholds in response to rectal balloon distension. Graphical representations of Recto Anal Inhibitory Reflex (RAIR) may be evident during this test.

When the rectal balloon is filled to the point of adequate sensation, the IAS will experience relaxation due to RAIR, and the patient should be able to relax the EAS.

Patient is to indicate rectal balloon fill volumes at which they feel:

- 1) Sensation first feel balloon,
- 2) Desire feel a need to use the restroom,
- 3) Urgency urgent need to use the restroom,
- 4) Pain the patient is experiencing discomfort (Note: achieving the Pain level is rarely necessary).

Considerations

- At what pressure does the patient first feel sensation?
- Are there regular, and increasing, volume intervals between each sensation level?
- Can the presence of Recto Anal Inhibitory Reflex (RAIR) be derived from the graphs?
- Is the patient able to experience the first three sensation levels (Sensation, Desire & Urgency) before reaching the maximum balloon fill volume of 180cc?
- Sensing very low rectal pressures, and/or very small/quick volume intervals between sensations, may be indicative of Incontinence due to Hypersensitivity.
- Sensing very high rectal pressures, and/or very large/slow volume intervals between sensations, may be indicative of Incontinence due to Hyposensitivity.

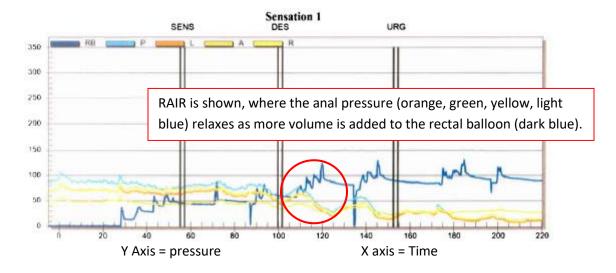
Report References

Sensation				
Maneuver #	1			
Catheter Depth (cm)	0			
Rectal Capacity (cc)	150			
RAIR (%)	present, 32	2		
RB Volume at RAIR Threshold (cc)	90			
Type	SENS	DES	URG	PAIN
P Max (mmHg)	27	22	28	34
L Max (mmHg)	40	42	46	48
A Max (mmHg)	39	28	32	27
R Max (mmHg)	27	31	40	43
P Mean (mmHg)	25	20	27	31
L Mean (mmHg)	39	37	44	46
A Mean (mmHg)	37	27	32	25
R Mean (mmHg)	26	30	39	41
Anal Max (mmHg)	33	30	36	38
Anal Mean (mmHg)	32	29	35	36
RB Volume (cc)	50	90	110	150
RB Diameter (mm)	48	57	61	68
RB Mean Pressure (mmHg)	9	14	22	34

The highlighted portion of the sensation numerical data provides the specific volumes of each sensation recorded during the test (sensation, desire, urgency, and pain). From this information one can determine when the patient first senses the balloon as well as the volume intervals between sensations.

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Summary:			
Resting		Expel Empty	
Anal mean (mmHg)	11	Rectal Pressure (Gradient) (mmHg)	55
Anal max (mmHg)	14	Anal Pressure (Gradient) (mmHg)	29
Squeeze		Anorectal Gradient (mmHg)	26
Anal mean (mmHg)	121	Expel Full	
Anal max (mmHg)	145	Rectal Pressure (Gradient) (mmHg)	47
Squeeze Duration (sec)	20	Anal Pressure (Gradient) (mmHg)	27
Sensation		Anorectal Gradient (mmHg)	20
Rectal Capacity (cc)	110	Exhale	
RAIR (%)	See graph	Anal mean (mmHg)	36
RB Volume at RAIR Threshold (cc)	See graph	Anal max (mmHg)	79



Test	Male	Female < 50 years	Female ≥ 50 Years
Sensation			
First Sensation	30 – 58 ml (cc)	30 – 60 ml (cc)	30 – 60 ml (cc)
Desire to Defecate	60 – 100 ml (cc)	60 – 108 ml (cc)	60 – 93 ml (cc)
Urgency	100 – 170 ml (cc)	100 – 160 ml (cc)	88 – 153 ml (cc)
Pain	130 – 180 ml (cc)	110 – 170 ml (cc)	100 – 155 ml (cc)

Relevant mcompass® Biofeedback Therapy Exercise

SENSORY EXERCISE – For Hyposensitivity

This exercise is to help the patient lower the sensory threshold for stool in the rectum to a more normal level.

URGE RESISTANCE EXERCISE – For Hypersensitivity

This exercise is to help the patient increase their tolerance of larger volumes of stool in the rectum, converting strong urges into normal urges.

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EXHALE (COUGH) TEST

Clinical Significance

This test is to determine the integrity of the local reflex arc responsible for maintaining continence during an abrupt increase of intra-abdominal pressure.

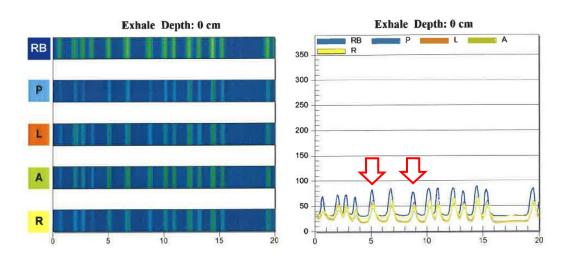
Normally, a cough (or sudden strong exhale) creates a sudden intra-abdominal pressure increase.

Considerations

- Are there increases in anal balloon pressures during the rectal balloon pressure spikes?
- Are these coordinated?
- A lack of coordinated anal pressure increase during cough may result in Incontinence.

Report References

Summary:			
Resting		Expel Empty	
Anal mean (mmHg)	11	Rectal Pressure (Gradient) (mmHg)	55
Anal max (mmHg)	14	Anal Pressure (Gradient) (mmHg)	29
Squeeze		Anorectal Gradient (mmHg)	26
Anal mean (mmHg)	121	Expel Full	
Anal max (mmHg)	145	Rectal Pressure (Gradient) (mmHg)	47
Squeeze Duration (sec)	20	Anal Pressure (Gradient) (mmHg)	27
Sensation		Anorectal Gradient (mmHg)	20
Rectal Capacity (cc)	110	Exhale	
RAIR (%)	See graph	Anal mean (mmHg)	36
RB Volume at RAIR Threshold (cc)	See graph	Anal max (mmHg)	79



Each of these spikes shows an increase in the anal balloon pressures (P,L,A,R) during the simulated patients coughs. (RB)

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There are no reference Normal Values related to the Exhale (Cough) Test.

Relevant mcompass® Biofeedback Therapy Exercise

STRENGTH EXERCISE

This exercise is to help the patient increase pelvic floor strength and duration of squeeze in the anal sphincter.

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Table of Reference Normal Values

Test		Male	Female < 50 years	Female ≥ 50 Years
Resting	Anal	64 – 88 mmHg	58 – 90 mmHg	44 – 59 mmHg
Squeeze	Anal	174 mmHg & Higher	123 mmHg & Higher	99 mmHg & Higher
Expel	· Rectai	45 – 80 mmHg	22 – 49 mmHg	40 – 71 mmHg
Empty	Anal	55 – 86 mmHg	56 – 81 mmHg	52 – 76 mmHg
Expel	Adjusted Rectal	65 – 127 mmHg	35 – 83 mmHg	65 – 130 mmHg
Full	Anal	51 – 81 mmHg	47 -75 mmHg	45 – 70 mmHg
Sensation				
First Sensation		30 – 58 ml (cc)	30 – 60 ml (cc)	30 – 60 ml (cc)
Desire to	Defecate	60 – 100 ml (cc)	60 – 108 ml (cc)	60 – 93 ml (cc)
Urgency		100 – 170 ml (cc)	100 – 160 ml (cc)	88 – 153 ml (cc)
Pain		130 – 180 ml (cc)	110 – 170 ml (cc)	100 – 155 ml (cc)

Note: Many patients will not exert full rectal pressure during Expel Exercises for fear of accidentally passing gas or stool.

This may result in a false negative gradient (Rectal to Anal pressures).

Encourage patients to truly try expelling the balloon.

Values derived from:

A multicenter study of anorectal pressures and rectal sensation measured with portable manometry in healthy women and men.

Sharma M, Lowry AC, Rao SS, Bharucha AE, Whitehead WE, et al. Neurogastroenterology & Motility. 2021;00:e14067

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PELVIC FLOOR RETRAINING

4 training exercises may be performed with the mcompass® Manometric Biofeedback System:

- Strength
- Urge Resistance
- Sensation
- Expel Full

After performing the Anorectal Manometry (ARM) tests, the referring physician should have provided the diagnosis and perhaps also the desired therapy path.

Clinical findings from ARM tests that may lead to each exercise being beneficial to a patient:

Chronic Constipation / Incontinence -Incontinence -Incontinence -Dyssynergia **Weak Sphincter Hyposensitivity Hypersensitivity** • Weak rectal squeeze Pressure values from Rectal balloon • Rectal balloon anal squeeze test and pressure during volumes from volumes from IF INDICATION IS defecation. resting test are below sensation test are sensation test are normal values. significantly above significantly below or normal values. normal values. Insufficient anal Anal squeeze relaxation – low or duration is shorter negative gradient. than acceptable. • Expel full/empty tests show paradoxical muscle contraction during defecation. **Urge Resistance Expel Full** Strength Sensory EXERCISE TO PERFORM Exercise **Exercise Exercise** Exercise To help the patient To help the patient To help the patient To help the patient visualize muscle increase pelvic floor lower the sensory increase their contractions associated strength and duration threshold for stool in tolerance of larger with defecation and of squeeze in anal the rectum to a more volumes of stool in the improve muscle strength sphincter. normal level. rectum, converting and coordination strong urges into abnormalities. normal urges. • Rectal pressure > anal • > 100 mmHg max < 40 cc volume sensory > 120 cc volume strong threshold urge threshold pressure (positive squeeze pressure GOALS gradient) • > 50 mmHg for 10 • Rectal pressure second duration of increase from baseline squeeze pressure • Anal pressure decrease • > 40 mmHg for from baseline (resting) resting pressure

Please note that this is a general guidance based on typical factors. Medical practitioners are expected to use their own best judgment.

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